(B) Stipend

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

(3) Reductions in the period of obligated service

The period of obligated service under paragraph (1)(A)(ii)(V) shall be reduced—

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

(B) in the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility (as defined in section 781(e))[1] that is located in a health professional shortage area (as defined in section 254e of this title), by 3 months for year[2] of full-time practice in such a facility (not to exceed a total of 12 months).

(c) Second 2 years of service

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

(d) Dentist, physician assistant, pharmacist, behavioral and mental health professional, public health professional, and nurse training

The Surgeon General shall establish provisions applicable with respect to dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students that are comparable to those for medical students under this section, including service obligations, tuition support, and stipend support. The Surgeon General shall give priority to health professions training institutions that train medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.

(e) Elite Federal disaster teams

The Surgeon General, in consultation with the Secretary, the Director of the Centers for Disease Control and Prevention, and other appropriate military and Federal government agencies, shall develop criteria for the appointment of highly qualified Track faculty, medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.

[1] So in original. Act July 1, 1944, does not contain a section 781.

[2] So in original. Probably should be preceded by ''each''.

(f) Student dropped from Track in affiliate school

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

(July 1, 1944, ch. 373, title II, § 273, as added Pub. L. 111–148, title V, § 5315, Mar. 23, 2010, 124 Stat. 639.)

§ 239*l*–3. Funding

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

(July 1, 1944, ch. 373, title II, § 274, as added Pub. L. 111–148, title V, § 5315, Mar. 23, 2010, 124 Stat. 642.)

TRANSFER OF APPROPRIATED FUNDS

Pub. L. 112–10, div. B, title VIII, § 1828, Apr. 15, 2011, 125 Stat. 162, provided that: ''Hereafter, no funds appropriated by this division or by any previous or subsequent Act shall be available for transfer under section 274 [42 U.S.C. 239*l*–3] of the PHS Act [Public Health Service Act].''

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATIONS

§ 241. Research and investigations generally

(a) Authority of Secretary

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

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

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

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

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

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

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

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

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

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Diseases not significantly occurring in United States

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

(d) Protection of privacy of individuals who are research subjects

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

(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research

if the research is funded wholly or in part by the Federal Government; and

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

(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

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

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

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

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

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

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

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

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

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

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

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

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

(A) through which an individual is identified; or

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

(e) Preterm labor and delivery and infant mortality

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

(f) Exemption of certain biomedical information from disclosure

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

(A) an individual is identified; or

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

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

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

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

(g) Inapplicability of Federal information policy

Subchapter I of chapter 35 of title 44 shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.

(h) Availability of substances and living organisms for biomedical and behavioral research

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

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

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

(July 1, 1944, ch. 373, title III, § 301, 58 Stat. 691; July 3, 1946, ch. 538, § 7(a), (b), 60 Stat. 423; June 16, 1948, ch. 481, § 4(e), (f), 62 Stat. 467; June 24, 1948, ch. 621, § 4(e), (f), 62 Stat. 601; June 25, 1948, ch. 654, § 1, 62 Stat. 1017; July 3, 1956, ch. 510, § 4, 70 Stat. 490; Pub. L. 86–798, Sept. 15, 1960, 74 Stat. 1053; Pub. L. 87–838, § 2, Oct. 17, 1962, 76 Stat. 1073; Pub. L. 89–115, § 3, Aug. 9, 1965, 79 Stat. 448; Pub. L. 90–174, § 9, Dec. 5, 1967, 81 Stat. 540; Pub. L. 91–513, title I, § 3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91–515, title II, § 292, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 92–218, § 6(a)(2), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92–423, § 7(b), Sept. 19, 1972, 86 Stat. 687; Pub. L. 93–282, title I, § 122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93–348, title I, § 104(a)(1), July 12, 1974, 88 Stat. 346; Pub. L. 93–352, title I, § 111, July 23, 1974, 88 Stat. 360; Pub. L. 94–278, title I, § 111, Apr. 22, 1976, 90 Stat. 405; Pub. L. 95–622, title II, §§ 261, 262, Nov. 9, 1978, 92 Stat. 3434; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–158, § 3(a)(5), Nov. 20, 1985, 99 Stat. 879; Pub. L. 99–570, title IV, § 4021(b)(2), Oct. 27, 1986, 100 Stat. 3207–124; Pub. L. 99–660, title I, § 104, Nov. 14, 1986, 100 Stat. 3751; Pub. L. 100–607, title I, § 163(1), (2), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 103–43, title XX, § 2009, June 10, 1993, 107 Stat. 213; Pub. L. 109–450, § 3(a), Dec. 22, 2006, 120 Stat. 3341; Pub. L. 114–255, div. A, title II, §§ 2012(a), 2013, 2035, 2043, Dec. 13, 2016, 130 Stat. 1049, 1050, 1062, 1074.)

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255, § 2043(1), redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h).

Subsec. (d). Pub. L. 114–255, § 2012(a), amended subsec. (d) generally. Prior to amendment, text read as follows: ''The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.''

Subsec. (f). Pub. L. 114–255, § 2013, added subsec. (f).

Subsec. (g). Pub. L. 114–255, § 2035, added subsec. (g).

Subsec. (h). Pub. L. 114–255, § 2043, redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h) and added pars. (2) and (3).

2006—Subsec. (e). Pub. L. 109–450 added subsec. (e).

1993—Subsec. (b)(4). Pub. L. 103–43 substituted ''a biennial report'' for ''an annual report'' in introductory provisions.

1988—Subsec. (d). Pub. L. 100–607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted ''biomedical, behavioral, clinical, or other research (including research on mental health, including'' for ''research on mental health, including'', and substituted ''drugs)'' for ''drugs,''.

1986—Subsec. (a)(3). Pub. L. 99–570 struck out ''or, in the case of mental health projects, by the National Advisory Mental Health Council;'' after ''Department supporting such projects'' and struck out ''or the National Advisory Mental Health Council'' after ''appropriate entity of the Department''.

Subsec. (c). Pub. L. 99–660 added subsec. (c).

1985—Subsec. (a)(3). Pub. L. 99–158, § 3(a)(5)(A), substituted ''as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research'' for ''as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided*, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year''.

Subsec. (a)(8). Pub. L. 99–158, § 3(a)(5)(B), substituted ''recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers'' for ''recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems''.

1978—Pub. L. 95–622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted ''Secretary'' for ''Surgeon General'' wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976—Subsecs. (c), (h). Pub. L. 94–278 substituted ''heart, blood vessel, lung, and blood diseases and blood resources'' for ''heart diseases'' and ''National Heart, Lung and Blood Advisory Council'' for ''National Heart and Lung Advisory Council''.

1974—Subsec. (c). Pub. L. 93–348, § 104(a)(1), redesignated subsec. (d) as (c) and substituted ''research projects'' for ''research or research training projects'' in two places, ''general support of their research'' for

''general support of their research and research training programs'' and ''research grants-in-aid'' for ''research and research training program grants-in-aid''. Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out.

Subsec. (d). Pub. L. 93–348, § 104(a)(1)(C), redesignated subsec. (e) as (d).

Pub. L. 93–282 substituted ''mental health, including research on the use and effect of alcohol and other psychoactive drugs'' for ''the use and effect of drugs'' in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above.

Subsecs. (e), (f). Pub. L. 93–348, § 104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d).

Subsec. (g). Pub. L. 93–352 struck out ''during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years'' after ''Enter into contracts''. Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93–348.

Pub. L. 93–348, § 104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsecs. (h), (i). Pub. L. 93–348, § 104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively.

1972—Subsecs. (d), (i). Pub. L. 92–423 substituted ''National Heart and Lung Advisory Council'' for ''National Advisory Heart Council''.

1971—Subsecs. (d), (i). Pub. L. 92–218 substituted ''National Cancer Advisory Board'' for ''National Advisory Cancer Council''.

1970—Subsec. (d). Pub. L. 91–513 added subsec. (d). See 1988 Amendment note above.

Subsec. (h). Pub. L. 91–515 substituted ''eight'' for ''five'' succeeding fiscal years.

1967—Subsec. (h). Pub. L. 90–174 substituted ''five'' for ''two'' succeeding fiscal years.

1965—Subsecs. (h), (i). Pub. L. 89–115 added subsec. (h) and redesignated former subsec. (h) as (i).

1962—Subsec. (d). Pub. L. 87–838 inserted ''or research training'' in two places.

1960—Subsec. (d). Pub. L. 86–798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health.

1956—Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h).

1948—Subsec. (d). Acts June 16, 1948, § 4(e), and June 24, 1948, § 4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects.

Subsec. (g). Acts June 16, 1948, § 4(f), and June 24, 1948, § 4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946—Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (a)(7), and ''Department of Health and Human Services'' substituted for ''Department of Health, Education, and Welfare'' in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1978 AMENDMENT

Sections 261 and 262 of Pub. L. 95–622 provided that the amendments made by those sections are effective Oct. 1, 1978.

EFFECTIVE DATE OF 1974 AMENDMENT

Section 104(b) of Pub. L. 93–348 provided that: ''The amendments made by subsection (a) [amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c–1, 289g, 289k, and heading preceding section 289*l* of this title] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a).''

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92–423, set out as a note under section 218 of this title.

EFFECTIVE DATE OF 1971 AMENDMENT

Amendment by Pub. L. 92–218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92–218, set out as a note under section 218 of this title.

APPLICABILITY OF 2016 AMENDMENT

Pub. L. 114–255, div. A, title II, § 2012(b), Dec. 13, 2016, 130 Stat. 1050, provided that: ''Beginning 180 days after the date of enactment of this Act [Dec. 13, 2016], all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).''

COORDINATION OF DATA SURVEYS AND REPORTS

Pub. L. 106–113, div. B, § 1000(a)(6) [title VII, § 703(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A–402, provided that: ''The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health.''

FEMALE GENITAL MUTILATION

Pub. L. 104–134, title I, § 101(d) [title V, § 520], Apr. 26, 1996, 110 Stat. 1321–211, 1321–250; renumbered title I, Pub. L. 104–140, § 1(a), May 2, 1996, 110 Stat. 1327, provided that:

''(a) Congress finds that—

''(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

''(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

''(b) The Secretary of Health and Human Services shall do the following:

''(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United

States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

''(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

''(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

''(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

''(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996].''

SENTINEL DISEASE CONCEPT STUDY

Pub. L. 103–43, title XIX, §1910, June 10, 1993, 107 Stat. 205, directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project.

STUDY OF THYROID MORBIDITY FOR HANFORD, WASHINGTON

Pub. L. 100–607, title I, §161, Nov. 4, 1988, 102 Stat. 3059, as amended by Pub. L. 102–531, title III, §312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH

Pub. L. 100–607,title I, §162, Nov. 4, 1988, 102 Stat. 3060, directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

RESEARCH WITH RESPECT TO HEALTH RESOURCES AND SERVICES ADMINISTRATION

Pub. L. 100–607, title VI, §632, Nov. 4, 1988, 102 Stat. 3147, provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

CONTINUING CARE FOR PSYCHIATRIC PATIENTS IN FORMER CLINICAL RESEARCH CENTER AT NATIONAL INSTITUTE ON DRUG ABUSE

Pub. L. 99–117, §10, Oct. 7, 1985, 99 Stat. 494, provided that: ''In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [42 U.S.C. 241] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations.''

ANALYSIS OF THYROID CANCER; CREATION AND PUBLICATION OF RADIOEPIDEMIOLOGICAL TABLES

Pub. L. 97–414, §7, Jan. 4, 1983, 96 Stat. 2059, as amended by Pub. L. 109–482, title I, §104(b)(3)(A), Jan. 15, 2007, 120 Stat. 3694, provided that:

''(a) In carrying out section 301 of the Public Health Service Act [42 U.S.C. 241], the Secretary of Health and Human Services shall—

''(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

''(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and

''(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

''(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

''(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish—

''(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

''(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

''(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise.''

TERMINATION OF ADVISORY COMMITTEES

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.

EXECUTIVE ORDER NO. 13435

Ex. Ord. No. 13435, June 20, 2007, 72 F.R. 34591, which directed research with stem cells not derived from the creation or destruction of a human embryo or fetus, was revoked by Ex. Ord. No. 13505, § 5(b), Mar. 9, 2009, 74 F.R. 10668, set out below.

EX. ORD. NO. 13505. REMOVING BARRIERS TO RESPONSIBLE SCIENTIFIC RESEARCH INVOLVING HUMAN STEM CELLS

Ex. Ord. No. 13505, Mar. 9, 2009, 74 F.R. 10667, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

SEC. 2. *Research*. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

SEC. 3. *Guidance*. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

SEC. 4. *General Provisions*. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 5. *Revocations*. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

BARACK OBAMA.

GUIDELINES FOR HUMAN STEM CELL RESEARCH

Memorandum of President of the United States, July 30, 2009, 74 F.R. 38885, provided:

Memorandum for the Heads of Executive Departments and Agencies

As outlined in Executive Order 13505 of March 9, 2009, my Administration is committed to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. Pursuant to that order, the National Institutes of Health (NIH) published final ''National Institutes of Health Guidelines for Human Stem Cell Research'' (Guidelines), effective July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illness, and that individuals donating embryos for research purposes should do so freely, with voluntary and informed consent. These Guidelines will ensure that NIH-funded research adheres to the highest ethical standards.

In order to ensure that all federally funded human stem cell research is conducted according to these same principles and to promote a uniform Federal policy across the executive branch, I hereby direct the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable in light of legal authorities and obligations. I also direct those departments and agencies to submit to the Director of the Office of Management and Budget (OMB), within 90 days, proposed additions or revisions to any other guidance, policies, or procedures related to human stem cell research, consistent with Executive Order 13505 and this memorandum. The Director of the OMB shall, in coordination with the Director of NIH, review these proposals to ensure consistent implementation of Executive Order 13505 and this memorandum.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

The Director of the OMB is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

ENGAGING IN PUBLIC HEALTH RESEARCH ON THE CAUSES AND PREVENTION OF GUN VIOLENCE

Memorandum of President of the United States, Jan. 16, 2013, 78 F.R. 4295, provided that:

Memorandum for the Secretary of Health and Human Services

In addition to being a law enforcement challenge, gun violence is also a serious public health issue that affects thousands of individuals, families, and communities across the Nation. Each year in the United States there are approximately 30,000 firearm-related deaths, and approximately 11,000 of those deaths result from homicides. Addressing this critical issue requires a comprehensive, multifaceted approach.

Recent research suggests that, in developing such an approach, a broader public health perspective is imperative. Significant strides can be made by assessing the causes of gun violence and the successful efforts in place for preventing the misuse of firearms. Taking these steps will improve our understanding of the gun violence epidemic and will aid in the continued development of gun violence prevention strategies.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

SECTION 1. *Research.* The Secretary of Health and Human Services (Secretary), through the Director of the Centers for Disease Control and Prevention and other scientific agencies within the Department of Health and Human Services, shall conduct or sponsor research into the causes of gun violence and the ways to prevent it. The Secretary shall begin by identifying the most pressing research questions with the greatest potential public health impact, and by assessing existing public health interventions being implemented across the Nation to prevent gun violence.

SEC. 2. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 3. *Publication.* You are hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§ 242. Studies and investigations on use and misuse of narcotic drugs and other drugs; annual report to Attorney General; cooperation with States

(a) In carrying out the purposes of section 241 of this title with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act [21 U.S.C. 801 et seq.] and Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.], together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

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

(July 1, 1944, ch. 373, title III, § 302, 58 Stat. 692; Pub. L. 91–513, title II, § 701(j), Oct. 27, 1970, 84 Stat. 1282.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (a), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, as amended, which is classified principally to subchapter II (§ 951 et seq.) of chapter 13 of Title 21. For complete classification of this Act to the Code, see Short Title note set out under section 951 of Title 21 and Tables.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91–513 inserted references to drug dependency, drugs other than narcotic drugs, and substances subject to control under the Controlled Substances Act and the Controlled Substances Import and Export Act, substituted the first day of April of each year for the first day of September of each year as the date by which the study results must be submitted, substituted the Attorney General for the Secretary of the Treasury as the officer to whom the report is to be submitted, and struck out references to the Narcotic Drugs Import and Export Act.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of Title 21, Food and Drugs.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of Title 21, Food and Drugs.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

MARIHUANA AND HEALTH REPORTING

Pub. L. 91–296, title V, June 30, 1970, 84 Stat. 352, as amended by Pub. L. 95–461, § 3(a), Oct. 14, 1978, 92 Stat. 1268; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, known as the Marihuana and Health Reporting Act, which required the Secretary of Health and Human Services, after consultation with the Surgeon General and other appropriate individuals, to transmit a report to the Congress on or before January 31, 1971, and biennially thereafter (1) containing current information on the health consequences of using marihuana, and (2)

containing such recommendations for legislative and administrative action as he may deem appropriate, was repealed by Pub. L. 98–24, § 2(d), Apr. 26, 1983, 97 Stat. 182.

§ 242a. Repealed. Pub. L. 106–310, div. B, title XXXII, § 3201(b)(1), Oct. 17, 2000, 114 Stat. 1190

Section, act July 1, 1944, ch. 373, title III, § 303, as added July 3, 1946, ch. 538, § 7(c), 60 Stat. 423; amended Aug. 2, 1956, ch. 871, title V, § 501, 70 Stat. 929; Pub. L. 91–513, title I, § 3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 93–282, title I, § 122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93–348, title I, § 104(a)(2), July 12, 1974, 88 Stat. 346; Pub. L. 95–633, title I, § 108(b), Nov. 10, 1978, 92 Stat. 3773; Pub. L. 96–398, title VIII, § 803(a), Oct. 7, 1980, 94 Stat. 1607; Pub. L. 100–177, title II, § 202(a), Dec. 1, 1987, 101 Stat. 996; Pub. L. 100–607, title I, § 163(1)(A), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 100–690, title II, § 2058(b), Nov. 18, 1988, 102 Stat. 4214; Pub. L. 101–597, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 102–321, title I, § 115(b), July 10, 1992, 106 Stat. 348; Pub. L. 102–408, title III, § 305, Oct. 13, 1992, 106 Stat. 2084; Pub. L. 105–392, title IV, § 403, Nov. 13, 1998, 112 Stat. 3588, related to mental health.

§ 242b. General authority respecting research, evaluations, and demonstrations in health statistics, health services, and health care technology

(a) Scope of activities

The Secretary may, through the Agency for Healthcare Research and Quality or the National Center for Health Statistics, or using Ruth L. Kirschstein National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in section 242k of this title and in subchapter VII.

(b) Additional authority; scope of activities

To implement subsection (a) and section 242k of this title, the Secretary may, in addition to any other authority which under other provisions of this chapter or any other law may be used by him to implement such subsection, do the following:

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

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

(3) Secure, from time to time and for such periods as the Secretary deems advisable but in accordance with section 3109 of title 5, the assistance and advice of consultants from the United States or abroad. The Secretary may for the purpose of carrying out the functions set forth in sections 242c,[1] 242k, and 242n[1] of this title, obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications.

(4) Acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to section 8141 of title 40, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

(c) Coordination of activities through units of Department

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

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

(July 1, 1944, ch. 373, title III, § 304, as added July 28, 1955, ch. 417, § 3, 69 Stat. 382; amended Aug. 2, 1956, ch. 871, title V, § 502, 70 Stat. 930; Pub. L. 90–174, § 3(a), Dec. 5, 1967, 81 Stat. 534; Pub. L. 91–296, title IV, § 401(b)(1)(A), June 30, 1970, 84 Stat. 352; Pub. L. 91–515, title II, §§ 201(a)–(c), 202, 203, Oct. 30, 1970, 84 Stat. 1301–1303; Pub. L. 93–45, title I, § 102, June 18, 1973, 87 Stat. 91; Pub. L. 93–353, title I, § 103, July 23, 1974, 88 Stat. 362; Pub. L. 95–623, §§ 3, 7, Nov. 9, 1978, 92 Stat. 3443, 3451; Pub. L. 96–32, § 5(a)–(c), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, § 918, Aug. 13, 1981, 95 Stat. 565; Pub. L. 98–551, § 5(c), Oct. 30, 1984, 98 Stat. 2819; Pub. L. 101–239, title VI, § 6103(e)(1), Dec. 19, 1989, 103 Stat. 2205; Pub. L. 103–183, title V, § 501(b), Dec. 14, 1993, 107 Stat. 2237; Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 107–206, title I, § 804(c), Aug. 2, 2002, 116 Stat. 874.)

REFERENCES IN TEXT

Sections 242c and 242n of this title, referred to in subsec. (b)(3), were repealed by Pub. L. 101–239, title VI, § 6103(d)(1), Dec. 19, 1989, 103 Stat. 2205.

CODIFICATION

In subsec. (b)(4), ''section 8141 of title 40'' substituted for ''the Act of March 3, 1877 (40 U.S.C. 34)'' on authority of Pub. L. 107–217, § 5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

[1] See References in Text note below.

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–206 substituted ''Ruth L. Kirschstein National Research Service Awards'' for ''National Research Service Awards''.

1999—Subsecs. (a), (c). Pub. L. 106–129 substituted ''Agency for Healthcare Research and Quality'' for ''Agency for Health Care Policy and Research'' wherever appearing.

1993—Subsec. (d). Pub. L. 103–183 struck out subsec. (d) which directed Secretary to conduct an ongoing study of present and projected future health costs of pollution and other environmental conditions resulting from human activity and to submit to Congress reports on the study.

1989—Subsec. (a). Pub. L. 101–239, §6103(e)(1)(B), substituted ''the Agency for Health Care Policy and Research'' for ''the National Center for Health Services Research and Health Care Technology Assessment'' and ''in section 242k of this title and in subchapter VII'' for ''in sections 242c, 242k, and 242n of this title''.

Pub. L. 101–239, §6103(e)(1)(A), redesignated par. (3) as entire subsec. (a) and struck out pars. (1) and (2) which required Secretary to conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for purpose of improving health services in the United States, and which specified types of activities Secretary was to emphasize in carrying out par. (1).

Subsec. (b). Pub. L. 101–239, §6103(e)(1)(C), substituted ''subsection (a) and section 242k of this title'' for ''subsection (a)''.

Subsec. (c)(1), (2). Pub. L. 101–239, §6103(e)(1)(D), substituted ''the Agency for Health Care Policy and Research'' for ''the National Center for Health Services Research and Health Care Technology Assessment''.

1984—Subsec. (a)(1). Pub. L. 98–551, §5(c)(1), (2), substituted ''the National Center for Health Services Research and Health Care Technology Assessment and the National Center for Health Statistics'' for ''the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology''.

Subsec. (a)(3). Pub. L. 98–551, §5(c)(1), (3), substituted ''the National Center for Health Services Research and Health Care Technology Assessment or the National Center for Health Statistics'' for ''the National Center for Health Services Research, the National Center for Health Statistics, or the National Center for Health Care Technology''.

Subsec. (c)(1), (2). Pub. L. 98–551, §5(c)(1), (2), substituted ''the National Center for Health Services Research and Health Care Technology Assessment and the National Center for Health Statistics'' for ''the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology''.

1981—Subsec. (a)(3). Pub. L. 97–35, §918(a), substituted ''may'' for ''shall'', ''or the'' for ''and the'', ''or using'' for ''and using'', and ''or other'' for ''and other''.

Subsecs. (b)(1), (c)(1). Pub. L. 97–35, §918(d)(1), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (d)(1). Pub. L. 97–35, §918(b)(1), (2), substituted provisions relating to advice and assistance of the National Academy of Sciences, for provisions relating to joint authority of the National Academy of Sciences, and struck out definition of ''Academy'' as meaning the National Academy of Sciences.

Subsec. (d)(3). Pub. L. 97–35, §918(b)(3), (c), (d)(2), substituted ''every three years'' for ''every two years'', and ''Energy and'' for ''Interstate and Foreign'', and struck out references to the Academy.

1979—Subsec. (b)(1), (3). Pub. L. 96–32, §5(a), (b), amended directory language of Pub. L. 95–623, §3(b), (d), and required no change in text. See 1978 Amendment note below.

Subsec. (d). Pub. L. 96–32, §5(c), substituted ''(d)'' for ''(e)'' as designation of subsection added by Pub. L. 95–623, §7, thereby correcting the subsection designation.

1978—Subsec. (a)(1). Pub. L. 95–623, §3(a), substituted provision for the Secretary acting through the National Center for Health Care Technology for such action through other units of the Department of Health, Education, and Welfare and ''conduct'' for ''undertake'', included epidemiological activities, and declared as an objective the improvement of the effectiveness, efficiency, and quality of Federal health services.

Subsec. (a)(2). Pub. L. 95–623, §3(a), provided for emphasis to demonstrations, evaluations, and epidemiological activities; redesignated as subpar. (A) former subpar. (C); struck out ''technology'' and ''quality'' after ''organization,'' and ''utilization,'', respectively, and end clause ''including systems for the delivery of preventive, personal, and mental health care'' and former subpar. (A) activities respecting ''the determination of an individual's health''; added subpars. (B) through (D); struck out former subpar. (D) activities respecting ''individual and community knowledge of individual health and the systems for the delivery of health care''; added subpars. (E) through (I); and redesignated as subpar. (J) former subpar. (B).

Subsec. (a)(3). Pub. L. 95–623, §3(a), added par. (3).

Subsec. (b)(1). Pub. L. 95–623, §3(b), as amended by Pub. L. 96–32, §5(a), substituted '', when appropriate, enter into contracts with public and private entities and individuals'' for ''enter into contracts with public and private entities and individuals, for (A) health services research, evaluation, and demonstrations, and (B) health services research and health statistics training, and (C) health statistical activities''.

Subsec. (b)(3). Pub. L. 95–623, §3(d), as amended by Pub. L. 96–32, §5(b), substituted ''advisable but in accordance with section 3109 of title 5'' for ''advisable'', struck out ''experts and'' before ''consultants'', and authorized the Secretary to obtain for the centers the services of experts with appropriate scientific or professional qualifications.

Subsec. (c). Pub. L. 95–623, §3(c), designated existing text as par. (1), substituted ''evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology'' for ''evaluation, demonstration, and health statistical activities'' before ''undertaken and supported'', required coordination of activities to also be carried out through the National Center for Health Care Technology, and added par. (2).

Subsec. (d). Pub. L. 95–623, §7, as amended by Pub. L. 96–32, §5(c), added subsec. (d).

1974—Pub. L. 93–353, in revising generally provisions of subsecs. (a) to (c), provided for general authority respecting health statistics and health services research, evaluation, and demonstrations, subsec. (a) relating to scope of activities, subsec. (b) relating to additional authority and scope of activities, and subsec. (c) relating to coordination of activities through units of the Department. Former provisions related to research and demonstrations relating to health facilities and services, subsec. (a) relating to grants and contracts for projects for research, experiments, or demonstrations and related training, cost limitation, wage rates, labor standards, and other conditions, and payments (former subsec. (a)(2) and (3) now being covered by section 242m(h) and (e), respectively), subsec. (b) relating to systems analysis of national health care plans, and cost and coverage report on existing legislative proposals, and subsec. (c) relating to authorization of appropriations.

1973—Subsec. (c)(1). Pub. L. 93–45 authorized appropriations of $42,617,000 for fiscal year ending June 30, 1974.

1970—Subsec. (a)(1). Pub. L. 91–515, §§201(a)(1), 203, redesignated subsec. (a) as (a)(1), substituted ''(A)'' and ''(B)'' for ''(1)'' and ''(2)'', and ''(i) to (iii)'' for ''(A) to (C)'', and added cls. (iv) and (v).

Subsec. (a)(2). Pub. L. 91–515, §201(a)(2), redesignated subsec. (b) as (a)(2), and substituted ''subsection'' for ''section'' wherever appearing.

Subsec. (a)(3). Pub. L. 91–515, §§201(a)(3), 202, redesignated subsec. (c) as (a)(3)(A), substituted ''subsection''

for ''section'' wherever appearing, and added subsec. (a)(3)(B).

Subsec. (b). Pub. L. 91–515, § 201(a)(2)(A), (b), added subsec. (b). Former subsec. (b) redesignated (a)(2).

Subsecs. (c), (d). Pub. L. 91–515, §§ 201(a)(3)(A), (c), 202(1), redesignated subsec. (d) as (c), and substituted provisions authorizing appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, and authorizing to be appropriated such additional sums for each fiscal year as may be necessary to carry out the provisions of subsec. (b), for provisions authorizing appropriations of $20,000,000 for the fiscal year ending June 30, 1968, $40,000,000 for the fiscal year ending June 30, 1969, and $60,000,000 for the fiscal year ending June 30, 1970. Former subsec. (c) redesignated (a)(3)(A).

Pub. L. 91–296 struck out provisions authorizing use of appropriated funds for evaluation of program authorized by this section. See section 229b of this title.

1967—Pub. L. 90–174 substituted provisions of subsecs. (a) to (d) for research and demonstrations relating to health facilities (incorporated from former section 291n of this title) for provisions of former subsecs. (a) to (d) for mental health study including grants for special projects, conditions thereof, and definition of ''organization'', authorization of appropriations, terms of grant, availability of amounts otherwise appropriated and noninterference with research and study programs of the National Institute of Mental Health, and acceptance of additional financial support.

1956—Act Aug. 2, 1956, changed heading of section 304 of act July 1, 1944 from ''Grants for special projects in mental health'' to ''Mental health study grants''. Section heading has been changed for purposes of codification.

EFFECTIVE DATE OF 1970 AMENDMENTS

Pub. L. 91–515, title II, § 201(d), Oct. 30, 1970, 84 Stat. 1303, provided that: ''The amendments made by subsection (c) of this section [amending this section] shall be effective only with respect to fiscal years ending after June 30, 1970.''

Pub. L. 91–296, title IV, § 401(b)(1), June 30, 1970, 84 Stat. 352, 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 1956 AMENDMENT

Amendment of section by act Aug. 2, 1956, effective July 1, 1956, see section 503 of act Aug. 2, 1956.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

COMMISSION ON SYSTEMIC INTEROPERABILITY

Pub. L. 108–173, title X, § 1012, Dec. 8, 2003, 117 Stat. 2435, directed the Secretary of Health and Human Services to establish a commission to be known as the ''Commission on Systemic Interoperability'', which would develop a comprehensive strategy for the adoption and implementation of health care information technology standards, and which would terminate 30 days after submitting a report, not later than Oct. 31, 2005, to the Secretary and to Congress, describing the strategy developed.

MODEL STANDARDS WITH RESPECT TO PREVENTIVE HEALTH SERVICES IN COMMUNITIES

Pub. L. 95–83, title III, § 314, Aug. 1, 1977, 91 Stat. 398, required the Secretary of Health, Education, and Welfare, within two years of Aug. 1, 1977, to establish model standards with respect to preventive health services in communities and report such standards to Congress.

TRANSFER OF EQUIPMENT

Pub. L. 94–573, § 15, Oct. 21, 1976, 90 Stat. 2719, provided that notwithstanding any other provision of law, the Secretary of Health, Education, and Welfare could vest title to equipment purchased with funds under the seven contracts for emergency medical services demonstration projects entered into in 1972 and 1973 under this section (as in effect at the time the contracts were entered into), and by contractors with the United States under such contracts or subcontractors under such contracts, in such contractors or subcontractors without further obligation to the Government or on such terms as the Secretary considered appropriate.

CONGRESSIONAL DECLARATION OF PURPOSE

Joint Res. July 28, 1955, ch. 417, § 2, 69 Stat. 382, provided a Congressional statement of the critical need for an analysis and reevaluation of the human and economic problems of mental illness and of the resources, methods, and practices utilized in diagnosing, treating, caring for, and rehabilitating the mentally ill, both within and outside of institutions, as might lead to the development of recommendations for such better utilization of those resources or such improvements on and new developments in methods of diagnosis, treatment, care, and rehabilitation as give promise of resulting in a marked reduction in the incidence or duration of mental illness and, in consequence, a lessening of the appalling emotional and financial drain on the families of those afflicted or on the economic resources of the States and of the Nation and a declaration of the policy to promote mental health and to help solve the complex and the interrelated problems posed by mental illness by encouraging the undertaking of nongovernmental, multidisciplinary research into and reevaluation of all aspects of our resources, methods, and practices for diagnosing, treating, caring for, and rehabilitating the mentally ill, including research aimed at the prevention of mental illness.

CHILDREN'S EMOTIONAL ILLNESS STUDY; PROGRAM GRANTS; CONDITIONS; DEFINITIONS; APPROPRIATIONS; TERMS OF GRANT

Pub. L. 89–97, title II, § 231, July 30, 1965, 79 Stat. 360, as amended by Pub. L. 90–248, title III, § 305, Jan. 2, 1968, 81 Stat. 929, authorized the Secretary of Health, Education, and Welfare upon the recommendation of the National Advisory Mental Health Council and after securing the advice of experts in pediatrics and child welfare, to make grants to organizations on certain conditions for carrying out a program of research into and study of resources, methods, and practices for diagnosing or preventing emotional illness in children and of treating, caring for, and rehabilitating children with emotional illnesses, defined ''organization'', and authorized appropriations for the making of such grants for fiscal years ending June 30, 1966, and June 30, 1967, with such research and study to be completed not later than three years from the date it was inaugurated.

§ 242c. Repealed. Pub. L. 101–239, title VI, § 6103(d)(1)(A), Dec. 19, 1989, 103 Stat. 2205

Section, act July 1, 1944, ch. 373, title III, § 305, as added July 3, 1956, ch. 510, § 3, 70 Stat. 490; amended Oct. 30, 1970, Pub. L. 91–515, title II, § 210, 84 Stat. 1303; June 18, 1973, Pub. L. 93–45, title I, § 103, 87 Stat. 91; July 23, 1974, Pub. L. 93–353, title I, § 104, 88 Stat. 363; Oct. 8, 1976, Pub. L. 94–460, title III, § 301, 90 Stat. 1960; Nov. 9, 1978, Pub. L. 95–623, § 4, 92 Stat. 3445; Aug. 13, 1981, Pub. L.

97–35, title IX, §919(a)(1), (2)(A), (3), (b)(1), (c), (d), 95 Stat. 565, 566; Oct. 30, 1984, Pub. L. 98–551, §§5(a), (b), 6, 98 Stat. 2817, 2819, 2820; Oct. 7, 1985, Pub. L. 99–117, §6, 99 Stat. 492; Nov. 14, 1986, Pub. L. 99–660, title III, §311(b)(2), 100 Stat. 3779; Dec. 1, 1987, Pub. L. 100–177, title I, §§101, 102, 101 Stat. 987; Nov. 4, 1988, Pub. L. 100–607, title II, §204(1), 102 Stat. 3079; Nov. 18, 1988, Pub. L. 100–690, title II, §2620(b)(3), 102 Stat. 4244; Aug. 16, 1989, Pub. L. 101–93, §5(e)(3), 103 Stat. 612, related to National Center for Health Services Research and Health Care Technology Assessment.

TERMINATION OF NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT

Pub. L. 101–239, title VI, §6103(d)(1)(A), Dec. 19, 1989, 103 Stat. 2205, provided in part that the National Center for Health Services Research and Health Care Technology Assessment is terminated.

TRANSITIONAL AND SAVINGS PROVISIONS FOR PUB. L. 101–239

For provision transferring personnel of Department of Health and Human Services employed on Dec. 19, 1989, in connection with functions vested in Administrator for Health Care Policy and Research pursuant to amendments made by section 6103 of Pub. L. 101–239, and assets, liabilities, etc., of Department arising from or employed, held, used, or available on that date, or to be made available after that date, in connection with those functions, to Administrator for appropriate allocation, and for provisions for continued effectiveness of actions, orders, rules, official documents, etc., of Department that have been issued, made, granted, or allowed to become effective in performance of those functions, and that were effective on Dec. 19, 1989, see section 6103(f) of Pub. L. 101–239, set out as a note under section 299 of this title.

§ 242d. Transferred

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, §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. 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, which related to graduate or specialized training for physicians, engineers, nurses, and other professional personnel, was renumbered section 312 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 244–1 of this title, and was subsequently repealed.

§ 242e. Repealed. Pub. L. 93–353, title I, § 102(a), July 23, 1974, 88 Stat. 362

Section, act July 1, 1944, ch. 373, title III, §307, as added Aug. 2, 1956, ch. 871, title II, §201, 70 Stat. 924; amended July 23, 1959, Pub. L. 86–105, §2, 73 Stat. 239; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311, provided for a professional nurse traineeship program for which authorization of appropriations were made through fiscal year ending June 30, 1964. Provision for the continuation of the program was made by the Nurse Training Act of 1964, which enacted section 297 et seq. of this title.

§§ 242f to 242j. Transferred

CODIFICATION

Section 242f, act July 1, 1944, ch. 373, title III, §308, as added July 12, 1960, Pub. L. 86–610, §3, 74 Stat. 364, which related to international cooperation with respect to biomedical research and health services research and statistical activities, was renumbered section 307 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 242*l* of this title.

Section 242g, act July 1, 1944, ch. 373, title III, §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. 90–147, §§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, which related to graduate public health training grants, was renumbered section 313 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 245a of this title, and was subsequently repealed.

Section 242h, act July 1, 1944, ch. 373, title III, §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592, and amended and renumbered, which related to health services for domestic agricultural migrants, was renumbered section 319 of act July 1, 1944, by Pub. L. 93–353, title I, §102(d), July 23, 1974, 88 Stat. 362, transferred to section 247d of this title, and subsequently renumbered 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.

Section 242i, act July 1, 1944, ch. 373, title III, §310A, as added Oct. 30, 1970, Pub. L. 91–515, title II, §270, 84 Stat. 1306; amended Nov. 18, 1971, Pub. L. 92–157, title II, §201, 85 Stat. 461, which related to administration of grants in multigrant projects, was renumbered section 226 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 235 of this title.

Section 242j, act July 1, 1944, ch. 373, title III, §310B, as added Oct. 30, 1970, Pub. L. 91–515, title II, §280, 84 Stat. 1307, which provided for and annual report by Secretary on activities related to health facilities and services and expenditure of funds, was renumbered section 227 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 236 of this title, and was subsequently repealed.

§ 242k. National Center for Health Statistics

(a) Establishment; appointment of Director; statistical and epidemiological activities

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

(b) Duties

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

(1) shall collect statistics on—

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

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

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

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health profes-

sionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

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

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

(H) family formation, growth, and dissolution;

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

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

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

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

(c) Statistical and epidemiological compilations and surveys

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

(d) Technical aid to States and localities

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

(e) Cooperative Health Statistics System

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

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

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

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

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

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system[1] produce uniform and timely data and assure appropriate access to such data.

(f) Federal-State cooperation

To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 6101 of title 41, of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) Collection of health data; data collection forms

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

(h) Registration area records

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

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

method authorized by him) its records for such data.

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

(i) Technical assistance in effective use of statistics

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

(j) Coordination of health statistical and epidemiological activities

In carrying out the requirements of section 242b(c) of this title and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by—

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

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

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

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

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

[2] See References in Text note below.

(k) National Committee on Vital and Health Statistics; establishment; membership; term of office; compensation; functions; consultations of Secretary with Committee and professional advisory groups

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

(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Of the members of the Committee—

(A) 1 shall be appointed, not later than 60 days after August 21, 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;

(B) 1 shall be appointed, not later than 60 days after August 21, 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and

(C) 16 shall be appointed by the Secretary.

(4) Members of the Committee shall be compensated in accordance with section 210(c) of this title.

(5) The Committee—

(A) shall assist and advise the Secretary—

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

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

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

(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect

to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

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

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

(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.];

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

(C) shall report to the Secretary not later than 4 years after August 21, 1996, recommendations and legislative proposals for such standards and electronic exchange; and

(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.].

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

(7) Not later than 1 year after August 21, 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.]. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

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

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

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

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

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

(*l*) Data specific to particular ethnic and racial populations

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

(m) Grants for assembly and analysis of data on ethnic and racial populations

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

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

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

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

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

(3) Provisions of section 242m(d) of this title do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

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

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

(n) Authorization of appropriations

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

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

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

(July 1, 1944, ch. 373, title III, § 306, as added Pub. L. 93–353, title I, § 105, July 23, 1974, 88 Stat. 365; amended Pub. L. 95–623, §§ 5, 8(a), Nov. 9, 1978, 92

Stat. 3445, 3453; Pub. L. 97–35, title IX, § 920, Aug. 13, 1981, 95 Stat. 566; Pub. L. 97–414, § 8(b), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 100–177, title I, §§ 104, 105(a), Dec. 1, 1987, 101 Stat. 988; Pub. L. 101–239, title VI, § 6103(e)(2), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 101–527, § 7(a), (b)(1), (c), Nov. 6, 1990, 104 Stat. 2327, 2328; Pub. L. 102–54, § 13(q)(1)(A)(i), June 13, 1991, 105 Stat. 278; Pub. L. 103–183, title V, § 501(a), (d), Dec. 14, 1993, 107 Stat. 2237, 2238; Pub. L. 104–191, title II, § 263, Aug. 21, 1996, 110 Stat. 2031; Pub. L. 105–340, title II, § 201, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 105–392, title II, § 201(b), Nov. 13, 1998, 112 Stat. 3585.)

REFERENCES IN TEXT

Section 3509 of title 44, referred to in subsec. (j)(4), (5), which required submission of certain plans and forms for collection of information to the Director of the Office of Management and Budget for approval, was omitted in the general amendment of chapter 35 of Title 44, Public Printing and Documents, by Pub. L. 96–511, § 2(a), Dec. 11, 1980, 94 Stat. 2812. Pub. L. 104–13 subsequently enacted a new section 3509 of Title 44 relating to designation of a central collection agency. Provisions appearing in former section 3509 are contained in section 3507 of Title 44.

The Social Security Act, referred to in subsec. (k)(5)(A)(viii), (D), (7), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Part C of title XI of the Act is classified generally to part C (§ 1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsec. (f), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes (41 U.S.C. 5)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

Provisions similar to those comprising subsec. (g) of this section were contained in section 313 of act July 1, 1944, ch. 373, title III, 58 Stat. 693; Oct. 30, 1970, Pub. L. 91–516, title II, § 282, 84 Stat. 1308 (formerly classified to section 245 of this title), prior to repeal by Pub. L. 93–353, § 102(a).

Provisions similar to those comprising subsec. (h) of this section were contained in section 312a of act July 1, 1944, ch. 373, title III, as added Aug. 31, 1954, ch. 1158, § 2, 68 Stat. 1025 (formerly classified to section 244a of this title), prior to repeal by Pub. L. 93–353, § 102(a).

AMENDMENTS

1998—Subsec. (m)(4). Pub. L. 105–392, § 201(b)(1), added par. (4).

Subsec. (n)(1). Pub. L. 105–340, § 201(1), and Pub. L. 105–392, § 201(b)(2), amended par. (1) identically, substituting ''2003'' for ''1998''.

Subsec. (n)(2). Pub. L. 105–392, § 201(b)(3)(A), in first sentence, substituted ''paragraphs (1) through (3) of subsection (m)'' for ''subsection (m)'' and substituted ''such sums as may be necessary for each of the fiscal years 1999 through 2003.'' for ''$5,000,000 for fiscal year 1991, $7,500,000 for fiscal year 1992, $10,000,000 for fiscal year 1993, and $10,000,000 for each of the fiscal years 1994 through 2003.''

Pub. L. 105–340, § 201(2), substituted ''2003'' for ''1998''.

Subsec. (n)(3). Pub. L. 105–392, § 201(b)(3)(B), added par. (3).

1996—Subsec. (k)(1). Pub. L. 104–191, § 263(1), substituted ''18'' for ''16''.

Subsec. (k)(2). Pub. L. 104–191, § 263(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''The members of the Committee shall be appointed by the Secretary from among persons who have distinguished themselves in the fields of health statistics, health planning, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.''

Subsec. (k)(3), (4). Pub. L. 104–191, § 263(3), added par. (3) and redesignated former par. (3) as (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 104–191, § 263(4), amended par. (5) generally. Prior to amendment, par. (5) consisted of subpars. (A) to (G) relating to Committee functions in assisting and advising the Secretary.

Pub. L. 104–191, § 263(3), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (k)(6). Pub. L. 104–191, § 263(3), redesignated par. (5) as (6).

Subsec. (k)(7). Pub. L. 104–191, § 263(5), added par. (7).

1993—Subsec. (c). Pub. L. 103–183, § 501(a)(1), substituted ''Committee on Labor and Human Resources'' for ''Committee on Human Resources''.

Subsec. (g). Pub. L. 103–183, § 501(a)(2), substituted ''data'' for ''data which shall be published as a part of the health reports published by the Secretary''.

Subsec. (i). Pub. L. 103–183, § 501(a)(3), struck out ''engaged in health planning activities'' after ''entities''.

Subsec. (k)(2). Pub. L. 103–183, § 501(a)(4), struck out subpar. (A) designation, substituted ''Members'' for ''Except as provided in subparagraph (B), members'', and struck out subpar. (B) which related to extensions of membership terms of members of National Committee on Vital and Health Statistics whose terms were to expire in calendar years 1988, 1989, and 1990.

Subsec. (*l*). Pub. L. 103–183, § 501(a)(5)(A)–(C), redesignated subsec. (m) as (*l*), substituted ''subsection (m)'' for ''subsection (n)'', and struck out former subsec. (*l*) which related to development of plan for collection and coordination of statistical and epidemiological data on effects of environment on health and establishment of guidelines for compilation, analysis, and distribution of statistics and information necessary for coordinated determination of effects of conditions of employment and indoor and outdoor environmental conditions on public health.

Subsec. (m). Pub. L. 103–183, § 501(a)(5)(B), redesignated subsec. (n) as (m). Former subsec. (m) redesignated (*l*).

Subsecs. (n), (*o*). Pub. L. 103–183, § 501(a)(5)(B), (D), (d), redesignated subsec. (*o*) as (n), in par. (1) substituted ''(*l*)'' for ''(m)'' and ''1998'' for ''1993'', and in par. (2) substituted ''(m)'' for ''(n)'', struck out ''and'' after ''1992,'', inserted '', and $10,000,000 for each of the fiscal years 1994 through 1998'', and substituted ''(m)(2)'' for ''(n)(2)''. Former subsec. (n) redesignated (m).

1991—Subsec. (k)(4)(C). Pub. L. 102–54 substituted ''Department of Veterans Affairs'' for ''Veterans' Administration''.

1990—Subsec. (h). Pub. L. 101–527, § 7(a), designated existing text as par. (1), inserted after second sentence ''The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area.'', and added par. (2).

Subsecs. (m) to (*o*). Pub. L. 101–527, § 7(b)(1), (c), added subsecs. (m) and (n) and redesignated former subsec. (m) as (*o*) and amended it generally. Prior to amendment, subsec. (*o*) read as follows: ''For health statistical and epidemiological activities undertaken or supported under this section, there are authorized to be appropriated $55,000,000 for fiscal year 1988 and such sums as may be necessary for each of the fiscal years 1989 and 1990.''

1989—Subsec. (a). Pub. L. 101–239, § 6103(e)(2)(A), inserted at end ''The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.''

Subsec. (b). Pub. L. 101–239, § 6103(e)(2)(B), substituted ''subsection (a)'' for ''section 242b(a) of this title''.

Subsec. (m). Pub. L. 101–239, § 6103(e)(2)(C), added subsec. (m).

1987—Subsec. (a). Pub. L. 100–177, §104, struck out ''and supervised by the Assistant Secretary for Health (or such other officer of the Department as may be designated by the Secretary as the principal adviser to him for health programs)''.

Subsec. (k)(1). Pub. L. 100–177, §105(a)(1), substituted ''16 members'' for ''fifteen members''.

Subsec. (k)(2)(A). Pub. L. 100–177, §105(a)(2), substituted ''terms of 4 years'' for ''terms of three years''.

Subsec. (k)(2)(B). Pub. L. 100–177, §105(a)(3), added subpar. (B) and struck out former subpar. (B) which read as follows: ''Of the members first appointed—

''(i) five shall be appointed for terms of one year,

''(ii) five shall be appointed for terms of two years, and

''(iii) five shall be appointed for terms of three years,

as designated by the Secretary at the time of appointment. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.''

1983—Subsec. (*l*)(2)(D). Pub. L. 97–414 redesignated subpar. (E) as (D) and struck out former subpar. (D) which provided that the Center would serve as a clearinghouse for statistics and information with respect to which guidelines had been established under subpar. (A).

Subsec. (*l*)(2)(E) to (G). Pub. L. 97–414 redesignated subpars. (F) and (G) as (E) and (F), respectively. Former subpar. (E) redesignated (D).

1981—Subsec. (a). Pub. L. 97–35, §920(d)(1), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (c). Pub. L. 97–35, §920(d)(2), substituted ''Energy and'' for ''Interstate and Foreign''.

Subsec. (e). Pub. L. 97–35, §920(a), (d)(1), in par. (3) inserted applicability to other activities, and in par. (4) substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsecs. (j), (k)(4)(C), (D). Pub. L. 97–35, §920(d)(1), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (*l*)(2). Pub. L. 97–35, §920(b), (c), (d)(1), in subpar. (A) inserted reference to Office of Federal Statistical Policy and Standards, in subpar. (B)(v) substituted ''Health and Human Services'' for ''Health, Education, and Welfare'', and in subpar. (D) struck out provisions relating to assistance to executive departments.

1978—Subsec. (b). Pub. L. 95–623, §5(a), struck out ''may'' after ''through the Center,'', substituted in pars. (1) and (2) ''shall collect'' and ''shall undertake'' for ''collect'' and ''undertake'', respectively, and added pars. (3) and (4) and provision for availability of certain appropriated funds from par. (4) payments until expended.

Subsec. (c). Pub. L. 95–623, §5(b), substituted ''statistical and epidemiological compilations'' for ''statistical compilations'' in two places and ''Committee on Human Resources'' for ''Committee on Labor and Public Welfare'' of the Senate.

Subsec. (e). Pub. L. 95–623, §5(c)(1), incorporated in introductory text prior cl. (1) provision requiring the Secretary to assist State and local health agencies and Federal agencies involved in health matters in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels; enacted in pars. (1) and (2) provisions almost identical to prior cls. (2) and (3); enacted par. (3); struck out former cl. (4) provision for the Federal share of the data collection costs under the system; enacted in par. (4) provisions almost identical to former cl. (5); and required State designation of a State administrative agency to be responsible for the statistical activities within the State under the System and Federal guidelines for production of uniform and timely data and appropriate access to the data.

Subsec. (f). Pub. L. 95–623, §5(d), substituted ''the Secretary, acting through the Center, shall cooperate and consult'' for ''the Secretary shall cooperate and consult''.

Subsecs. (i), (j). Pub. L. 95–623, §5(f), added subsecs. (i) and (j). Former subsec. (i) redesignated (k).

Subsec. (k). Pub. L. 95–623, §5(c)(2), (e), (f), struck from par. (1) ''United States'' before ''National Committee on Vital and Health Statistics''; authorized in par. (2)(A) the appointment of Committee members from distinguished persons in field of health planning; required the Committee to assist and advise the Secretary with respect to the Cooperative Health Statistics System and the standardized means for the collection of health information and statistics to be established by the Secretary; and redesignated such amended subsec. (i) as (k).

Subsec. (*l*). Pub. L. 95–623, §8(a), added subsec. (*l*).

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 1990 AMENDMENT

Pub. L. 101–527, §12, Nov. 6, 1990, 104 Stat. 2335, provided that: ''This Act and the amendments made by this Act [enacting sections 254c–1, 254t, 256a, 294bb, 294cc, and 300u–6 of this title, amending this section and sections 242m, 254b, 254c, 294m, 294*o*, and 295g–2 of this title, enacting provisions set out as notes under sections 201 and 300u–6 of this title, and repealing provisions set out as a note under section 292h of this title] shall take effect October 1, 1990, or upon the date of the enactment of this Act [Nov. 6, 1990], whichever occurs later.''

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–177, title I, §105(b), Dec. 1, 1987, 101 Stat. 988, provided that: ''The amendments made by this section [amending this section] shall become effective on January 1, 1988.''

MONEY RECEIVED BY CENTER FROM REIMBURSEMENTS, INTERAGENCY AGREEMENTS, AND SALE OF DATA TAPES TO REMAIN AVAILABLE UNTIL EXPENDED

Pub. L. 103–333, title II, Sept. 30, 1994, 108 Stat. 2550, provided in part: ''That for fiscal year 1995 and subsequent fiscal years amounts received by the National Center for Health Statistics from reimbursements and interagency agreements and the sale of data tapes may be credited to this appropriation and shall remain available until expended''.

§ 242*l*. International cooperation

(a) Cooperative endeavors

The Secretary may participate with other countries in cooperative endeavors in—

(1) biomedical research, health care technology, and the health services research and statistical analysis authorized under section 242k of this title and subchapter VII; and

(2) biomedical research, health care services, health care research, or other related activi-

ties in furtherance of the activities, objectives or goals authorized under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(b) Authority of Secretary; building construction prohibition

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

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

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

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

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

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

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or health care technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b)[1] of title 5 for persons in the Government service employed intermittently;

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

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

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

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

(c) Benefits for overseas assignees

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

(d) Strategies to improve injection safety

In carrying out immunization programs and other programs in developing countries for the prevention, treatment, and control of infectious diseases, including HIV/AIDS, tuberculosis, and malaria, the Director of the Centers for Disease Control and Prevention, in coordination with the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the National Institutes of Health, national and local government, and other organizations, such as the World Health Organization and the United Nations Children's Fund, shall develop and implement effective strategies to improve injection safety, including eliminating unnecessary injections, promoting sterile injection practices and technologies, strengthening the procedures for proper needle and syringe disposal, and improving the education and information provided to the public and to health professionals.

(July 1, 1944, ch. 373, title III, § 307, formerly § 308, as added Pub. L. 86–610, § 3, July 12, 1960, 74 Stat. 364; renumbered § 307 and amended Pub. L. 93–353, title I, § 106, July 23, 1974, 88 Stat. 367; Pub. L. 97–35, title IX, § 921, Aug. 13, 1981, 95 Stat. 566; Pub. L. 101–239, title VI, § 6103(e)(3), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 102–531, title III, § 310, Oct. 27, 1992, 106 Stat. 3503; Pub. L. 103–183, title VII, § 702, Dec. 14, 1993, 107 Stat. 2239; Pub. L. 108–25, title III, § 306, May 27, 2003, 117 Stat. 739; Pub. L. 110–293, title II, § 205, July 30, 2008, 122 Stat. 2943.)

REFERENCES IN TEXT

The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, referred to in subsec. (a)(2), is Pub. L. 110–293, July 30, 2008, 122 Stat. 2918. For complete classification of this Act to the Code, see Short Title of 2008 Amendment note set out under section 7601 of Title 22, Foreign Relations and Intercourse, and Tables.

Section 5703 of title 5, referred to in subsec. (b)(6), was amended generally by Pub. L. 94–22, § 4, May 19, 1975, 89 Stat. 85, and, as so amended, does not contain a subsec. (b).

The Foreign Service Act of 1980, referred to in subsec. (c), is Pub. L. 96–465, Oct. 17, 1980, 94 Stat. 2071. Chapter 9 of title I of the Act is classified generally to subchapter IX (§ 4081 et seq.) of chapter 52 of Title 22, Foreign Relations and Intercourse. For complete classification of this Act to the Code, see Short Title note set out under section 3901 of Title 22 and Tables.

CODIFICATION

Section was formerly classified to section 242f of this title.

[1] See References in Text note below.

PRIOR PROVISIONS

A prior section 307 of act July 1, 1944, was classified to section 242e of this title, prior to repeal by Pub. L. 93–353, title I, § 102(a), July 23, 1974, 88 Stat. 362.

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–293, § 205(1), amended subsec. (a) generally. Prior to amendment, text read as follows: ''For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 242k of this title and by subchapter VII of this chapter.''

Subsec. (b). Pub. L. 110–293, § 205(2)(B), struck out concluding provisions which read as follows: ''The Secretary may not, in the exercise of his authority under this section, provide financial assistance for the construction of any facility in any foreign country.''

Subsec. (b)(8). Pub. L. 110–293, § 205(2)(C), substituted ''for the purpose of any law administered by the Office of Personnel Management;'' for ''for any purpose.''

Subsec. (b)(9), (10). Pub. L. 110–293, § 205(2)(A), (D), added pars. (9) and (10).

Subsec. (c). Pub. L. 110–293, § 205(3), substituted ''1980'' for ''1990'' and inserted ''or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083)'' after ''title 5''.

2003—Subsec. (d). Pub. L. 108–25 added subsec. (d).

1993—Subsec. (c). Pub. L. 103–183 added subsec. (c).

1992—Subsec. (b)(8). Pub. L. 102–531, which directed amendment of subsec. (b) by adding par. (8) at the end thereof, was executed by adding par. (8) after par. (7) to reflect the probable intent of Congress.

1989—Subsec. (a). Pub. L. 101–239 substituted ''section 242k of this title and by subchapter VII of this chapter'' for ''sections 242b, 242c, 242k, and 242n of this title''.

1981—Subsec. (a). Pub. L. 97–35, § 921(a), inserted reference to health care technology and section 242n of this title.

Subsec. (b). Pub. L. 97–35, § 921(b), in par. (5) inserted reference to health care technology, and in par. (6) inserted reference to health care technology activities.

1974—Pub. L. 93–353 amended section generally.

INTERNATIONAL HEALTH STUDY

Pub. L. 95–83, title III, § 315, Aug. 1, 1977, 91 Stat. 398, provided that the Secretary of Health, Education, and Welfare arrange through the National Academy of Sciences or other nonprofit private groups or associations, for a study to determine opportunities for broadened Federal program activities in areas of international health, which study was to consider biomedical and behavioral research, health services research, health professions education, immunization and public health activities, and other areas that might improve our and other nations' capacities to prevent, diagnose, control, or cure disease, and to organize and deliver effective and efficient health services, with an interim report on such study completed no later than Oct. 1, 1977 and a final report completed no later than Jan. 1, 1978 and both reports submitted to the Secretary, the Committee on Human Resources of the Senate, and the Committee on Interstate and Foreign Commerce of the House of Representatives.

§ 242m. General provisions respecting effectiveness, efficiency, and quality of health services

(a) Reports to Congress and President; preparation; review by Office of Management and Budget

(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 242k(b)(1)(G) of this title.

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 242k(b)(1)(E) of this title.

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(F) of this title.

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(A) of this title.

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

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

(b) Grants or contracts; applications, submittal; application peer review group, findings and recommendations; necessity of favorable recommendation; appointments

(1) No grant or contract may be made under section 242b, 242k, or 242*l* of this title unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)(A) Each application submitted for a grant or contract under section 242k of this title in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section 242k(m) of this title, shall be submitted to a peer review group for an evaluation of the technical and scientific merits of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

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

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that

peer review groups regarding grants under section 242k(m) of this title may include appropriately qualified such officers and employees.

(c) Development and dissemination of statistics

The Secretary shall take such action as may be necessary to assure that statistics developed under sections 242b and 242k of this title are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) Information; publication restrictions

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 242b, 242k, or 242*l* of this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose; and in the case of information obtained in the course of health statistical or epidemiological activities under section 242b or 242k of this title, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e) Payment procedures; advances or reimbursement; installments; conditions; reductions

(1) Payments of any grant or under any contract under section 242b, 242k, or 242*l* of this title may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 242b, 242k, or 242*l* of this title shall be reduced by—

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

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or employee was assigned or detailed by the Secretary to perform such services,

but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts without regard to section 3324 of title 31 and section 6101 of title 41

Contracts may be entered into under section 242b or 242k of this title without regard to section 3324 of title 31 and section 6101 of title 41.

(July 1, 1944, ch. 373, title III, §308, as added Pub. L. 93–353, title I, §107(a), July 23, 1974, 88 Stat. 368; amended Pub. L. 94–273, §7(2), Apr. 21, 1976, 90 Stat. 378; Pub. L. 95–83, title I, §104, Aug. 1, 1977, 91 Stat. 384; Pub. L. 95–623, §§2, 6(d), 8(b), Nov. 9, 1978, 92 Stat. 3443, 3451, 3455; Pub. L. 97–35, title IX, §§917(a), (b), 919(a)(2)(B), 922, Aug. 13, 1981, 95 Stat. 564, 565, 567; Pub. L. 97–414, §8(c), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 98–551, §7, Oct. 30, 1984, 98 Stat. 2820; Pub. L. 100–177, title I, §§106(a), 107, 108, Dec. 1, 1987, 101 Stat. 988–990; Pub. L. 100–690, title II, §2612, Nov. 18, 1988, 102 Stat. 4235; Pub. L. 101–239, title VI, §6103(e)(4), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 101–527, §7(b)(2), (d), Nov. 6, 1990, 104 Stat. 2328; Pub. L. 103–183, title V, §501(c), Dec. 14, 1993, 107 Stat. 2237; Pub. L. 105–392, title IV, §401(d), Nov. 13, 1998, 112 Stat. 3587.)

CODIFICATION

In subsec. (f), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes (41 U.S.C. 5)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

Provisions similar to those comprising subsec. (e) of this section were contained in subsec. (a)(3) of section 304 of act July 1, 1944, ch. 373, title III, as added July 28, 1955, ch. 417, §3, 69 Stat. 382, and amended (formerly classified to section 242b(a)(3) of this title), prior to general amendment of section 304 by Pub. L. 93–353, §103.

AMENDMENTS

1998—Subsec. (b)(2)(A), (C). Pub. L. 105–392 substituted ''242k(m)'' for ''242k(n)''.

1993—Subsec. (a)(1). Pub. L. 103–183, §501(c)(1)(A), redesignated subpars. (B) to (E) as (A) to (D), respectively, and struck out former subpar. (A) which read as follows: ''A report on—

''(i) the administration of sections 242b, 242k, and 242*l* of this title and subchapter VII of this chapter during the preceding fiscal year; and

''(ii) the current state and progress of health services research, health statistics, and health care technology.''

Subsec. (a)(2). Pub. L. 103–183, §501(c)(1)(B), substituted ''reports required in paragraph (1) shall be prepared through the National Center'' for ''reports required by subparagraphs (B) through (E) of paragraph (2) shall be prepared through the Agency for Health Care Policy and Research and the National Center''.

Subsec. (c). Pub. L. 103–183, §501(c)(2)(A)–(D), (3), redesignated subsec. (g)(2) as subsec. (c), substituted ''shall take'' for ''shall (A) take'' and ''and shall publish'' for ''and (B) publish'', and struck out former subsec. (c) which read as follows: ''The aggregate number of grants and contracts made or entered into under sections 242b and 242c of this title for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed twenty; and the aggregate amount of funds obligated under grants and contracts under such sections for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed $5,000,000.''

Subsec. (f). Pub. L. 103–183, §501(c)(4), substituted ''section 3324 of title 31 and section 5 of title 41'' for ''sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)''.

Subsec. (g). Pub. L. 103–183, §501(c)(2)(B), (C), (E), redesignated par. (2) as subsec. (c) and struck out par. (1) which read as follows: ''The Secretary shall—

''(A) publish, make available and disseminate, promptly in understandable form and on as broad a basis as practicable, the results of health services research, demonstrations, and evaluations undertaken and supported under sections 242b and 242c of this title;

''(B) make available to the public data developed in such research, demonstrations, and evaluations; and

''(C) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on health services research, demonstrations, and evaluations in health care delivery to public and private entities and individuals engaged in the improvement of health care delivery and the general public; and undertake programs to develop new or improved methods for making such information available.''

Subsec. (h). Pub. L. 103–183, § 501(c)(5), struck out subsec. (h) which read as follows:

''(1) Except where the Secretary determines that unusual circumstances make a larger percentage necessary in order to effectuate the purposes of section 242k of this title, a grant or contract under any of such sections of this title with respect to any project for construction of a facility or for acquisition of equipment may not provide for payment of more than 50 per centum of so much of the cost of the facility or equipment as the Secretary determines is reasonably attributable to research, evaluation, or demonstration purposes.

''(2) Laborers and mechanics employed by contractors and subcontractors in the construction of such a facility shall be paid wages at rates not less than those prevailing on similar work in the locality, as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 267a—267a–5, known as the Davis-Bacon Act); and the Secretary of Labor shall have with respect to any labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (5 U.S.C. Appendix) and section 276c of title 40.

''(3) Such grants and contracts shall be subject to such additional requirements as the Secretary may by regulation prescribe.''

1990—Subsec. (b)(2)(A). Pub. L. 101–527, § 7(b)(2)(A), inserted ''or for a grant under section 242k(n) of this title,'' after ''demonstration project,''.

Subsec. (b)(2)(C). Pub. L. 101–527, § 7(b)(2)(B), inserted before period at end '', except that peer review groups regarding grants under section 242k(n) of this title may include appropriately qualified such officers and employees''.

Subsec. (b)(3). Pub. L. 101–527, § 7(d), struck out par. (3) which related to applications submitted under section 242k of this title for which a grant or contract may be made under another provision of this chapter.

1989—Pub. L. 101–239, § 6103(e)(4)(A), amended section catchline.

Subsec. (a)(1)(A)(i). Pub. L. 101–239, § 6103(e)(4)(B)(i), substituted ''sections 242b, 242k, and 242*l* of this title and subchapter VII of this chapter'' for ''sections 242b, 242c, 242k, and 242*l* of this title and section 242n of this title''.

Subsec. (a)(2). Pub. L. 101–239, § 6103(e)(4)(B)(ii), substituted ''the Agency for Health Care Policy and Research'' for ''the National Center for Health Services Research and Health Care Technology Assessment''.

Subsec. (b)(1). Pub. L. 101–239, § 6103(e)(4)(C)(i), which directed amendment of par. (1) by substituting ''section 242b, 242k, or 242*l* of this title'' for ''sections 242b, 242c, 242k, 242*l*, and 242n of this title'', was executed by making the substitution for ''section 242b, 242c, 242k, 242*l*, or 242n of this title'' as the probable intent of Congress.

Subsec. (b)(2)(A). Pub. L. 101–239, § 6103(e)(4)(C)(ii), substituted ''under section 242k of this title'' for ''under section 242b or 242c of this title,'' in first sentence, struck out second sentence which read as follows: ''Each application for a grant, contract, or cooperative agreement in an amount exceeding $50,000 of direct costs for the dissemination of research findings or the development of research agendas (including conferences, workshops, and meetings) shall be submitted to a standing peer review group with persons with appropriate expertise and shall not be submitted to any peer review group established to review applications for research, evaluation, or demonstration projects.'', and amended last sentence generally. Prior to amendment, last sentence read as follows: ''The Secretary, acting through the Director of the National Center for Health Services Research and Health Care Technology Assessment (or, as appropriate, through the Director of the National Center for Health Statistics), shall establish such peer review groups as may be necessary to provide for such an evaluation of an application described in the first two sentences of this subparagraph.''

Subsec. (b)(2)(B). Pub. L. 101–239, § 6103(e)(4)(C)(iii), substituted ''the Director of the National Center for Health Statistics'' for ''the Director involved''.

Subsec. (b)(2)(C). Pub. L. 101–239, § 6103(e)(4)(C)(iv), substituted ''the Director of the National Center for Health Statistics'' for ''the Directors''.

Subsec. (b)(3). Pub. L. 101–239, § 6103(e)(4)(C)(v), substituted ''submitted under section 242k of this title'' for ''submitted under section 242b, 242c, or 242k of this title'' and ''approved under any of such sections'' for ''approved under section 242b, 242c, or 242k of this title''.

Subsec. (d). Pub. L. 101–239, § 6103(e)(4)(D), substituted ''section 242b, 242k, or 242*l* of this title'' for ''section 242b, 242c, 242k, 242*l*, or 242n of this title'', struck out ''(1)'' after ''for such other purpose; and'', and substituted ''publication or release in other form.'' for ''publication or release in other form, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 242b or 242c of this title or in the course of health care technology activities under section 242n of this title, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.''

Subsec. (e)(1), (2). Pub. L. 101–239, § 6103(e)(4)(E), substituted ''section 242b, 242k, or 242*l* of this title'' for ''section 242b, 242c, 242k, 242*l*, or 242n of this title''.

Subsec. (f). Pub. L. 101–239, § 6103(e)(4)(F), substituted ''section 242b or 242k of this title'' for ''section 242b, 242c, 242k, or 242n of this title''.

Subsec. (g)(1). Pub. L. 101–239, § 6103(e)(4)(G)(i), struck out at end ''Except as provided in subsection (d) of this section, the Secretary may not restrict the publication and dissemination of data from, and results of projects undertaken by, centers supported under section 242c(d) of this title.''

Subsec. (g)(2). Pub. L. 101–239, § 6103(e)(4)(G)(ii), substituted ''sections 242b and 242k of this title'' for ''sections 242b, 242c, 242k, and 242n of this title''.

Subsec. (h)(1). Pub. L. 101–239, § 6103(e)(4)(H), substituted ''effectuate the purposes of section 242k of this title'' for ''effectuate the purposes of section 242b, 242c, 242k, or 242n of this title'' and ''contract under any of such sections'' for ''contract under section 242b, 242c, 242k, or 242n of this title''.

Subsec. (i). Pub. L. 101–239, § 6103(e)(4)(I), struck out subsec. (i) which authorized appropriations for carrying out certain programs under sections 242b, 242c, 242k, and 242n of this title during fiscal years 1988 to 1990.

1988—Subsec. (b)(2)(A). Pub. L. 100–690 inserted after first sentence ''Each application for a grant, contract, or cooperative agreement in an amount exceeding $50,000 of direct costs for the dissemination of research findings or the development of research agendas (including conferences, workshops, and meetings) shall be submitted to a standing peer review group with persons with appropriate expertise and shall not be submitted to any peer review group established to review applications for research, evaluation, or demonstration projects.'' and substituted ''an application described in the first two sentences of this subparagraph'' for ''each such application'' in last sentence.

1987—Subsec. (a)(1), (2). Pub. L. 100–177, § 106(a)(1), added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

''(1) Not later than December 1 of each year, the Secretary shall make a report to Congress respecting (A)

the administration of sections 242b, 242c, 242k, and 242*l* and section 242n of this title during the preceding fiscal year, and (B) the current state and progress of health services research and, health statistics, and health care technology.

''(2) The Secretary, acting through the National Center for Health Services Research and the National Center for Health Statistics, shall assemble and submit to the President and the Congress not later than December 1 of each year the following reports:

''(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 242k(b)(1)(G) of this title.

''(B) A report on health resources. Such report shall include a description and analysis, by geographic area, of the statistics collected under section 242k(b)(1)(E) of this title.

''(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(F) of this title.

''(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(A) of this title.''

Subsec. (a)(3). Pub. L. 100–177, §106(a)(2), struck out ''or (2)'' after ''paragraph (1)''.

Subsec. (b)(1). Pub. L. 100–177, §107(1), inserted ''and unless a peer review group referred to in paragraph (2) has recommended the application for approval'' before period at end.

Subsec. (b)(2). Pub. L. 100–177, §107(2), added par. (2) and struck out former par. (2) which read as follows: ''Each application submitted for a grant or contract under section 242b or 242c of this title, in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, shall be submitted by the Secretary for review for scientific merit to a panel of experts appointed by him from persons who are not officers or employees of the United States and who possess qualifications relevant to the project for which the application was made. A panel to which an application is submitted under this paragraph shall report its findings and recommendations respecting the application to the Secretary in such form and manner as the Secretary shall by regulation prescribe.''

Subsec. (i). Pub. L. 100–177, §108, amended subsec. (i) generally, substituting provisions authorizing appropriations for fiscal years 1988 to 1990 for carrying out activities under sections 242b, 242c, 242k, and 242n of this title for former provisions authorizing appropriations for fiscal years 1975 to 1987 for carrying out activities under those sections.

1984—Subsec. (i)(1). Pub. L. 98–551, §7(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987, inserted ''and Health Care Technology Assessment'' after ''Research'', substituted ''and at least 10 per centum of such amount or $1,500,000, whichever is less, shall be available only for the user liaison program and the technical assistance program referred to in section 242c(c)(2) of this title and for dissemination activities directly undertaken through such Center'' for ''and at least 5 per centum of such amount or $1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken through such Center'', inserted ''For health care technology assessment activities undertaken under subsections (b)(5), (e), (f), and (g) of section 242c of this title the Secretary shall obligate from funds appropriated under this paragraph not less than $3,000,000 for the fiscal year ending September 30, 1985, $3,500,000 for the fiscal year ending September 30, 1986, and $4,000,000 for the fiscal year ending September 30, 1987. For grants under section 242n of this title the Secretary shall obligate from funds appropriated under this paragraph not less than $500,000 for the fiscal year ending September 30, 1985, $750,000 for the fiscal year ending September 30, 1986, and $750,000 for the fiscal year ending September 30, 1987.'', and in last sentence substituted ''for any fiscal year'' for ''for each of the fiscal years ending September 30, 1982, September 30, 1983, and September 30, 1984,''.

Subsec. (i)(2). Pub. L. 98–551, §7(b), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

1983—Subsec. (d). Pub. L. 97–414 inserted '', if an establishment or person supplying the information or described in it is identifiable,'' after ''No information'', and substituted ''such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose'' for ''authorized by guidelines in effect under section 242k(*l*)(2) of this title or under regulations of the Secretary''.

1981—Subsec. (a)(2). Pub. L. 97–35, §922(a), substituted ''December'' for ''September'', which change had already been made by Pub. L. 94–273.

Subsec. (b)(2). Pub. L. 97–35, §922(b), substituted ''$50,000'' for ''$35,000''.

Subsec. (d)(2). Pub. L. 97–35, §922(c), inserted applicability to health care technology activities under section 242n of this title.

Subsec. (i)(1). Pub. L. 97–35, §§917(a), 919(a)(2)(B), inserted provisions respecting amounts of and limitations on uses for appropriations for the fiscal years ending Sept. 30, 1982, 1983, and 1984.

Subsec. (i)(2). Pub. L. 97–35, §917(b), inserted provisions respecting appropriations for the fiscal years ending Sept. 30, 1982, 1983, and 1984.

1978—Subsec. (a)(1). Pub. L. 95–623, §6(d)(1), required the report to cover the administration of section 242n of this title and the current state and progress of health care technology.

Subsec. (b)(1). Pub. L. 95–623, §6(d)(2), inserted reference to grant or contract under section 242n of this title.

Subsec. (d). Pub. L. 95–623, §§6(d)(3), 8(b), inserted reference to section 242n of this title and substituted in cl. (1) ''statistical or epidemiological activities'' for ''statistical activities''; and authorized use of information for purposes other than for which supplied when authorized by guidelines in effect under section 242k(*l*)(2) of this title.

Subsecs. (e), (f), (g)(2), (h)(1). Pub. L. 95–623, §6(d)(4)–(7), inserted references to section 242n of this title.

Subsec. (i)(1). Pub. L. 95–623, §2(a), authorized appropriation of $35,000,000; $40,000,000; and $45,000,000 for fiscal years ending Sept. 30, 1979, through 1981, and substituted minimum amounts of the lesser of 20 per centum of appropriated funds or $6,000,000 for health services research, evaluation and demonstration activities of the National Center for Health Services Research and 5 per centum of such funds or $1,000,000 for dissemination activities of such Center for prior similar requirement of 25 per centum of appropriated funds for the applicable fiscal years for health services research, evaluation, and demonstration activities of the Secretary.

Subsec. (i)(2). Pub. L. 95–623, §2(b), authorized appropriation of $50,000,000; $65,000,000; and $70,000,000 for fiscal years ending Sept. 30, 1979, through 1981.

1977—Subsec. (i)(1). Pub. L. 95–83, §104(a), authorized appropriation of $28,600,000 for fiscal year ending Sept. 30, 1978.

Subsec. (i)(2). Pub. L. 95–83, §104(b), authorized appropriation of $33,600,000 for fiscal year ending Sept. 30, 1978.

1976—Subsec. (a). Pub. L. 94–273 substituted ''December'' for ''September'' wherever appearing.

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title IV, §401(e), Nov. 13, 1998, 112 Stat. 3587, provided that: ''This section [amending this section and sections 247b–5, 247b–6, 247c, 285f–2, 300d–1 to 300d–3, 300d–13, 300d–32, 300k, and 300n–1 of this title] is deemed to have taken effect immediately after the enactment of Public Law 103–183 [Dec. 14, 1993].''

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–690, title II, § 2600, 102 Stat. 4233, provided that: ''Except as provided in section 2613(b)(1) [42 U.S.C. 285m note], the amendments made by this subtitle [subtitle G (§§ 2600–2641) of title II of Pub. L. 100–690, enacting sections 285m–4 to 285m–6 of this title, amending this section, sections 242c, 281, 284, 284c, 285j, 285m, 285m–1 to 285m–6, 286, 289f, 290cc–28, 290cc–36, 292h, 294a, 295g–4, 295g–7, 295g–8b, 295h, 295h–5, 295j, 297j, 297n, 300cc–3, 300cc–13, 300cc–17, 300cc–20, 300cc–31, 300dd–1, 300dd–3, 300dd–8, 300dd–10, 300dd–12 to 300dd–14, 300dd–21, 300dd–32, 300ee, 300ee–2, 300ee–5, 300ee–12, 300ee–13, 300ee–15 to 300ee–18, 300ee–20, 300ee–22, 300ee–34, 300ff–48, and 300aaa to 300aaa–13 of this title, and section 393 of Title 21, Food and Drugs, enacting provisions set out as notes under section 285m of this title, amending provisions set out as notes under sections 201, 292h, 300cc, 300ee–1, and 300ff–48 of this title, and repealing provisions set out as a note under section 285m of this title] shall take effect immediately after the enactment of the Health Omnibus Programs Extension of 1988 [Nov. 4, 1988].''

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–177, title I, § 106(c), Dec. 1, 1987, 101 Stat. 989, provided that: ''The amendments made by subsections (a) and (b) [amending this section and section 242p of this title] shall apply to reports and profiles required to be submitted after November 1, 1987.''

MINE WORKERS STUDY; REPORT COMPLETED AND SUBMITTED NO LATER THAN 30 MONTHS AFTER NOVEMBER 9, 1978

Pub. L. 95–623, § 10, Nov. 9, 1978, 92 Stat. 3455, as amended by S. Res. 30, Mar. 7, 1979; H. Res. 549, Mar. 25, 1980, required the Secretary, acting through the National Center for Health Services Research, to arrange for the conduct of a study to evaluate the impact upon the utilization of health services by and the health status of members of the United Mine Workers and their dependents as a result of changes in the United Mine Workers' collective-bargaining agreements of Mar. 1978 with a report to be submitted to the Secretary and specific committees of the Senate and House of Representatives within 30 months after Nov. 9, 1978.

AUTHORIZATION OF APPROPRIATIONS FOR FISCAL YEAR ENDING JUNE 30, 1977

Pub. L. 93–353, title I, § 107(b), July 23, 1974, 88 Stat. 371, provided that: ''The authorizations of appropriations provided by section 308(i) of the Public Health Service Act [42 U.S.C. 242m(i)] is extended for the fiscal year ending June 30, 1977, in the amounts authorized for the preceding fiscal year unless before June 30, 1976, Congress has passed legislation repealing this subsection.''

§ 242n. Repealed. Pub. L. 101–239, title VI, § 6103(d)(1)(B), Dec. 19, 1989, 103 Stat. 2205

Section, act July 1, 1944, ch. 373, title III, § 309, as added Nov. 9, 1978, Pub. L. 95–623, § 6(c), 92 Stat. 3447; amended July 10, 1979, Pub. L. 96–32, § 5(d), 93 Stat. 83; Aug. 13, 1981, Pub. L. 97–35, title IX, §§ 917(c), 923, 95 Stat. 565, 567; Oct. 30, 1984, Pub. L. 98–551, § 8, 98 Stat. 2820; Oct. 7, 1985, Pub. L. 99–117, § 8(a), 99 Stat. 493; Dec. 1, 1987, Pub. L. 100–177, title I, § 109, 101 Stat. 990, related to grants for a council on health care technology.

TERMINATION OF COUNCIL ON HEALTH CARE TECHNOLOGY

Pub. L. 101–239, title VI, § 6103(d)(1)(B), Dec. 19, 1989, 103 Stat. 2205, provided in part that the council on health care technology established under this section is terminated.

TRANSITIONAL AND SAVINGS PROVISIONS FOR PUB. L. 101–239

For provision transferring personnel of Department of Health and Human Services employed on Dec. 19, 1989, in connection with functions vested in Administrator for Health Care Policy and Research pursuant to amendments made by section 6103 of Pub. L. 101–239, and assets, liabilities, etc., of Department arising from or employed, held, used, or available on that date, or to be made available after that date, in connection with those functions, to Administrator for appropriate allocation, and for provisions for continued effectiveness of actions, orders, rules, official documents, etc., of Department that have been issued, made, granted, or allowed to become effective in performance of those functions, and that were effective on Dec. 19, 1989, see section 6103(f) of Pub. L. 101–239, set out as a note under section 299 of this title.

§ 242*o*. Health conferences; publication of health educational information

(a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

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

(July 1, 1944, ch. 373, title III, § 310, formerly §§ 309, 310, as added Pub. L. 93–353, title I, § 107(a), July 23, 1974, 88 Stat. 371; renumbered § 310, Pub. L. 95–623, § 6(a), (b), Nov. 9, 1978, 92 Stat. 3447.)

CODIFICATION

Subsec. (a) of this section consists of former section 309 of act July 1, 1944, prior to the renumbering of that section as section 310(a) by Pub. L. 95–623. Subsec. (b) of this section consists of former section 310 of act July 1, 1944, prior to the renumbering of that section as section 310(b) by Pub. L. 95–623.

PRIOR PROVISIONS

A prior section 310 of act July 1, 1944, was renumbered section 329, and was classified to section 254b of this title prior to the general amendment of subpart I (§ 254b et seq.) of part D of this subchapter by Pub. L. 104–299.

Provisions similar to those comprising subsec. (a) of this section were contained in section 312 of act July 1, 1944, ch. 373, title III, 58 Stat. 693, as amended (formerly classified to section 244 of this title), prior to repeal by Pub. L. 93–353, § 102(a).

Provisions similar to those comprising subsec. (b) of this section were contained in section 315 of act July 1, 1944, ch. 373, title III, 58 Stat. 695; Oct. 30, 1970, Pub. L. 91–515, title II, § 282, 84 Stat. 1308 (formerly classified to section 247 of this title), prior to repeal by Pub. L. 93–353, § 102(a).

§ 242p. National disease prevention data profile

(a) The Secretary, acting through the National Center for Health Statistics, shall submit

to Congress on March 15, 1990, and on March 15 of every third year thereafter, a national disease prevention data profile in order to provide a data base for the effective implementation of this Act and to increase public awareness of the prevalence, incidence, and any trends in the preventable causes of death and disability in the United States. Such profile shall include at a minimum—

(1) mortality rates for preventable diseases;

(2) morbidity rates associated with preventable diseases;

(3) the physical determinants of health of the population of the United States and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability; and

(4) the behavioral determinants of health of the population of the United States including, but not limited to, smoking, nutritional and dietary habits, exercise, and alcohol consumption, and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability.

(b) In preparing the profile required by subsection (a), the Secretary, acting through the National Center for Health Statistics, shall comply with all relevant provisions of sections 242k and 242m of this title.

(Pub. L. 95–626, title IV, § 404, Nov. 10, 1978, 92 Stat. 3591; Pub. L. 100–177, title I, § 106(b), Dec. 1, 1987, 101 Stat. 989.)

REFERENCES IN TEXT

This Act, referred to in subsec. (a), is Pub. L. 95–626, Nov. 10, 1978, 92 Stat. 3551, known as the Health Services and Centers Amendments of 1978. For complete classification of this Act to the Code, see Short Title of 1978 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Health Services and Centers Amendments of 1978, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–177 substituted ''on March 15, 1990, and on March 15 of every third year thereafter'' for ''on December 1, 1980, and on December 1 of every third year thereafter'' in first sentence.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–177 applicable to reports and profiles required to be submitted after Nov. 1, 1987, see section 106(c) of Pub. L. 100–177, set out as a note under section 242m of this title.

§ 242q. Task Force on Aging Research; establishment and duties

(a) Establishment

The Secretary of Health and Human Services shall establish a Task Force on Aging Research.

(b) Duties

With respect to aging research (as defined in section 242q–4[1] of this title), the Task Force each fiscal year shall—

(1) make recommendations to the Secretary specifying the particular projects of research, or the particular categories of research, that should be conducted or supported by the Secretary;

(2) of the projects specified under paragraph (1), make recommendations to the Secretary of the projects that should be given priority in the provision of funds; and

(3) make recommendations to the Secretary of the amount of funds that should be appropriated for such research.

(c) Provision of information to public

The Task Force may make available to health professionals, and to other members of the public, information regarding the research described in subsection (b).

(Pub. L. 101–557, title III, § 301, Nov. 15, 1990, 104 Stat. 2768.)

REFERENCES IN TEXT

Section 242q–4 of this title, referred to in subsec. (b), was in the original ''section 305'', meaning section 305 of Pub. L. 101–557. Section 305 was renumbered section 304 by 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.

§ 242q–1. Membership

(a) Composition

The Task Force shall be composed of—

(1) the Assistant Secretary for Health;

(2) the Surgeon General of the Public Health Service;

(3) the Assistant Secretary for Planning and Evaluation;

(4) the Director of the National Institute on Aging, and the Directors of such other agencies of the National Institutes of Health as the Secretary determines to be appropriate;

(5) the Commissioner of the Administration on Aging;

(6) the Commissioner of Food and Drugs;

(7) the Under Secretary for Health of the Department of Veterans Affairs;

(8) the Administrator of the the[1] Substance Abuse and Mental Health Services Administration;

(9) the Administrator of the Centers for Medicare & Medicaid Services;

(10) the Commissioner of Social Security;

(11) the Director of the Agency for Healthcare Research and Quality;

(12) two Members of the House of Representatives appointed by the Speaker of the House in consultation with the Minority Leader, and two members of the Senate appointed by the Majority Leader in consultation with the Minority Leader, not more than one of whom from each body shall be members of the same political party; and

(13) three members of the general public, to be appointed by the Secretary, that shall include one representative each from—

[1] See References in Text note below.

[1] So in original.

(A) a nonprofit group representing older Americans;

(B) a private voluntary health organization concerned with the health problems affecting older Americans; and

(C) a nonprofit organization concerned with research related to the health and independence of older Americans.

(b) Chair

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall serve as the Chair of the Task Force.

(c) Quorum

A majority of the members of the Task Force shall constitute a quorum, and a lesser number may hold hearings.

(d) Meetings

The Task Force shall meet periodically at the call of the Chair, but in no event less than twice each year.

(e) Compensation and expenses

(1) Compensation

Members of the Task Force who are not regular full-time employees of the United States Government shall, while attending meetings and conferences of the Task Force or otherwise engaged in the business of the Task Force (including traveltime), be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding the rate specified at the time of such service under GS–18 of the General Schedules established under section 5332 of title 5.

(2) Expenses

While away from their homes or regular places of business on the business of the Task Force, members of such Task Force may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of title 5 for persons employed intermittently in the Government service.

(Pub. L. 101–557, title III, § 302, Nov. 15, 1990, 104 Stat. 2769; Pub. L. 102–321, title I, § 161, July 10, 1992, 106 Stat. 375; Pub. L. 102–405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 108–173, title IX, § 900(e)(6)(D), Dec. 8, 2003, 117 Stat. 2373.)

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.

AMENDMENTS

2003—Subsec. (a)(9). Pub. L. 108–173 substituted ''Centers for Medicare & Medicaid Services'' for ''Health Care Financing Administration''.

1999—Subsec. (a)(11). Pub. L. 106–129 substituted ''Director of the Agency for Healthcare Research and Quality'' for ''Administrator for Health Care Policy and Research''.

1992—Subsec. (a)(7). Pub. L. 102–405 substituted ''Under Secretary for Health of the Department of Veterans Affairs'' for ''Chief Medical Director of the Department of Veterans Affairs''.

Subsec. (a)(8). Pub. L. 102–321 substituted ''Substance Abuse and Mental Health Services Administration'' for ''Alcohol, Drug Abuse and Mental Health Administration''.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 242q–2. Administrative staff and support

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall appoint an Executive Secretary for the Task Force and shall provide the Task Force with such administrative staff and support as may be necessary to enable the Task Force to carry out subsections (b) and (c) of section 242q of this title.

(Pub. L. 101–557, title III, § 303, Nov. 15, 1990, 104 Stat. 2770.)

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.

§ 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.

§ 242s. Centers for Disease Control and Prevention Office of Women's Health

(a) Establishment

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

(b) Purpose

The Director of the Office shall—

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

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

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

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of this title).

(c) Definition

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

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

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

(d) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 310A, as added Pub. L. 111–148, title III, § 3509(b), Mar. 23, 2010, 124 Stat. 533.)

PRIOR PROVISIONS

A prior section 310A of act July 1, 1944, was renumbered section 226 and transferred to section 235 of this title.

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

Pub. L. 89–749, § 5(a), Nov. 3, 1966, 80 Stat. 1190, provided that subsec. (b) of this section is effective July 1, 1966.

Pub. L. 89–749, § 5(b), Nov. 3, 1966, 80 Stat. 1190, 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 ap-

propriation 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), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

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

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

(c) Use of funds

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

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

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

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

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

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

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

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

(d) Application

(1) In general

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

(2) Contents

An application submitted under paragraph (1) shall—

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

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

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

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

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

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

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for for[1] each of fiscal years 2003

[1] So in original.

through 2014. 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; Pub. L. 111–148, title X, § 10412, Mar. 23, 2010, 124 Stat. 990.)

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

2010—Subsec. (c)(6). Pub. L. 111–148, § 10412(1), inserted '', that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death,'' after ''clearinghouse''.

Subsec. (e). Pub. L. 111–148, § 10412(2), substituted ''for each of fiscal years 2003 through 2014'' for ''fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006''.

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

Pub. L. 94–484, title V, § 503(c), Oct. 12, 1976, 90 Stat. 2300, 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) shall use the funds provided through the grant to—

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

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

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

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

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

(c) Application

(1) In general

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

(2) Contents

An application submitted under paragraph (1) may—

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

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

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

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

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

(d) Authorization of appropriations

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

(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 establish-

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

30, 1967, $7,500,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $20,000,000 for the fiscal year ending June 30, 1971, $30,000,000 for the fiscal year ending June 30, 1972, $40,000,000 for the fiscal year ending June 30, 1973, and $25,100,000 for the fiscal year ending June 30, 1974.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) with respect to a particular region or area, but only if (i) no application for such a grant with respect to such region or area has been filed by any other agency or organization qualified to receive such a grant, and (ii) such State agency certifies, and the Secretary finds, that ample opportunity has been afforded to qualified agencies and organizations to file application for such a grant with respect to such region or area and that it is improbable that, in the 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 areawide health planning agency has made provision for assisting health care facilities in its area to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan which will meet the needs of the State and the area for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner.

(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 authorized 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

Pub. L. 95–626, title II, § 201(b)(2), Nov. 10, 1978, 92 Stat. 3570, provided that the amendment made by section is effective Oct. 1, 1979.

Pub. L. 91–648, title IV, § 403(b), as added by Pub. L. 95–454, title VI, § 602(c), Oct. 13, 1978, 92 Stat. 1189, 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

Pub. L. 94–63, title I, § 102, July 29, 1975, 89 Stat. 304, 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

Pub. L. 91–515, title II, § 260(c)(2), Oct. 30, 1970, 84 Stat. 1306, 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 [42 U.S.C. 246(e)] which are made after the date of enactment of this Act [Oct. 30, 1970.]''

Pub. L. 91–296, title IV, § 401(b)(1), June 30, 1970, 84 Stat. 352, 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

Pub. L. 90–174, § 2(d)(2), (f), Dec. 5, 1967, 81 Stat. 534, provided that the amendments made by that section are effective July 1, 1968.

Pub. L. 90–174, § 3(b), Dec. 5, 1967, 81 Stat. 535, 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

Pub. L. 89–749, § 6, Nov. 3, 1966, 80 Stat. 1190, 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 [42 U.S.C. 246] 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 as amended by this Act.''

EFFECTIVE DATE OF 1962 AMENDMENT

Pub. L. 87–688, § 4(b), Sept. 25, 1962, 76 Stat. 587, 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

Pub. L. 85–544, § 2, July 22, 1958, 72 Stat. 401, 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

Act Aug. 1, 1956, ch. 852, §18, 70 Stat. 910, 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

Pub. L. 95–626, title II, §201(b)(1), Nov. 10, 1978, 92 Stat. 3570, provided that: ''The Congress finds and declares that—

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

Pub. L. 89–749, §2, Nov. 3, 1966, 80 Stat. 1180, 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.''

Act July 3, 1956, ch. 852, §2, 70 Stat. 908, 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

Pub. L. 85–544, §2, July 22, 1958, 72 Stat. 401, 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

Pub. L. 89–749, §7, Nov. 3, 1966, 80 Stat. 1190, 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 [42 U.S.C. 202 note].''

§ 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. Assisting veterans with military emergency medical training to meet requirements for becoming civilian health care professionals

(a) Program

(1) In general

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

(2) Consultation and collaboration

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

(b) Use of funds

Amounts received as a demonstration grant under this section shall be used to—

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

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

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

(2) if necessary to meet workforce shortages or address gaps in education, training, or skill level to meet certification, licensure or other requirements applicable to becoming a civilian health care professional (such as an emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State, develop or expand career pathways at institutions of higher education to support veterans in meeting such requirements.

(c) Report

Upon the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on the program.

(d) Funding

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

(e) Sunset

The demonstration program under this section shall not exceed 5 years.

(July 1, 1944, ch. 373, title III, § 315, as added Pub. L. 114–198, title I, § 105, July 22, 2016, 130 Stat. 701.)

PRIOR PROVISIONS

A prior section 247, 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.

Another 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).

(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 section (a)[1] unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide—

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

(2) with respect to each such program (A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period, (C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;

(3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) will be provided in a manner consistent with the State health plan in effect under section 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);

(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) for a grant for a program for which a grant was previously made under subsection (a) unless the Secretary determines—

(A) the program for which the application was submitted is operating effectively to achieve its stated purpose,

(B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and

(C) the applicant will comply with the assurances provided with the application.

[1] So in original. Probably should be ''subsection (a)''.

[1] See References in Text note below.

(2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) Amount of grant; payment

The amount of a grant under subsection (a) shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) Reduction

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee,

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f) Recordkeeping; audit authority

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

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

(g) 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).

(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); on the amount of funds obligated under grants under subsection (a) in the preceding fiscal year for each of the programs listed in subsection (j); and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions.

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

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

(k) 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.

(*l*) Authority to purchase recommended vaccines for adults

(1) In general

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

(2) State purchase

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

(m) Demonstration program to improve immunization coverage

(1) In general

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

(2) State plan

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

(3) Use of funds

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

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

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

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

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

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

(F) providing reminders or recalls for immunization providers;

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

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

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

(4) Consideration

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

(5) Evaluation

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

(6) Report to Congress

Not later than 4 years after March 23, 2010,[1] the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.

(7) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.

(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; Pub. L. 111–148, title IV, § 4204(a)–(c), Mar. 23, 2010, 124 Stat. 571, 572.)

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.

March 23, 2010, referred to in subsec. (m)(6), was in the original ''the date of enactment of the Affordable Health Choices Act'', and was translated as meaning the date of enactment of the Patient Protection and Affordable Care Act, Pub. L. 111–148, to reflect the probable intent of Congress. No act named the ''Affordable Health Choices Act'' has been enacted.

AMENDMENTS

2010—Subsec. (j)(1). Pub. L. 111–148, § 4204(c)(1), struck out ''for each of the fiscal years 1998 through 2005'' after ''necessary''.

Subsec. (j)(2). Pub. L. 111–148, § 4204(c)(2), struck out ''after October 1, 1997,'' after ''routine use,''.

Subsecs. (*l*), (m). Pub. L. 111–148, § 4204(a), (b), added subsecs. (*l*) and (m).

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

Pub. L. 95–626, title II, § 202, Nov. 10, 1978, 92 Stat. 3574, 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

Pub. L. 94–317, title II, § 202(a), Nov. 10, 1978, 92 Stat. 3574, 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

Pub. L. 94–63, title VI, § 608, July 29, 1975, 89 Stat. 352, 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

Pub. L. 92–449, title I, § 102, Sept. 30, 1972, 86 Stat. 750, 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 [42 U.S.C. 247b] after June 30, 1972, except that subsection (d) of such section as amended by section 101 shall take effect on the date of enactment of this Act [Sept. 30, 1972].''

RULE OF CONSTRUCTION REGARDING ACCESS TO IMMUNIZATIONS

Pub. L. 111–148, title IV, § 4204(d), Mar. 23, 2010, 124 Stat. 572, provided that: ''Nothing in this section [amending this section] (including the amendments made by this section), or any other provision of this Act [see Tables for classification] (including any amendments made by this Act) shall be construed to decrease children's access to immunizations.''

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. 247b(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

Pub. L. 94–380, § 3, Aug. 12, 1976, 90 Stat. 1118, 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) 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

[1] See References in Text notes below.

(B) the applicant will enter into an agreement with a provider under which the provider will provide the service, and the provider has entered into such a participation agreement and is qualified to receive such payments.

(2) Waiver regarding certain secondary agreements

(A) In the case of a provider making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the provider does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(B) A determination by the Secretary of whether a provider referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the provider accepts voluntary donations regarding the provision of services to the public.

(c) Priority in making grants

In making grants under subsection (a), the Secretary shall give priority to applications for programs that will serve areas with a high incidence of elevated blood lead levels in infants and children.

(d) Grant application

No grant may be made under subsection (a), unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall prescribe and shall include each of the following:

(1) A complete description of the program which is to be provided by or through the applicant.

(2) Assurances satisfactory to the Secretary that the program to be provided under the grant applied for will include educational programs designed to—

(A) communicate to parents, educators, and local health officials the significance and prevalence of lead poisoning in infants and children (including the sources of lead exposure, the importance of screening young children for lead, and the preventive steps that parents can take in reducing the risk of lead poisoning) which the program is designed to detect and prevent; and

(B) communicate to health professionals and paraprofessionals updated knowledge concerning lead poisoning and research (including the health consequences, if any, of low-level lead burden; the prevalence of lead poisoning among all socioeconomic groupings; the benefits of expanded lead screening; and the therapeutic and other interventions available to prevent and combat lead poisoning in affected children and families).

(3) Assurances satisfactory to the Secretary that the applicant will report on a quarterly basis the number of infants and children screened for elevated blood lead levels, the number of infants and children who were found to have elevated blood lead levels, the number and type of medical referrals made for such infants and children, the outcome of such referrals, and other information to measure program effectiveness.

(4) Assurances satisfactory to the Secretary that the applicant will make such reports respecting the program involved as the Secretary may require.

(5) Assurances satisfactory to the Secretary that the applicant will coordinate the activities carried out pursuant to subsection (a) with related activities and services carried out in the State by grantees under title V or XIX of the Social Security Act [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).

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

(e) Relationship to services and activities under other programs

(1) In general

A recipient of a grant under subsection (a) may not make payments from the grant for any service or activity to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service or activity—

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

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

(2) Applicability to certain secondary agreements for provision of services

Paragraph (1) shall not apply in the case of a provider through which a grantee under subsection (a) provides services under such subsection if the Secretary has provided a waiver under subsection (b)(2) regarding the provider.

(f) Method and amount of payment

The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants. Not more than 10 per-

cent of any grant may be obligated for administrative costs.

(g) Supplies, equipment, and employee detail

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies or equipment furnished the grant recipient; and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(h) Records

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

(i) Audit and examination of records

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

(j) Annual report

(1) In general

Not later than May 1 of each year, the Secretary shall submit to the Congress a report on the effectiveness during the preceding fiscal year of programs carried out with grants under subsection (a) and of any programs that are carried out by the Secretary pursuant to subsection (*l*)(2).

(2) Certain requirements

Each report under paragraph (1) shall include, in addition to any other information that the Secretary may require, the following information:

(A) The number of infants and children screened.

(B) Demographic information on the population of infants and children screened, including the age and racial or ethnic status of such population.

(C) The number of screening sites.

(D) A description of the severity of the extent of the blood lead levels of the infants and children screened, expressed in categories of severity.

(E) The sources of payment for the screenings.

(F) The number of grantees that have established systems to ensure mandatory reporting of all blood lead tests from laboratories and health care providers to State and local health departments.

(G) A comparison of the data provided pursuant to subparagraphs (A) through (F) with the equivalent data, if any, provided in the report under paragraph (1) preceding the report involved.

(k) Indian tribes

For purposes of this section, the term ''political subdivision'' includes Indian tribes.

(*l*) Funding

(1) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 2005.

(2) Allocation for other programs

Of the amounts appropriated under paragraph (1) for any fiscal year, the Secretary may reserve not more than 20 percent for carrying out programs regarding the activities described in subsection (a) in addition to the program of grants established in such subsection.

(m) Guidelines for standardized reporting

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop national guidelines for the uniform reporting of all blood lead test results to State and local health departments.

(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 ''Compre-

hensive 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''.

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

§ 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)), 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; intellectual disabilities; child development; newborn screening; autism; fragile X syndrome; fetal alcohol syndrome; pediatric genetic disorders; disability prevention; or other relevant diseases, disorders, or conditions as determined[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), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

(2) Supplies and services in lieu of award funds

(A) Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

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

(3) Application for award

The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

(c) Biennial report

Not later than February 1 of fiscal year 1999 and of every second such year thereafter, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report that, with respect to the preceding 2 fiscal years—

(1) contains information regarding the incidence and prevalence of birth defects, developmental disabilities, and the health status of individuals with disabilities and the extent to which these conditions have contributed to the incidence and prevalence of infant mortality and affected quality of life;

(2) contains information under paragraph (1) that is specific to various racial and ethnic groups (including Hispanics, non-Hispanic whites, Blacks, Native Americans, and Asian Americans);

(3) contains an assessment of the extent to which various approaches of preventing birth

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

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; Pub. L. 111–256, § 2(f)(1), Oct. 5, 2010, 124 Stat. 2644.)

AMENDMENTS

2010—Subsec. (a)(4)(B)(i). Pub. L. 111–256 substituted ''intellectual disabilities;'' for ''mental retardation;''.

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.''

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

§ 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) and to develop a data collection system under subsection (d).

(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) 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) 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) 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 and activities on preterm birth

(1) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, may, subject to the availability of appropriations—

(A) conduct epidemiological studies on the clinical, biological, social, environmental, genetic, and behavioral factors relating to prematurity, as appropriate;

(B) conduct activities to improve national data to facilitate tracking the burden of preterm birth; and

(C) continue efforts to prevent preterm birth, including late preterm birth, through the identification of opportunities for prevention and the assessment of the impact of such efforts.

(2) Report

Not later than 2 years after November 27, 2013, and every 2 years thereafter, the Secretary 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), $1,880,000 for each of fiscal years 2014 through 2018.

(Pub. L. 109–450, § 3, Dec. 22, 2006, 120 Stat. 3341; Pub. L. 113–55, title I, § 102, Nov. 27, 2013, 127 Stat. 641.)

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.

AMENDMENTS

2013—Subsec. (b). Pub. L. 113–55, § 102(a), added subsec. (b) and struck out former subsec. (b) which related to studies and reports on the relationship between prematurity and birth defects.

Subsec. (e). Pub. L. 113–55, § 102(b), substituted ''$1,880,000 for each of fiscal years 2014 through 2018.'' for ''$5,000,000 for each of fiscal years 2007 through 2011.''

ADVISORY COMMITTEE ON INFANT MORTALITY

Pub. L. 113–55, title I, § 104(b), Nov. 27, 2013, 127 Stat. 643, provided that:

''(1) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section [enacting this note and repealing section 247b–4g of this title] as the 'Secretary') may establish an advisory committee known as the 'Advisory Committee on Infant Mortality' (referred to in this section as the 'Advisory Committee').

''(2) DUTIES.—The Advisory Committee shall provide advice and recommendations to the Secretary concerning the following activities:

''(A) Programs of the Department of Health and Human Services that are directed at reducing infant mortality and improving the health status of pregnant women and infants.

''(B) Strategies to coordinate the various Federal programs and activities with State, local, and private programs and efforts that address factors that affect infant mortality.

''(C) Implementation of the Healthy Start program under section 330H of the Public Health Service Act (42 U.S.C. 254c–8) and Healthy People 2020 infant mortality objectives.

''(D) Strategies to reduce preterm birth rates through research, programs, and education.

''(3) PLAN FOR HHS PRETERM BIRTH ACTIVITIES.—Not later than 1 year after the date of enactment of this section [Nov. 27, 2013], the Advisory Committee (or an advisory committee in existence as of the date of enactment of this Act [Nov. 27, 2013] and designated by the Secretary) shall develop a plan for conducting and supporting research, education, and programs on preterm birth through the Department of Health and Human Services and shall periodically review and revise the plan, as appropriate. The plan shall—

''(A) examine research and educational activities that receive Federal funding in order to enable the plan to provide informed recommendations to reduce preterm birth and address racial and ethnic disparities in preterm birth rates;

''(B) identify research gaps and opportunities to implement evidence-based strategies to reduce preterm birth rates among the programs and activities of the Department of Health and Human Services regarding preterm birth, including opportunities to minimize duplication; and

''(C) reflect input from a broad range of scientists, patients, and advocacy groups, as appropriate.

''(4) MEMBERSHIP.—The Secretary shall ensure that the membership of the Advisory Committee includes the following:

''(A) Representatives provided for in the original charter of the Advisory Committee.

''(B) A representative of the National Center for Health Statistics.''

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. Repealed. Pub. L. 113–55, title I, § 104(a), Nov. 27, 2013, 127 Stat. 643

Section, Pub. L. 109–450, § 5, Dec. 22, 2006, 120 Stat. 3343, related to establishment and activities of the Interagency Coordinating Council on Prematurity and Low Birthweight.

§ 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 screening for the general public, health care providers, policy makers and other appropriate individuals.

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

(5) To improve surveillance for prostate cancer.

(6) To address the needs of underserved and minority populations regarding prostate cancer.

(7) Upon a determination by the Secretary, who shall take into consideration recommendations by the United States Preventive Services Task Force and shall seek input, where appropriate, from professional societies and other private and public entities, that there is sufficient consensus on the effectiveness of prostate cancer screening—

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

(B) to provide appropriate referrals for the medical treatment of men who have been screened under subparagraph (A) and to ensure, to the extent practicable, the provision of appropriate followup services and support services such as case management;

(C) to establish mechanisms through which State and local health departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and

(D) to improve, in consultation with the Health Resources and Services Administration, the education, training, and skills of health practitioners (including appropriate allied health professionals) in the detection and control of prostate cancer.

(8) To evaluate activities conducted under paragraphs (1) through (7) through appropriate surveillance or program monitoring activities.

(b) Requirement of matching funds

(1) In general

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) Determination of amount of non-Federal contribution

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the applicant involved toward the purpose described in subsection (a) for the 2-year period preceding the fiscal year for which the applicant involved is applying to receive a grant under such subsection.

(C) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] by the applicant involved toward the purpose described in paragraphs (1) and (2) of subsection (a).

(c) Education on significance of early detection

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, in carrying out subsection (a)(3), the applicant will carry out education programs to communicate to men, and to local health officials, the significance of the early detection of prostate cancer.

(d) Requirement of provision of all services by date certain

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of such subsection;

(2) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in such subsection is provided; and

(3) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.[2]

(e) Additional required agreements

(1) Priority for low-income men

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that low-income men, and men at risk of prostate cancer, will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of such subsection.

(2) Limitation on imposition of fees for services

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

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

(B) will be adjusted to reflect the income of the man involved; and

(C) will not be imposed on any man with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(3) Relationship to items and services under other programs

The Secretary may not make a grant under subsection (a) unless the applicant involved

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

agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

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

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

(4) Coordination with other prostate cancer programs

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

(5) Limitation on administrative expenses

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(6) Restrictions on use of grant

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(7) Records and audits

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that—

(A) the applicant will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the applicant under such section;[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) unless the applicant involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

(g) Description of intended uses of grant

The Secretary may not make a grant under subsection (a) unless—

(1) the applicant involved submits to the Secretary a description of the purposes for which the applicant intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the applicant[4] with a need for the services or activities described in subsection (a);

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

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

(h) Requirement of submission of application

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

(i) Method and amount of payment

The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of the underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(j) Technical assistance and provision of supplies and services in lieu of grant funds

(1) Technical assistance

The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to subsection (a). The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(2) Provision of supplies and services in lieu of grant funds

(A) Upon the request of an applicant receiving a grant under subsection (a), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the applicant in carrying out such section and, for such purpose, may detail to the applicant any officer or employee of the Department of Health and Human Services.

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

(k) "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

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

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

$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).

(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. National strategy for combating and eliminating 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 and development; demonstration projects; education and training

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

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

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

(3) Demonstration projects for—

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

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

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

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

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

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

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

(F) tuberculosis detection, control, and prevention.

(4) Public information and education activities.

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

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

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

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

(c) Cooperation with providers of primary health services

The Secretary may make a grant under subsection (a) or (b) only if the applicant for the grant agrees that, in carrying out activities under the grant, the applicant will cooperate with public and nonprofit private providers of primary health services or substance abuse services, including entities receiving assistance under section 254b, 254b, or 256a of this title[1] or under subchapter III–A or XVII.

(d) Application for grant

(1) In general

The Secretary may make a grant under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application, subject to paragraph (2), is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the subsection involved.

(2) Plan for prevention, control, and elimination

The Secretary may make a grant under subsection (a) only if the application under paragraph (1) contains a plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought.

(3) Determination of amount of nonfederal contributions

(A) Priority

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

(B) Federal amounts not to be included as contributions

Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).

(e) Supplies and services in lieu of grant funds

(1) In general

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

(2) Corresponding reduction in payments

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

(f) Advisory Council

(1) In general

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

(2) Duties

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

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

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

(C) efficiently utilizing the Federal resources involved.

(3) Comprehensive plan

(A) In general

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

(B) Consultation

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

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

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

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

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

(v) scientists, physicians, laboratorians, and other health professionals who reside

[1] See References in Text notes below.

in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(C) Certain components of plan

In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

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

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

(4) Biennial report

(A) In general

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

(i) activities under subsection (b); and

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

(B) Public

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

(5) Composition

The Council shall be composed of—

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

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

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

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

(6) Staff, information, and other assistance

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

(g) Federal Tuberculosis Task Force

(1) Duties

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

(2) Comprehensive plan for new tools development

In carrying out paragraph (1), the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

(3) Consultation

In developing the comprehensive plan under paragraph (1),[2] the Task Force shall consult with external parties including representatives from groups such as—

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

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

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

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

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

(h) Authorization of appropriations

(1) General program

(A) In general

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

(B) Reservation for emergency grants

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

(C) Priority

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

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[2] So in original. Probably should be ''paragraph (2),''.

(D) Allocation of funds

(i) Requirement of formula

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

(ii) Relevant factors

The formula developed by the Secretary under clause (i) shall take into account the level of tuberculosis morbidity and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

(iii) No change to formula required

This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

(2) Limitation

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

(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; Pub. L. 110–392, title I, §§ 101, 111(a), (c), 131, Oct. 13, 2008, 122 Stat. 4196, 4197, 4199, 4200.)

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

2008—Pub. L. 110–392, § 101(1), substituted ''National strategy for combating and eliminating tuberculosis'' for ''Preventive health services regarding tuberculosis'' in section catchline.

Subsec. (b). Pub. L. 110–392, § 101(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to research, demonstration projects, education, and training for the purpose of prevention, control, and elimination of tuberculosis.

Subsec. (d)(3). Pub. L. 110–392, § 101(3), added par. (3).

Subsec. (f)(2) to (6). Pub. L. 110–392, § 111(a), added pars. (2) to (5), redesignated former par. (5) as (6), and struck out former pars. (2) to (4) which related to general duties, certain activities, and composition of the Council, respectively.

Subsec. (g). Pub. L. 110–392, § 111(c)(2), added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 110–392, § 131, added subsec. (h) and struck out former subsec. (h) which authorized appropriations for grants, research, demonstration projects, education, and training for fiscal years 1994 to 2002.

Pub. L. 110–392, § 111(c)(1), redesignated subsec. (g) as (h).

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.

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–392, title I, § 111(b), Oct. 13, 2008, 122 Stat. 4199, provided that: ''With respect to the advisory council under section 317E(f) of the Public Health Service Act [42 U.S.C. 247b–6(f)], the amendments made by subsection (a) [amending this section] may not be construed as terminating the membership on such council of any individual serving as such a member as of the day before the date of the enactment of this Act [Oct. 13, 2008].''

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), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

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

(d) Availability of appropriations

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

(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

Pub. L. 105–115, title IV, § 408(b)(2), Nov. 21, 1997, 111 Stat. 2371, 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–9a. Better diabetes care

(a) Short title

This section may be cited as the ''Catalyst to Better Diabetes Care Act of 2009''.

(b) National diabetes report card

(1) In general

The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention (referred to in this section as the ''Director''), shall prepare on a biennial basis a national diabetes report card (referred to in this section as a ''Report Card'') and, to the extent possible, for each State.[1]

(2) Contents

(A) In general

Each Report Card shall include aggregate health outcomes related to individuals diagnosed with diabetes and prediabetes including—

(i) preventative care practices and quality of care;

(ii) risk factors; and

(iii) outcomes.

(B) Updated reports

Each Report Card that is prepared after the initial Report Card shall include trend

[1] So in original.

analysis for the Nation and, to the extent possible, for each State, for the purpose of—

(i) tracking progress in meeting established national goals and objectives for improving diabetes care, costs, and prevalence (including Healthy People 2010); and

(ii) informing policy and program development.

(3) Availability

The Secretary, in collaboration with the Director, shall make each Report Card publicly available, including by posting the Report Card on the Internet.

(c) Improvement of vital statistics collection

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with appropriate agencies and States, shall—

(A) promote the education and training of physicians on the importance of birth and death certificate data and how to properly complete these documents, including the collection of such data for diabetes and other chronic diseases;

(B) encourage State adoption of the latest standard revisions of birth and death certificates; and

(C) work with States to re-engineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data.

(2) Death certificate additional language

In carrying out this subsection, the Secretary may promote improvements to the collection of diabetes mortality data, including the addition of a question for the individual certifying the cause of death regarding whether the deceased had diabetes.

(d) Study on appropriate level of diabetes medical education

(1) In general

The Secretary shall, in collaboration with the Institute of Medicine and appropriate associations and councils, conduct a study of the impact of diabetes on the practice of medicine in the United States and the appropriateness of the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(2) Report

Not later than 2 years after March 23, 2010, the Secretary shall submit a report on the study under paragraph (1) to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate.

(e) Authorization of appropriations

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

(Pub. L. 111–148, title X, § 10407, Mar. 23, 2010, 124 Stat. 976.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 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), provide an update on surveillance activities at each Committee meeting.

(c) Collaborative efforts

The activities described in subsection (a)(1) may be conducted in collaboration with eligible entities awarded a grant under section 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), the Secretary shall consult with the States and with other appropriate public or private entities, including national nonprofit private organizations, health professionals, and providers of health insurance and health plans.

(c) Technical assistance

The Secretary may (directly or through grants or contracts) provide technical assistance to public and nonprofit private entities in carrying out the activities described in subsection (a).

(d) Evaluations

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

(e) Authorization of appropriations

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

(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), 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.)

IMPROVING DATA AND THE PUBLIC HEALTH RESPONSE

Pub. L. 114–91, § 4, Nov. 25, 2015, 129 Stat. 725, provided that: ''The Secretary [of Health and Human Services] may continue activities, as appropriate, related to—

''(1) providing technical assistance to support States and Federally recognized Indian Tribes in collecting information on neonatal abstinence syndrome through the utilization of existing surveillance systems and collaborating with States and Federally recognized Indian Tribes to improve the quality, consistency, and collection of such data; and

''(2) providing technical assistance to support States in implementing effective public health measures, such as disseminating information to educate the public, health care providers, and other stakeholders on prenatal opioid use and neonatal abstinence syndrome.''

§ 247b–13a. Screening and treatment for maternal depression

(a) Grants

The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

(b) Application

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

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

(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal depression.

(c) Priority

In awarding grants under this section, the Secretary may give priority to States proposing to improve or enhance access to screening services for maternal depression in primary care settings.

(d) Use of funds

The activities eligible for funding through a grant under subsection (a)—

(1) shall include—

(A) providing appropriate training to health care providers; and

(B) providing information to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and

(2) may include—

(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;

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

(C) utilizing telehealth services for rural areas and medically underserved areas (as defined in section 254c–14(a) of this title).

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 317L–1, as added Pub. L. 114–255, div. B, title X, § 10005, Dec. 13, 2016, 130 Stat. 1266.)

§ 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 Preven-

tion and in collaboration with the Director of the Indian Health Service, shall establish a demonstration project that is designed to assist rural water systems in successfully implementing the water fluoridation guidelines of the Centers for Disease Control and Prevention that are entitled ''Engineering and Administrative Recommendations for Water Fluoridation, 1995'' (referred to in this subsection as the ''EARWF'').

(2) Requirements

(A) Collaboration

In collaborating under paragraph (1), the Directors referred to in such paragraph shall ensure that technical assistance and training are provided to tribal programs located in each of the 12 areas of the Indian Health Service. The Director of the Indian Health Service shall provide coordination and administrative support to tribes under this section.

(B) General use of funds

Amounts made available under paragraph (1) shall be used to assist small water systems in improving the effectiveness of water fluoridation and to meet the recommendations of the EARWF.

(C) Fluoridation specialists

(i) In general

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

(ii) Liaison

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

(iii) CDC

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

(D) Implementation

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

(3) Evaluation

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

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

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

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

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

(c) School-based dental sealant program

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Administrator of the Health Resources and Services Administration, shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 1603 of title 25) 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) Oral health infrastructure

(1) Cooperative agreements

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into cooperative agreements with State, territorial, and Indian tribes or tribal organizations (as those terms are defined in section 1603 of title 25) to establish oral health leadership and program guidance,

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

oral health data collection and interpretation,[2] (including determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health.

(2) Authorization of appropriations

There is authorized to be appropriated such sums as necessary to carry out this subsection for fiscal years 2010 through 2014.

(e) Definitions

For purposes of this section, the term ''Indian tribe'' means an Indian tribe or tribal organization as defined in section 5304(b) and section 5304(c)[3] of title 25.

(f) Authorization of appropriations

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

(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; amended Pub. L. 111–148, title IV, § 4102(b), (c), Mar. 23, 2010, 124 Stat. 551, 552.)

REFERENCES IN TEXT

Section 5304 of title 25, referred to in subsec. (e), has been amended, and subsecs. (b) and (c) of section 5304 no longer define the terms ''Indian tribe'' and ''tribal organization''. However, such terms are defined elsewhere in that section.

AMENDMENTS

2010—Subsec. (c)(1). Pub. L. 111–148, § 4102(b), substituted ''shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 1603 of title 25)'' for ''may award grants to States and Indian tribes''.

Subsecs. (d) to (f). Pub. L. 111–148, § 4102(c), added subsec. (d) and redesignated former subsecs. (d) and (e) as (e) and (f), respectively.

§ 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 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

[2] So in original. The comma probably should not appear.

[3] See References in Text note below.

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

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 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) Consultation with nonprofit gynecologic cancer organizations

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

(6)[1] Authorization of appropriations

For the purpose of carrying out this subsection, there is authorized to be appropriated $16,500,000 for the period of fiscal years 2007 through 2009 and $18,000,000 for the period of fiscal years 2012 through 2014.

(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; Pub. L. 111–324, § 1, Dec. 22, 2010, 124 Stat. 3536.)

REFERENCES IN TEXT

Johanna's Law, referred to in section catchline and subsec. (d), is Pub. L. 109–475, Jan. 12, 2007, 120 Stat.

[1] So in original. No par. (5) has been enacted.

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

2010—Subsec. (d)(4). Pub. L. 111–324, §1(b), added par. (4). Former par. (4) redesignated (6).

Pub. L. 111–324, §1(a)(1), inserted ''and $18,000,000 for the period of fiscal years 2012 through 2014'' after ''2009''.

Subsec. (d)(6). Pub. L. 111–324, §1(a)(2), redesignated par. (4) as (6).

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 and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner. In making awards under this subsection, the Secretary may provide direct technical assistance in lieu of cash.

(c) Coordination with centers of excellence

The Secretary shall ensure that epidemiological information under subsections (a) and (b) is made available to centers of excellence supported under section 283g(b) of this title by the Director of the National Institutes of Health.

(d) Data

In carrying out this section, the Secretary may ensure that any data on patients that is collected as part of the Muscular Dystrophy STARnet (under a grant under this section) is regularly updated to reflect changes in patient condition over time.

(e) Reports and study

(1) Annual report

Not later than 18 months after October 8, 2008, and annually thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress a report—

(A) concerning the activities carried out by MD STARnet site[1] funded under this section during the year for which the report is prepared;

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

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

(2) Tracking health outcomes

The Secretary may provide health outcome data on the health and survival of people with muscular dystrophy.

(f) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, §317Q, as added Pub. L. 107–84, §4, Dec. 18, 2001, 115 Stat. 828; amended Pub. L. 110–361, §3, Oct. 8, 2008, 122 Stat. 4010; Pub. L. 113–166, §3, Sept. 26, 2014, 128 Stat. 1880.)

AMENDMENTS

2014—Subsec. (b). Pub. L. 113–166 inserted ''and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner'' after ''surveillance program''.

2008—Subsecs. (d) to (f). Pub. L. 110–361 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

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.

[1] So in original. Probably should be plural.

''(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) Requirements

In carrying out this section, the Secretary may—

(1) partner with leaders in the muscular dystrophy patient community;

(2) cooperate with professional organizations and the patient community in the development and issuance of care considerations for pediatric and adult patients, including acute care considerations, for Duchenne-Becker muscular dystrophy, and various other forms of muscular dystrophy, and in periodic review and updates, as appropriate;

(3) in developing and updating care considerations under paragraph (2), incorporate strategies specifically responding to the findings of the national transitions survey of minority, young adult, and adult communities of muscular dystrophy patients; and

(4) widely disseminate the Duchenne-Becker muscular dystrophy and various other forms of muscular dystrophy care considerations as broadly as possible, including through partnership opportunities with the muscular dystrophy patient community.

(d) 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; Pub. L. 110–361, § 4, Oct. 8, 2008, 122 Stat. 4011; Pub. L. 113–166, § 4, Sept. 26, 2014, 128 Stat. 1880.)

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.

AMENDMENTS

2014—Subsec. (c)(2). Pub. L. 113–166, § 4(1), inserted ''for pediatric and adult patients, including acute care considerations,'' after ''issuance of care considerations'' and ''various'' before ''other forms of muscular dystrophy'' and struck out ''and'' at end.

Subsec. (c)(3), (4). Pub. L. 113–166, § 4(2)–(4), added par. (3), redesignated former par. (3) as (4), and, in par. (4), inserted ''various'' before ''other forms of muscular dystrophy''.

2008—Subsecs. (c), (d). Pub. L. 110–361 added subsec. (c) and redesignated former subsec. (c) as (d).

§ 247b–20. Food safety grants

(a) In general

The Secretary may award grants to States and Indian tribes (as defined in section 5304(e) of

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

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 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2015.

(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; Pub. L. 111–353, title II, § 205(d), Jan. 4, 2011, 124 Stat. 3939.)

AMENDMENTS

2011—Subsec. (b). Pub. L. 111–353 substituted ''2010'' for ''2002'' and ''2011 through 2015'' for ''2003 through 2006''.

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

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

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

(1) In general

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

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

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

(2) Preference in making grants

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

(3) Certain requirements

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

(A) the State involved has developed, or agrees to develop, a plan for coordinating control programs in the State, and the plan takes into account any assessments or plans described in subsection (b)(3) that have been conducted or developed, respectively, by political subdivisions in the State;

(B) in developing such plan, the State consulted or will consult (as the case may be under subparagraph (A)) with political subdivisions in the State that are carrying out or planning to carry out control programs;

(C) the State agrees to monitor control programs in the State in order to ensure that the programs are carried out in accordance with such plan, with priority given to coordination of control programs in political subdivisions described in paragraph (2) that are contiguous;

(D) the State agrees that the State will make grants to political subdivisions as described in paragraph (1)(B), and that such a grant will not exceed $10,000; and

(E) the State agrees that the grant will be used to supplement, and not supplant, State and local funds available for the purpose described in paragraph (1).

(4) Reports to Secretary

A grant may be made under paragraph (1) only if the State involved agrees that, promptly after the end of the fiscal year for which the grant is made, the State will submit to the Secretary a report that—

(A) describes the activities of the State under the grant; and

(B) contains an evaluation of whether the control programs of political subdivisions in the State were effectively coordinated with each other, which evaluation takes into account any reports that the State received under subsection (b)(5) from such subdivisions.

(5) Number of grants

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

(b) Prevention and control grants to political subdivisions

(1) In general

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

(2) Preference in making grants

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

(A) has—

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

(ii) a population of infected mosquitoes; or

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

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

(C) demonstrates to the Secretary (directly or through State officials) that the State in which such a political subdivision

or consortium of political subdivisions is located has identified or will identify geographic areas in such State that have a significant need for control programs and will effectively coordinate such programs in such areas; and

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

(3) Requirement of assessment and plan

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

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

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

(4) Requirement of matching funds

(A) In general

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

(B) Determination of amount contributed

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

(C) Waiver

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

(5) Reports to Secretary

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

(6) Amount of grant; number of grants

(A) Amount of grant

(i) Single political subdivision

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

(ii) Consortium

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

(iii) Waiver of requirement

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

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

(II) the mosquito population in such geographical area.

(B) Number of grants

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

(c) Applications for grants

A grant may be made under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(d) Technical assistance

Amounts appropriated under subsection (f) may be used by the Secretary to provide training and technical assistance with respect to the planning, development, and operation of assessments and plans under subsection (a) and control programs under subsection (b). The Secretary may provide such technical assistance directly or through awards of grants or contracts to public and private entities.

(e) Definition of political subdivision

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

(f) Authorization of appropriations

(1) In general

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

(2) Public health emergencies

In the case of control programs carried out in response to a mosquito-borne disease that

constitutes a public health emergency, the authorization of appropriations under paragraph (1) is in addition to applicable authorizations of appropriations under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(3) Fiscal year 2004 appropriations

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

(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.

§ 247b–22. Microbicide research

(a) In general

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

(b) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out this section.

(July 1, 1944, ch. 373, title III, § 317T, as added Pub. L. 110–293, title II, § 203(d), July 30, 2008, 122 Stat. 2941.)

§ 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), 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

Pub. L. 95–626, title II, § 204(a), Nov. 10, 1978, 92 Stat. 3582, 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.''

Pub. L. 94–317, title II, § 203(a), June 23, 1976, 90 Stat. 703, 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.''

Pub. L. 92–449, title II, § 202, Sept. 30, 1972, 86 Stat. 750, 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 [enacting this section, amending sections 247b and 300 of this title, and enacting provisions set out as notes under sections 201 and 247b of this title] 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) regarding any treatable sexually transmitted disease that can cause infertility in women if treatment is not received for the disease.

(b) Authority regarding individual diseases

With respect to diseases described in subsection (a), the Secretary shall, in making a grant under such subsection, specify the particular disease or diseases with respect to which the grant is to be made. The Secretary may not make the grant unless the applicant involved agrees to carry out this section only with respect to the disease or diseases so specified.

(c) Authorized activities

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

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

(2) providing treatment to women for the disease;

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

(4) providing follow-up services;

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

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

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

(8) providing to the public information and education on the prevention and control of the

disease, including disseminating such information; and

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

(d) Requirement of availability of all services through each grantee

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

(e) Required providers regarding certain services

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c), the services described in paragraphs (1) through (7) of such subsection will be provided only through entities that are State or local health departments, grantees under section 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 of screening procedures for diseases described in subsection (a).

(g) Confidentiality

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

(h) Limitation on imposition of fees for services

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

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

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

(3) will not be imposed on any individual with an income of less than 150 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(i) Limitations on certain expenditures

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

[1] See References in Text notes below.

(j) Reports to Secretary

(1) Collection of data

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

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

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

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

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

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

(2) Utility and comparability of data

The Secretary shall carry out activities for the purpose of ensuring the utility and comparability of data collected pursuant to paragraph (1).

(k) Maintenance of effort

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

***(l)* Requirement of application**

(1) In general

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the plan required in paragraph (2), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(2) Submission of plan for program of grantee

(A) In general

The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary a plan describing the manner in which the applicant will comply with the agreements required as a condition of receiving such a grant, including a specification of the entities through which activities authorized in subsection (c) will be provided.

(B) Participation of certain entities

The Secretary may make a grant under subsection (a) only if the applicant provides

assurances satisfactory to the Secretary that the plan submitted under subparagraph (A) has been prepared in consultation with an appropriate number and variety of—

(i) representatives of entities in the geographic area involved that provide services for the prevention and control of sexually transmitted diseases, including programs to provide to the public information and education regarding such diseases; and

(ii) representatives of entities in such area that provide family planning services.

(m) Duration of grant

The period during which payments are made to an entity from a grant under subsection (a) may not exceed 3 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments in such year. The preceding sentence may not be construed to establish a limitation on the number of grants under such subsection that may be made to an entity.

(n) Technical assistance, and supplies and services in lieu of grant funds

(1) Technical assistance

The Secretary may provide training and technical assistance to grantees under subsection (a) with respect to the planning, development, and operation of any program or service carried out under such subsection. The Secretary may provide such technical assistance directly or through grants or contracts.

(2) Supplies, equipment, and employee detail

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(A) the fair market value of any supplies or equipment furnished the grant recipient; and

(B) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(*o*) Evaluations and reports by Secretary

(1) Evaluations

The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to subsection (a) in order to determine the quality and effectiveness of the programs.

(2) Report to Congress

Not later than 1 year after the date on which amounts are first appropriated pursuant to subsection (q), and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report—

(A) summarizing the information provided to the Secretary in reports made pursuant to subsection (j)(1), including information on the incidence of sexually transmitted diseases described in subsection (a); and

(B) summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year.

(p) Coordination of Federal programs

The Secretary shall coordinate the program carried out under this section with any similar programs administered by the Secretary (including coordination between the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health).

(q) Authorization of appropriations

For the purpose of carrying out this section, other than subsections (*o*) and (r), there are authorized to be appropriated $25,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(r) Separate grants for research on delivery of services

(1) In general

The Secretary may make grants for the purpose of conducting research on the manner in which the delivery of services under subsection (a) may be improved. The Secretary may make such grants only to grantees under such subsection and to public and nonprofit private entities that are carrying out programs substantially similar to programs carried out under such subsection.

(2) Authorization of appropriations

For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 through 1998.

(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, 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) only if a public health emergency has been declared by the Secretary under such subsection. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—

(A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and

(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(c) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(d) Data submittal and reporting deadlines

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

waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) Temporary reassignment of State and local personnel during a public health emergency

(1) Emergency reassignment of federally funded personnel

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

(2) Activation of emergency reassignment

(A) Public health emergency

The Secretary may authorize a temporary reassignment of personnel under paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) Contents of request

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

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

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

(iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 247d–3a of this title.

(iv) An identification of—

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

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

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

(C) Consideration

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

(D) Termination and extension

(i) Termination

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

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

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

(ii) Extension of reassignment flexibility

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

(I) the State or Indian tribe that submitted the initial request for a temporary reassignment of personnel submits a request for an extension of such temporary reassignment; and

(II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) Voluntary nature of temporary reassignment of State and local personnel

(A) In general

Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization—

(i) shall have the opportunity to volunteer for temporary reassignment; and

(ii) shall not be required to agree to a temporary reassignment.

(B) Prohibition on conditioning Federal awards

The Secretary may not condition the award of a grant, contract, or cooperative agreement under this chapter on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) Notice to Congress

The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of—

(A) any initial request for temporary reassignment of personnel; and

(B) any request for an extension of such temporary reassignment.

(5) Guidance

The Secretary shall—

(A) not later than 6 months after March 13, 2013, issue proposed guidance on the temporary reassignment of personnel under this subsection; and

(B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) Report to Congress

Not later than 4 years after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including—

(A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes;

(B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies;

(C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies;

(D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and

(E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) Definitions

In this subsection—

(A) the terms ''Indian tribe'' and ''tribal organization'' have the meanings given such terms in section 5304 of title 25; and

(B) the term ''State'' includes, in addition to the entities listed in the definition of such term in section 201 of this title, the Freely Associated States.

(8) Sunset

This subsection shall terminate on September 30, 2018.

(f) Determination with respect to Paperwork Reduction Act waiver during a public health emergency

(1) Determination

If the Secretary determines, after consultation with such public health officials as may be necessary, that—

(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44 (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

(2) Transparency

If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

(3) Effectiveness of waiver

Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

(4) Termination of waiver

Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

(5) Limitations

(A) Period of waiver

The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

(B) Subsequent compliance

An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44 and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.

(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; Pub. L. 113–5, title II, § 201, Mar. 13, 2013, 127 Stat. 170; Pub. L. 114–255, div. A, title III, § 3087, Dec. 13, 2016, 130 Stat. 1147.)

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

2016—Subsec. (f). Pub. L. 114–255 added subsec. (f).

2013—Subsec. (e). Pub. L. 113–5 added subsec. (e).

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 [42 U.S.C. 247d(a)], 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, $30,800,000 for each of fiscal years 2014 through 2018.

(f) Report to Congress

As part of the National Health Security Strategy described in section 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; Pub. L. 113–5, title II, § 202(b), Mar. 13, 2013, 127 Stat. 175.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2013—Subsec. (e). Pub. L. 113–5 substituted ''$30,800,000 for each of fiscal years 2014 through 2018'' for ''such sums for each of fiscal years 2007 through 2011''.

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 (h)(4)); or

(C) be a consortium of States; and

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

(A) an All-Hazards Public Health Emergency Preparedness and Response Plan which shall include—

(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 300hh–1 of this title, including with respect to chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate;

(ii) a description of the activities such entity will carry out with respect to pandemic influenza, as a component of the activities carried out under clause (i), and consistent with the requirements of paragraphs (2) and (5) of subsection (g);

(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact or other mutual aid agreements for medical and public health mutual aid;

(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

(vi) a description of how, as appropriate, the entity may partner with relevant public and private stakeholders in public health emergency preparedness and response;

(vii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State educational agencies (as defined in section 7801 of title 20) and State child care lead agencies (designated under section 9858b of this title);

(viii) in the case of entities that operate on the United States-Mexico border or the United States-Canada border, a description of the activities such entity will carry out under the agreement that are specific to the border area including disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally occurring or due to bioterrorism, consistent with the requirements of this section; and

(ix) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;

(B) an assurance that the entity will report to the Secretary on an annual basis (or more frequently as determined by the Secretary) on the evidence-based benchmarks and objective standards established by the Secretary to evaluate the preparedness and response capabilities of such entity under subsection (g);

(C) an assurance that the entity will conduct, on at least an annual basis, an exercise or drill that meets any criteria established by the Secretary to test the preparedness and response capabilities of such entity, including addressing the needs of at-risk individuals,[1] 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

[1] So in original.

under section 247d–4(c)(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[2] satisfactory annual improvement and describe[3] 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; and

(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities.

(g) Achievement of measurable evidence-based benchmarks and objective standards

(1) In general

Not later than 180 days after 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 achievements of the National Preparedness Goals developed under section 300hh–1(b) of this title with respect to all-hazards, including chemical, biological, radiological, or nuclear threats; and

(B) at a minimum, require entities to—

(i) measure progress toward achieving the outcome goals; and

(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

(2) Criteria for pandemic influenza plans

(A) In general

Not later than 180 days after 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. The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).

(B) Rule of construction

Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after December 19, 2006.[4]

(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 develop-

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

[3] So in original. Probably should be ''describes''.

[4] See Codification note below.

ment 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).

(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) Funding

(1) Authorization of appropriations

(A) In general

For the purpose of carrying out this section, there is authorized to be appropriated $641,900,000 for fiscal year 2014 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and $641,900,000 for each of fiscal years 2015 through 2018.

(B) Requirement for State matching funds

Beginning in fiscal year 2009, in the case of any State or consortium of two or more States, the Secretary may not award a cooperative agreement under this section unless the State or consortium of States agree that, with respect to the amount of the cooperative agreement awarded by the Secretary, the State or consortium of States will make available (directly or through donations from public or private entities) non-Federal contributions in an amount equal to—

(i) for the first fiscal year of the cooperative agreement, not less than 5 percent of such costs ($1 for each $20 of Federal funds provided in the cooperative agreement); and

(ii) for any second fiscal year of the cooperative agreement, and for any subsequent fiscal year of such cooperative agreement, not less than 10 percent of such costs ($1 for each $10 of Federal funds provided in the cooperative agreement).

(C) Determination of amount of non-Federal contributions

As determined by the Secretary, non-Federal contributions required in subparagraph (B) may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the Federal government, or services assisted or subsidized to any significant extent by the Federal government, may not be included in determining the amount of such non-Federal contributions.

(2) Maintaining State funding

(A) In general

An entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(B) Rule of construction

Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal public health agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(3) Determination of amount

(A) In general

The Secretary shall award cooperative agreements under subsection (a) to each State or consortium of 2 or more States that submits to the Secretary an application that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards.

(B) Base amount

In determining the amount of an award pursuant to subparagraph (A) for a State, the Secretary shall first determine an amount the Secretary considers appropriate for the State (referred to in this paragraph as the ''base amount''), except that such amount may not be greater than the minimum amount determined under subparagraph (D).

(C) Increase on basis of population

After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

(i) the amount appropriated under paragraph (1)(A) for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

(D) Minimum amount

Subject to the amount appropriated under paragraph (1)(A), an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) $5,000,000; or

(II) if the amount appropriated under paragraph (1)(A) is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

(ii) in the case of each of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Virgin Islands, an amount determined by the Secretary to be appropriate, except that such amount may not exceed the amount determined under clause (i).

(4) Certain political subdivisions

(A) In general

For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

(B) Coordination with Statewide plans

An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (b).

(C) Relationship to formula grants

In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

(D) Continuity of funding

In determining whether to make an award pursuant to subparagraph (A) to a political

subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2006.

(5) Significant unmet needs; degree of risk

(A) In general

For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

(ii) face a particularly high degree of risk of such a threat.

(B) Recipients of grants

Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

(C) Finding with respect to District of Columbia

The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

(6) Funding of local entities

The Secretary shall, in making awards under this section, ensure that with respect to the cooperative agreement awarded, the entity make available appropriate portions of such award to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities.

(7) Availability of cooperative agreement funds

(A) In general

Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) Funds contingent on achieving benchmarks

The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as described in subsection (g).

(i) Administrative and fiscal responsibility

(1) Annual reporting requirements

Each entity shall prepare and submit to the Secretary annual reports on its activities under this section and section 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 (j).

(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.

(j) Compilation and availability of data

The Secretary shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website in a format that is useful to the public and to other entities and that provides information on what activities are best contributing to the achievement of the outcome goals described in subsection (g).

(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; Pub. L. 113–5, title II, §§ 202(a), (c)(1), 204(b), Mar. 13, 2013, 127 Stat. 173, 175, 179; Pub. L. 114–95, title IX, § 9215(kkk)(1), Dec. 10, 2015, 129 Stat. 2187.)

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

2015—Subsec. (b)(2)(A)(vii). Pub. L. 114–95 substituted ''including State educational agencies (as defined in section 7801 of title 20)'' for ''including State educational agencies (as defined in section 7801(41) of title 20)''.

2013—Subsec. (b)(1)(B). Pub. L. 113–5, § 202(c)(1), substituted ''subsection (h)(4)'' for ''subsection (i)(4)''.

Subsec. (b)(1)(C). Pub. L. 113–5, § 202(a)(1), substituted ''consortium of States'' for ''consortium of entities described in subparagraph (A)''.

Subsec. (b)(2)(A)(i), (ii). Pub. L. 113–5, § 202(a)(2)(A)(i), added cls. (i) and (ii) and struck out former cls. (i) and (ii) which read as follows:

''(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);''.

Subsec. (b)(2)(A)(vi) to (ix). Pub. L. 113–5, § 202(a)(2)(A)(ii), (iii), added cls. (vi) to (ix).

Subsec. (b)(2)(C). Pub. L. 113–5, § 202(a)(2)(B), inserted '', including addressing the needs of at-risk individuals,'' after ''capabilities of such entity''.

Subsec. (b)(2)(D). Pub. L. 113–5, § 204(b), substituted ''section 247d–4(c)(3)'' for ''section 247d–4(d)(3)''.

Subsec. (f)(2) to (4). Pub. L. 113–5, § 202(a)(3), inserted ''and'' at end of par. (2), substituted period for ''; and'' at end of par. (3), and struck out par. (4) which read as follows: ''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 public health best practices and lessons learned from drills, exercises, disasters, and other emergencies.''

Subsec. (g)(1)(A). Pub. L. 113–5, § 202(a)(4)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: ''include outcome goals representing operational achievement of the National Preparedness Goals developed under section 300hh–1(b) of this title; and''.

Subsec. (g)(2)(A). Pub. L. 113–5, § 202(a)(4)(B), inserted at end ''The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).''

Subsec. (h). Pub. L. 113–5, § 202(a)(5), (6), redesignated subsec. (i) as (h) and struck out former subsec. (h) which related to grants for real-time disease detection improvement.

Subsec. (h)(1)(A). Pub. L. 113–5, § 202(a)(7)(A)(i), substituted ''$641,900,000 for fiscal year 2014'' for ''$824,000,000 for fiscal year 2007, of which $35,000,000 shall be used to carry out subsection (h),'' and ''$641,900,000 for each of fiscal years 2015 through 2018'' for ''such sums as may be necessary for each of fiscal years 2008 through 2011''.

Subsec. (h)(1)(B) to (D). Pub. L. 113–5, § 202(a)(7)(A)(ii)–(iv), redesignated subpars. (C) and (D) as (B) and (C), respectively, substituted ''subparagraph (B)'' for ''subparagraph (C)'' in subpar. (C), and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: ''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.''

Subsec. (h)(3)(C), (D). Pub. L. 113–5, § 202(a)(7)(B), substituted ''paragraph (1)(A)'' for ''paragraph (1)(A)(i)(I)'' wherever appearing.

Subsec. (h)(4)(B). Pub. L. 113–5, § 202(a)(7)(C), substituted ''subsection (b)'' for ''subsection (c)''.

Subsec. (h)(7). Pub. L. 113–5, § 202(a)(7)(D), added par. (7).

Subsec. (i). Pub. L. 113–5, § 202(a)(6), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (i)(1)(E). Pub. L. 113–5, § 202(a)(8)(A), substituted ''subsection (j)'' for ''subsection (k)''.

Subsec. (i)(3). Pub. L. 113–5, § 202(a)(8)(B), struck out par. (3) which related to maximum amount of an award under this section that may be carried over to the succeeding fiscal year.

Subsecs. (j), (k). Pub. L. 113–5, § 202(a)(6), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

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).

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive pro-

grams and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

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, including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals.

(b) Eligibility

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

(1)(A) be a partnership consisting of—

(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 300d–13(c) of this title;

(ii) one or more other local health care facilities, including clinics, health centers, community health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and

(iii)(I) one or more political subdivisions;

(II) one or more States; or

(III) one or more States and one or more political subdivisions; and

(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

(2)(A) be an entity described in section 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 with respect to all-hazards, including chemical, biological, radiological, or nuclear threats.

(d) Preferences

(1) Regional coordination

In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

(A) will enhance coordination—

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

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

(B) include, in the partnership described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such partnership.

(2) Other preferences

In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

(A) include one or more hospitals that are participants in the National Disaster Medical System;

(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

(C) have a significant need for funds to achieve the medical preparedness goals described in section 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

(1) Local response capabilities

An eligible entity shall, to the extent practicable, ensure that activities carried out

under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the local Cities Readiness Initiative, and local emergency plans.

(2) National collaboration

Partnerships consisting of one or more eligible entities under this section may, to the extent practicable, collaborate with other partnerships consisting of one or more eligible entities under this section for purposes of national coordination and collaboration with respect to activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 300hh–1(b) of this title.

(h) Maintenance of funding

(1) In general

An entity that receives an award under this section shall maintain expenditures for health care preparedness at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(2) Rule of construction

Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(i) Performance and accountability

(1) In general

The requirements of section 247d–3a(g), (i), and (j) 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.

(2) Meeting goals of National Health Security Strategy

The Secretary shall implement objective, evidence-based metrics to ensure that entities receiving awards under this section are meeting, to the extent practicable, the applicable goals of the National Health Security Strategy under section 300hh–1 of this title.

(j) Authorization of appropriations

(1) In general

For purposes of carrying out this section, there is authorized to be appropriated $374,700,000 for each of fiscal years 2014 through 2018.

(2) Reservation of amounts for partnerships

Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1) for a fiscal year, an amount determined appropriate by the Secretary for making awards to entities described in subsection (b)(1)(A).

(3) Awards to States and political subdivisions

(A) In general

From amounts appropriated for a fiscal year under paragraph (1) and not reserved under paragraph (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

(B) Amount

The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 247d–3a(h) of this title.

(4) Availability of cooperative agreement funds

(A) In general

Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) Funds contingent on achieving benchmarks

The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as required under subsection (i).

(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; Pub. L. 113–5, title II, §§ 202(c)(2), 203(c), Mar. 13, 2013, 127 Stat. 175, 176.)

AMENDMENTS

2013—Subsec. (a). Pub. L. 113–5, § 203(c)(1), inserted '', including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals'' before period at end.

Subsec. (b)(1)(A)(ii). Pub. L. 113–5, § 203(c)(2), substituted ''centers, community health centers, primary'' for ''centers, primary''.

Subsec. (c). Pub. L. 113–5, § 203(c)(3), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: ''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.''

Subsec. (g). Pub. L. 113–5, § 203(c)(4), added subsec. (g) and struck out former subsec. (g). Prior to amendment, text read as follows: ''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.''

Subsec. (i). Pub. L. 113–5, § 203(c)(5), designated existing provisions as par. (1), inserted heading, and added par. (2).

Pub. L. 113–5, § 202(c)(2)(A), substituted ''(i), and (j)'' for ''(j), and (k)''.

Subsec. (j)(1). Pub. L. 113–5, § 203(c)(6)(A), amended par. (1) generally. Prior to amendment, text read as fol-

lows: ''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.''

Subsec. (j)(3)(B). Pub. L. 113–5, § 202(c)(2)(B), substituted ''247d–3a(h)'' for ''247d–3a(i)''.

Subsec. (j)(4). Pub. L. 113–5, § 203(c)(6)(B), added par. (4).

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); and

(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

(b) National communications and surveillance networks

(1) In general

The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

(A) Federal, State, and local public health officials;

(B) public and private health-related laboratories, hospitals, poison control centers, and other health care facilities; and

(C) any other entities determined appropriate by the Secretary.

(2) Requirements

The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency, allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort.

(3) Standards

Not later than one year after 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) and update such standards as necessary.

(c) Modernizing public health situational awareness and biosurveillance

(1) In general

Not later than 2 years after March 13, 2013, the Secretary, in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

(2) Strategy and implementation plan

Not later than 180 days after March 13, 2013, the Secretary shall submit to the appropriate committees of Congress a coordinated strategy and an accompanying implementation

plan that identifies and demonstrates the measurable steps the Secretary will carry out to—

(A) develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3);

(B) modernize and enhance biosurveillance activities; and

(C) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services.

(3) Elements

The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

(A) State, local, and tribal public health entities, including public health laboratories;

(B) Federal health agencies;

(C) zoonotic disease monitoring systems;

(D) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, community health centers, health centers and clinical laboratories, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and tribal public health agencies; and

(E) such other sources as the Secretary may deem appropriate.

(4) Rule of construction

Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

(5) Required activities

In establishing and operating the network described in paragraph (1), the Secretary shall—

(A) utilize applicable interoperability standards as determined by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology, through a joint public and private sector process;

(B) define minimal data elements for such network;

(C) in collaboration with State, local, and tribal public health officials, integrate and build upon existing State, local, and tribal capabilities, ensuring simultaneous sharing of data, information, and analyses from the network described in paragraph (1) with State, local, and tribal public health agencies; and

(D) in collaboration with State, local, and tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1).

(6) Consultation with the National Biodefense Science Board

In carrying out this section and consistent with section 247d–7f of this title, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Human Services to ensure comprehensive, real-time, all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

(A) identify the steps necessary to achieve a national biosurveillance system for human health, with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

(B) identify any duplicative surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such activities under the authority of the Secretary, and achieve real-time and appropriate data that relate to disease activity, both human and zoonotic; and

(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and tribal public health authorities and appropriate public and private sector health care entities and academic institutions, in order to provide guidance on public health surveillance activities.

(d) State and regional systems to enhance situational awareness in public health emergencies

(1) In general

To implement the network described in subsection (c), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, other health care organizations, and animal health organizations within such States.

(2) Eligibility

To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such data, information, and metrics as the Secretary may require;

(B) a report on the effectiveness of the systems funded under the grant; and

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies.

(3) Use of funds

A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) Limitation

Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (c).

(5) Independent evaluation

Not later than 3 years after March 13, 2013, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under this subsection and subsection (c).

(e) Telehealth enhancements for emergency response

(1) Evaluation

The Secretary, in consultation with the Federal Communications Commission and other relevant Federal agencies, shall—

(A) conduct an inventory of telehealth initiatives in existence on 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).

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $138,300,000 for each of fiscal years 2014 through 2018.

(g) Definition

For purposes of this section the term ''biosurveillance'' means the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.

(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; Pub. L. 113–5, title II, § 204(a), Mar. 13, 2013, 127 Stat. 177.)

AMENDMENTS

2013—Subsec. (b)(1)(B). Pub. L. 113–5, § 204(a)(1)(A), inserted ''poison control centers,'' after ''hospitals,''.

Subsec. (b)(2). Pub. L. 113–5, § 204(a)(1)(B), inserted '', allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort'' before period at end.

Subsec. (b)(3). Pub. L. 113–5, § 204(a)(1)(C), inserted ''and update such standards as necessary'' before period at end.

Subsec. (c). Pub. L. 113–5, § 204(a)(4)(A), substituted ''Modernizing public health situational awareness and biosurveillance'' for ''Public health situational awareness'' in heading.

Pub. L. 113–5, § 204(a)(2), (3), redesignated subsec. (d) as (c) and struck out former subsec. (c) which related to authorization of appropriations for fiscal years 2002 through 2006.

Subsec. (c)(1). Pub. L. 113–5, § 204(a)(4)(B), substituted ''March 13, 2013'' for ''December 19, 2006'' and inserted '', novel emerging threats,'' after ''disease outbreaks''.

Subsec. (c)(2). Pub. L. 113–5, § 204(a)(4)(C), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: ''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).''

Subsec. (c)(3)(D). Pub. L. 113–5, § 204(a)(4)(D), inserted ''community health centers, health centers'' after ''of poison control,''.

Subsec. (c)(5)(A). Pub. L. 113–5, § 204(a)(4)(E), added subpar. (A) and struck out former subpar. (A) which read as follows: ''utilize applicable interoperability standards as determined by the Secretary through a joint public and private sector process;''.

Subsec. (c)(6). Pub. L. 113–5, § 204(a)(4)(F), added par. (6).

Subsec. (d). Pub. L. 113–5, § 204(a)(3), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1), (4)(B). Pub. L. 113–5, § 204(a)(5)(A), (B), substituted ''subsection (c)'' for ''subsection (d)''.

Subsec. (d)(5). Pub. L. 113–5, § 204(a)(5)(C), substituted ''3 years after March 13, 2013'' for ''4 years after December 19, 2006'' and ''subsection (c)'' for ''subsection (d)''.

Subsec. (e). Pub. L. 113–5, § 204(a)(3), redesignated subsec. (f) as (e). Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 113–5, § 204(a)(3), (6), redesignated subsec. (g) as (f) and substituted ''$138,300,000 for each of fiscal years 2014 through 2018'' for ''such sums as may be necessary in each of fiscal years 2007 through 2011''. Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 113–5, § 204(a)(7), added subsec. (g). Former subsec. (g) redesignated (f).

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.

WORKING CAPITAL FUND

Pub. L. 113–76, div. H, title II, Jan. 17, 2014, 128 Stat. 368, provided in part: ''That to facilitate the implementation of the permanent Working Capital Fund ('WCF') authorized under this heading [CDC-WIDE ACTIVITIES AND PROGRAM SUPPORT] in division F of Public Law 112–74 [see note below], on or after enactment of this Act [Jan. 17, 2014], unobligated balances of amounts appropriated for business services for fiscal year 2013 shall be transferred to the WCF: *Provided further*, That on or after enactment of this Act, CDC shall transfer amounts available for business services to other CDC appropriations consistent with the benefit each appropriation received from the business services appropriation in fiscal year 2013: *Provided further*, That once the WCF is implemented in fiscal year 2014, assets purchased in any prior fiscal year with funds appropriated for or reimbursed to business services may be transferred to the WCF and customers billed for depreciation of those assets: *Provided further*, That CDC shall, consistent with the authorities provided in 42 U.S.C. 231, ensure that the WCF is used only for administrative support services and not for programmatic activities: *Provided further*, That CDC shall notify the Committees on Appropriations of the House of Representatives and the Senate not later than 15 days prior to any transfers made with funds provided under this heading.''

Similar provisions were contained in the following prior appropriation act:

Pub. L. 113–6, div. F, title V, § 1507, Mar. 26, 2013, 127 Stat. 423.

Pub. L. 112–74, div. F, title II, Dec. 23, 2011, 125 Stat. 1070, provided in part: ''That CDC [Centers for Disease Control and Prevention] may establish a Working Capital Fund, with the authorities equivalent to those provided in 42 U.S.C. 231, to improve the provision of supplies and service.''

§ 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), shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of research, investigations, experiments, demonstrations, and studies in the health sciences that are related to—

(1) the development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens;

(2) the development or testing of medical diagnostics to detect pathogens resistant to antimicrobials;

(3) the epidemiology, mechanisms, and pathogenesis of antimicrobial resistance;

(4) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy; and

(5) other relevant research areas.

(c) Education of medical and public health personnel

The Secretary, after consultation with the Assistant Secretary for Health, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, members of the task force described in subsection (a), professional organizations and societies, and such other public health officials as may be necessary, shall—

(1) develop and implement educational programs to increase the awareness of the general public with respect to the public health threat of antimicrobial resistance and the appropriate use of antibiotics;

(2) develop and implement educational programs to instruct health care professionals in the prudent use of antibiotics; and

(3) develop and implement programs to train laboratory personnel in the recognition or identification of resistance in pathogens.

(d) Grants

(1) In general

The Secretary shall award competitive grants to eligible entities to enable such entities to increase the capacity to detect, monitor, and combat antimicrobial resistance.

(2) Eligible entities

Eligible entities for grants under paragraph (1) shall be State or local public health agencies, Indian tribes or tribal organizations, or other public or private nonprofit entities.

(3) Use of funds

An eligible entity receiving a grant under paragraph (1) shall use funds from such grant for activities that are consistent with the factors identified by the task force under subsection (a)(3), which may include activities that—

(A) provide training to enable such entity to identify patterns of resistance rapidly and accurately;

(B) develop, improve, coordinate or enhance participation in information systems by which data on resistant infections can be shared rapidly among relevant national, State, and local health agencies and health care providers; and

(C) develop and implement policies to control the spread of antimicrobial resistance.

(e) Grants for demonstration programs

(1) In general

The Secretary shall award competitive grants to eligible entities to establish demonstration programs to promote judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens.

(2) Eligible entities

Eligible entities for grants under paragraph (1) may include hospitals, clinics, institutions of long-term care, professional medical societies, schools or programs that train medical laboratory personnel, or other public or private nonprofit entities.

(3) Technical assistance

The Secretary shall provide appropriate technical assistance to eligible entities that receive grants under paragraph (1).

(f) Monitoring at Federal health care facilities

The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

(g) Report on antimicrobial resistance in humans and use of antimicrobial drugs

Not later than 1 year after December 13, 2016, and annually thereafter, the Secretary shall pre-

pare and make publicly available data and information concerning—

(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 356(h) of title 21;

(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

(A) any applicable resistance under paragraph (1); and

(B) drugs approved under section 356(h) of title 21.

(h) Information related to antimicrobial stewardship programs

The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

(i) Supporting State-based activities to combat antimicrobial resistance

The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

(3) promoting antimicrobial stewardship.

(j) Antimicrobial resistance and stewardship activities

(1) In general

For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 356(h) of title 21, the Secretary shall—

(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

(B) evaluate—

(i) antimicrobial resistance data using a standardized approach; and

(ii) trends in the utilization of drugs approved under such section 356(h) of title 21 with respect to patient populations.

(2) Use of systems

The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

(k) Antimicrobial

For purposes of subsections (f) through (j), the term ''antimicrobial'' includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.

***(l)* 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.

(m) 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; Pub. L. 114–255, div. A, title III, § 3041(a), Dec. 13, 2016, 130 Stat. 1111.)

AMENDMENTS

2016—Subsecs. (f) to (m). Pub. L. 114–255 added subsecs. (f) to (k) and redesignated former subsecs. (f) and (g) as (*l*) and (m), respectively.

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''.

CONSTRUCTION OF 2016 AMENDMENT

Nothing in amendment by Pub. L. 114–255 to be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under section 356(h) of Title 21, Food and Drugs, by health care professionals, or to limit the practice of health care, see section 3043 of Pub. L. 114–255, set out as a note under section 356 of Title 21.

AVAILABILITY OF DATA

Pub. L. 114–255, div. A, title III, § 3041(b), Dec. 13, 2016, 130 Stat. 1112, provided that: ''The Secretary shall make the data collected pursuant to this subsection [probably refers to the amendments made to this section by section 3041(a) of Pub. L. 114–255] public. Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''

EX. ORD. NO. 13676. COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Ex. Ord. No. 13676, Sept. 18, 2014, 79 F.R. 56931, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

SECTION 1. *Policy*. The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the United States and around the world. The rise of antibiotic-resistant bacteria, however, represents a serious threat to public health and the economy. The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) estimates that annually at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone.

Detecting, preventing, and controlling antibiotic resistance requires a strategic, coordinated, and sustained effort. It also depends on the engagement of governments, academia, industry, healthcare providers, the general public, and the agricultural community, as well as international partners. Success in this effort will require significant efforts to: minimize the emergence of antibiotic-resistant bacteria; preserve the efficacy of new and existing antibacterial drugs; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance efforts in public health and agriculture; develop and promote the use of new, rapid diagnostic technologies; accelerate scientific research and facilitate the development of new antibacterial drugs, vaccines, diagnostics, and other novel therapeutics; maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public and healthcare providers; work with the pharmaceutical industry to include information on the proper use of over-the-counter and prescription antibiotic medications for humans and animals; and improve international collaboration and capabilities for prevention, surveillance, stewardship, basic research, and drug and diagnostics development.

The Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.

SEC. 2. *Oversight and Coordination*. Combating antibiotic-resistant bacteria is a national security priority. The National Security Council staff, in collaboration with the Office of Science and Technology Policy, the Domestic Policy Council, and the Office of Management and Budget, shall coordinate the development and implementation of Federal Government policies to combat antibiotic-resistant bacteria, including the activities, reports, and recommendations of the Task Force for Combating Antibiotic-Resistant Bacteria established in section 3 of this order.

SEC. 3. *Task Force for Combating Antibiotic-Resistant Bacteria*. There is hereby established the Task Force for Combating Antibiotic-Resistant Bacteria (Task Force), to be co-chaired by the Secretaries of Defense, Agriculture, and HHS.

(a) Membership. In addition to the Co-Chairs, the Task Force shall consist of representatives from:

(i) the Department of State;

(ii) the Department of Justice;

(iii) the Department of Veterans Affairs;

(iv) the Department of Homeland Security;

(v) the Environmental Protection Agency;

(vi) the United States Agency for International Development;

(vii) the Office of Management and Budget;

(viii) the Domestic Policy Council;

(ix) the National Security Council staff;

(x) the Office of Science and Technology Policy;

(xi) the National Science Foundation; and

(xii) such executive departments, agencies, or offices as the Co-Chairs may designate.

Each executive department, agency, or office represented on the Task Force (Task Force agency) shall designate an employee of the Federal Government to perform the functions of the Task Force. In performing its functions, the Task Force may make use of existing interagency task forces on antibiotic resistance.

(b) *Mission*. The Task Force shall identify actions that will provide for the facilitation and monitoring of implementation of this order and the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy).

(c) *Functions*.

(i) By February 15, 2015, the Task Force shall submit a 5-year National Action Plan (Action Plan) to the President that outlines specific actions to be taken to implement the Strategy. The Action Plan shall include goals, milestones, and metrics for measuring progress, as well as associated timelines for implementation. The Action Plan shall address recommendations made by the President's Council of Advisors on Science and Technology regarding combating antibiotic resistance.

(ii) Within 180 days of the release of the Action Plan and each year thereafter, the Task Force shall provide the President with an update on Federal Government actions to combat antibiotic resistance consistent with this order, including progress made in implementing the Strategy and Action Plan, plans for addressing any barriers preventing full implementation of the Strategy and Action Plan, and recommendations for new or modified actions. Annual updates shall include specific goals, milestones, and metrics for all proposed actions and recommendations. The Task Force shall take Federal Government resources into consideration when developing these proposed actions and recommendations.

(iii) In performing its functions, the Task Force shall review relevant statutes, regulations, policies, and programs, and shall consult with relevant domestic and international organizations and experts, as necessary.

(iv) The Task Force shall conduct an assessment of progress made towards achieving the milestones and goals outlined in the Strategy in conjunction with the Advisory Council established pursuant to section 4 of this order.

SEC. 4. *Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria*. (a) The Secretary of HHS (Secretary), in consultation with the Secretaries of Defense and Agriculture, shall establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council shall be composed of not more than 30 members to be appointed or designated by the Secretary.

(b) The Secretary shall designate a chairperson from among the members of the Advisory Council.

(c) The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to: preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance. The Secretary shall provide the President with all written reports created by the Advisory Council.

(d) Task Force agencies shall, to the extent permitted by law, provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

(e) To the extent permitted by law, and subject to the availability of appropriations, HHS shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions.

SEC. 5. *Improved Antibiotic Stewardship*. (a) By the end of calendar year 2016, HHS shall review existing regula-

tions and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs.

(b) Task Force agencies shall, as appropriate, define, promulgate, and implement stewardship programs in other healthcare settings, including office-based practices, outpatient settings, emergency departments, and institutional and long-term care facilities such as nursing homes, pharmacies, and correctional facilities.

(c) By the end of calendar year 2016, the Department of Defense (DoD) and the Department of Veterans Affairs (VA) shall review their existing regulations and, as appropriate, propose new regulations and other actions that require their hospitals and long-term care facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those defined by the CDC. DoD and the VA shall also take steps to encourage their other healthcare facilities, such as ambulatory surgery centers and outpatient clinics, to adopt antibiotic stewardship programs.

(d) Task Force agencies shall, as appropriate, monitor improvements in antibiotic use through the National Healthcare Safety Network and other systems.

(e) The Food and Drug Administration (FDA) in HHS, in coordination with the Department of Agriculture (USDA), shall continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.

(f) USDA, the Environmental Protection Agency (EPA), and FDA shall strengthen coordination in common program areas, such as surveillance of antibiotic use and resistance patterns in food-producing animals, inter-species disease transmissibility, and research findings.

(g) DoD, HHS, and the VA shall review existing regulations and propose new regulations and other actions, as appropriate, to standardize the collection and sharing of antibiotic resistance data across all their healthcare settings.

SEC. 6. *Strengthening National Surveillance Efforts for Resistant Bacteria.* (a) The Task Force shall ensure that the Action Plan includes procedures for creating and integrating surveillance systems and laboratory networks to provide timely, high-quality data across healthcare and agricultural settings, including detailed genomic and other information, adequate to track resistant bacteria across diverse settings. The network-integrated surveillance systems and laboratory networks shall include common information requirements, repositories for bacteria isolates and other samples, a curated genomic database, rules for access to samples and scientific data, standards for electronic health record-based reporting, data transparency, budget coordination, and international coordination.

(b) Task Force agencies shall, as appropriate, link data from Federal Government sample isolate repositories for bacteria strains to an integrated surveillance system, and, where feasible, the repositories shall enhance their sample collections and further interoperable data systems with national surveillance efforts.

(c) USDA, EPA, and FDA shall work together with stakeholders to monitor and report on changes in antibiotic use in agriculture and their impact on the environment.

(d) Task Force agencies shall, as appropriate, monitor antibiotic resistance in healthcare settings through the National Healthcare Safety Network and related systems.

SEC. 7. *Preventing and Responding to Infections and Outbreaks with Antibiotic-Resistant Organisms.* (a) Task Force agencies shall, as appropriate, utilize the enhanced surveillance activities described in section 6 of this order to prevent antibiotic-resistant infections by: actively identifying and responding to antibiotic-resistant outbreaks; preventing outbreaks and transmission of antibiotic-resistant infections in healthcare, community, and agricultural settings through early detection and tracking of resistant organisms; and identifying and evaluating additional strategies in the healthcare and community settings for the effective prevention and control of antibiotic-resistant infections.

(b) Task Force agencies shall take steps to implement the measures and achieve the milestones outlined in the Strategy and Action Plan.

(c) DoD, HHS, and the VA shall review and, as appropriate, update their hospital and long-term care infectious disease protocols for identifying, isolating, and treating antibiotic-resistant bacterial infection cases.

SEC. 8. *Promoting New and Next Generation Antibiotics and Diagnostics.* (a) As part of the Action Plan, the Task Force shall describe steps that agencies can take to encourage the development of new and next-generation antibacterial drugs, diagnostics, vaccines, and novel therapeutics for both the public and agricultural sectors, including steps to develop infrastructure for clinical trials and options for attracting greater private investment in the development of new antibiotics and rapid point-of-care diagnostics. Task Force agency efforts shall focus on addressing areas of unmet medical need for individuals, including those antibiotic-resistant bacteria CDC has identified as public and agricultural health threats.

(b) Together with the countermeasures it develops for biodefense threats, the Biomedical Advanced Research Development Authority in HHS shall develop new and next-generation countermeasures that target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

(c) The Public Health Emergency Medical Countermeasures Enterprise in HHS shall, as appropriate, coordinate with Task Force agencies' efforts to promote new and next-generation countermeasures to target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

SEC. 9. *International Cooperation.* Within 30 days of the date of this order, the Secretaries of State, USDA, and HHS shall designate representatives to engage in international action to combat antibiotic-resistant bacteria, including the development of the World Health Organization (WHO) Global Action Plan for Antimicrobial Resistance with the WHO, Member States, and other relevant organizations. The Secretaries of State, USDA, and HHS shall conduct a review of international collaboration activities and partnerships, and identify and pursue opportunities for enhanced prevention, surveillance, research and development, and policy engagement. All Task Force agencies with research and development activities related to antibiotic resistance shall, as appropriate, expand existing bilateral and multilateral scientific cooperation and research pursuant to the Action Plan.

SEC. 10. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (the ''Act''), may apply to the Advisory Council, any functions of the President under the Act, except for that of reporting to the Congress, shall be performed by the Secretary in accordance with the guidelines issued by the Administrator of General Services.

BARACK OBAMA.

EXTENSION OF TERM OF PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Term of Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria extended until Sept. 30, 2019, by Ex. Ord. No. 13811, Sept. 29, 2017, 82 F.R. 46363, set out as a note under section 14 of the Federal Advisory Committee Act in the Appendix to Title 5, Government Organization and Employees.

Previous extension of term of Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria was contained in the following prior Executive Order:

Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271, extended term until Sept. 30, 2017.

§ 247d–5a. Repealed. Pub. L. 114–255, div. A, title III, § 3044(b)(1), Dec. 13, 2016, 130 Stat. 1121

Section, Pub. L. 110–85, title XI, § 1111, Sept. 27, 2007, 121 Stat. 975, related to identification of clinically susceptible concentrations of antimicrobials. See section 360a–2 of Title 21, Food and Drugs.

§ 247d–6. Public health countermeasures to a bioterrorist attack

(a) All-hazards public health and medical response curricula and training

(1) In general

The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

(2) Curriculum

The public health and medical response training program may include course work related to—

(A) medical management of casualties, taking into account the needs of at-risk individuals;

(B) public health aspects of public health emergencies;

(C) mental health aspects of public health emergencies;

(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(3) Peer review

On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

(4) Credit

The Secretary and the Secretary of Defense shall—

(A) take into account continuing professional education requirements of public health and healthcare professions; and

(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

(5) Dissemination and training

(A) In general

The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

(B) Certain entities

The education and training activities described in subparagraph (A) may be carried out by Federal public health, medical, or dental entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(C) Grants and contracts

In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.

(b) Advice to the Federal Government

(1) Required advisory committees

In coordination with the working group under subsection (a), the Secretary shall establish advisory committees in accordance with paragraphs (2) and (3) to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b).

(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), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

(A) the epidemiology and pathogenesis of such pathogens;

(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

(C) the development of priority countermeasures; and

(D) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

(2) Priority

The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures.

(3) Role of Department of Veterans Affairs

In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

(4) Priority countermeasures

For purposes of this section, the term ''priority countermeasure'' means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 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; Pub. L. 113–5, title II, § 203(a), Mar. 13, 2013, 127 Stat. 175.)

AMENDMENTS

2013—Subsec. (a)(5)(B). Pub. L. 113–5 substituted ''public health, medical, or dental'' for ''public health or medical''.

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 section 319F(b)(2), 42 U.S.C. 247d–6(b)(2)];

''(B) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3) of such Act [probably means section 319F(b)(3), 42 U.S.C. 247d–6(b)(3)];

''(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 [42 U.S.C. 254b]) 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 counter-

measures 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)—

(i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

(ii) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph; or

(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

(B) Infectious disease

The term ''infectious disease'' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) Interagency cooperation

(A) In general

In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) Availability of facilities to the Secretary

In any grant, contract, or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, or supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant, contract, or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(5) Transfers of qualified countermeasures

Each agreement for an award of a grant, contract, or cooperative agreement under section 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 134 of title 41, as applicable pursuant to section 3101(b)(1)(A) of title 41, shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 3305(a)(1) of title 41 and its implementing regulations; and

(ii) section 3101(b)(1)(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) Section 8703(a) of title 41.

(iii) Section 4706 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) Section 3901 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 3304(a)(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 3304(a)(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 3304(a)(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 (a), (d), and (e) of section 1902 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), 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; Pub. L. 113–5, title IV, § 402(g)(1), Mar. 13, 2013, 127 Stat. 195.)

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.

CODIFICATION

In subsec. (b)(1)(A), ''section 134 of title 41'' substituted for ''section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))'' and ''section 3101(b)(1)(A) of title 41'' substituted for ''section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(i), ''section 3305(a)(1) of title 41'' substituted for ''section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(ii), ''section 3101(b)(1)(B) of title 41'' substituted for ''section 302A(b) of such Act (41 U.S.C. 252a(b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(ii), ''Section 8703(a) of title 41'' substituted for ''Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(iii), ''Section 4706 of title 41'' substituted for ''Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(v), ''Section 3901 of title 41'' substituted for ''Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(A), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' and ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(C), ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(3)(A), ''subsections (a), (d), and (e) of section 1902 of title 41'' substituted for ''subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2013—Subsec. (a)(2)(A). Pub. L. 113–5 struck out ''to'' before dash at end of introductory provisions, inserted ''to'' before ''diagnose'' in cls. (i) and (ii), and added cl. (iii).

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, as amended by Pub. L. 113–5, § 402(e)(1), Mar. 13, 2013, 127 Stat. 195, 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 12-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 activi-

ties, 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.''

[Pub. L. 113–5, title IV, §402(e)(2), Mar. 13, 2013, 127 Stat. 195, provided that: ''This subsection [amending section 405 of Pub. L. 109–417, set out above] shall take effect as if enacted on December 17, 2012.'']

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 consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.

(2) Procedures

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

(A) consult with the working group under section 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 and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and

(H) ensure the adequate physical security of the stockpile.

(3) Utilization guidelines

The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 247d–6a of this title), qualified pandemic and epidemic products (as defined in section 247d–6d of this title), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.

(b) Smallpox vaccine development

(1) In general

The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) Rule of construction

Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) Additional authority regarding procurement of certain countermeasures; availability of special reserve fund

(1) In general

(A) Use of fund

A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) Security countermeasure

For purposes of this subsection, the term ''security countermeasure'' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 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 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [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 appropriate committees of Congress that a determination has been made pursuant to subparagraph (A) or (B).

(D) Assuring access to threat information

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 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, and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable.

(B) Countermeasure specifications

The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) Presidential approval

If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund

(A) In general

The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a ''procurement under this subsection'').

(B) Requirements

In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendations for procurement

(A) Notice to appropriate congressional committees

The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection.

(B) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(7) Procurement

(A) Payments from special reserve fund

The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.

(B) Procurement

(i) In general

The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) Contract terms

A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) Payment conditioned on delivery

The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) Discounted payment

The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) Contract duration

The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) Storage by vendor

The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable

export-related controls with respect to such countermeasure.

(VII) Sales exclusivity

The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 3304(a)(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—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) Availability of simplified acquisition procedures

(I) In general

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 134 of title 41, for purposes of application to such procurement, pursuant to section 3101(b)(1)(A) of title 41, of—

(aa) section 3305(a)(1) of title 41 and its implementing regulations; and

(bb) section 3101(b)(1)(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) Section 8703(a) of title 41.

(cc) Section 4706 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) Section 3901 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 3304(a)(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 3304(a)(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 3304(a)(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 3306(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.

(viii) Flexibility

In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) Disclosures

No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) Definition

For purposes of subsection (a), the term ''stockpile'' includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) Authorization of appropriations

(1) Strategic National Stockpile

For the purpose of carrying out subsection (a), there are authorized to be appropriated $533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) Smallpox vaccine development

For the purpose of carrying out subsection (b), there are authorized to be appropriated

$509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) Special reserve fund

(1) Authorization of appropriations

In addition to amounts appropriated to the special reserve fund prior to March 13, 2013, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

(2) Use of special reserve fund for advanced research and development

The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 247d–7e of this title (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 247d–7e of this title are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) Restrictions on use of funds

Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 247d–7e of this title) or for procurement of a security countermeasure under subsection (c)(7).

(4) Report on security countermeasure procurement

Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title).

(5) Clarification on contracting authority

The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 247d–7e of this title.

(h) Definitions

In this section:

(1) The term ''advanced research and development'' has the meaning given such term in section 247d–7e(a) of this title.

(2) The term ''special reserve fund'' means the ''Biodefense Countermeasures'' appropriations account, any appropriation made available pursuant to section 321j(a) of title 6, and any appropriation made available pursuant to subsection (g)(1).

(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; Pub. L. 113–5, title IV, §§401, 403, Mar. 13, 2013, 127 Stat. 192, 196; Pub. L. 114–255, div. A, title III, §§3081, 3082(a), 3085, Dec. 13, 2016, 130 Stat. 1140, 1144.)

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)(B)(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.

CODIFICATION

In subsec. (c)(7)(B)(ii)(VII), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I), ''section 134 of title 41'' substituted for ''section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))'' and ''section 3101(b)(1)(A) of title 41'' substituted for ''section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(aa), ''section 3305(a)(1) of title 41'' substituted for ''section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(bb), ''section 3101(b)(1)(B) of title 41'' substituted for ''section 302A(b) of such Act (41 U.S.C. 252a(b))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(bb), ''Section 8703(a) of title 41'' substituted for ''Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(cc), ''Section 4706 of title 41'' substituted for ''Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011,

124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(ee), ''Section 3901 of title 41'' substituted for ''Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(I), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' and ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(III), ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(vii), ''section 3306(a)(1)(B) of title 41'' substituted for ''section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was formerly classified to section 300hh–12 of this title prior to renumbering by Pub. L. 108–276.

AMENDMENTS

2016—Subsec. (a)(3). Pub. L. 114–255, §3081(1), added par. (3).

Subsec. (c)(4)(A)(ii). Pub. L. 114–255, §3085(1), substituted ''and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable'' for ''make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure''.

Subsec. (c)(6). Pub. L. 114–255, §3085(2)(D), substituted ''Recommendations for procurement'' for ''Recommendation for President's approval'' in heading.

Subsec. (c)(6)(A). Pub. L. 114–255, §3085(2)(C), amended subpar. (A) generally. Prior to amendment, text read as follows: ''The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.''

Pub. L. 114–255, §3085(2)(A), (B), redesignated subpar. (C) as (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: ''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 as defined in subsection (h) be made available for the procurement of such countermeasure.''

Subsec. (c)(6)(B). Pub. L. 114–255, §3085(2)(A), (B), redesignated subpar. (D) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: ''The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.''

Subsec. (c)(6)(C), (D). Pub. L. 114–255, §3085(2)(B), redesignated subpars. (C) and (D) as (A) and (B), respectively.

Subsec. (c)(6)(E). Pub. L. 114–255, §3085(2)(A), struck out subpar. (E). Text read as follows: ''Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.''

Subsec. (c)(7)(A). Pub. L. 114–255, §3085(3)(A), added subpar. (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: ''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).''

Subsec. (c)(7)(B), (C). Pub. L. 114–255, §3085(3), redesignated subpar. (C) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: ''The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement.''

Subsec. (g)(4). Pub. L. 114–255, §3081(2), amended par. (4) generally. Prior to amendment, text read as follows: ''Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

''(A) in meeting the security countermeasure needs identified under this section; and

''(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title).''

Subsec. (g)(5). Pub. L. 114–255, §3082(a), added par. (5).

2013—Subsec. (a)(1). Pub. L. 113–5, §403(1)(A), inserted ''consistent with section 300hh–10 of this title'' after ''amounts as are determined'' and ''and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security'' after ''based on such review''.

Subsec. (a)(2)(D). Pub. L. 113–5, §403(1)(B), inserted ''and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment'' before semicolon at end.

Subsec. (c). Pub. L. 113–5, §401(b)(1)(A), substituted ''special reserve fund as defined in subsection (h)'' for ''special reserve fund under paragraph (10)'' wherever appearing.

Subsec. (c)(1)(B)(i)(III)(bb). Pub. L. 113–5, §401(a)(1), substituted ''10 years'' for ''eight years''.

Subsec. (c)(2)(C). Pub. L. 113–5, §401(a)(2), substituted ''the appropriate committees of Congress'' for ''the designated congressional committees (as defined in paragraph (10))''.

Subsec. (c)(5)(B)(ii). Pub. L. 113–5, §401(a)(3), substituted ''10 years'' for ''eight years''.

Subsec. (c)(6)(C). Pub. L. 113–5, §401(a)(4), substituted ''appropriate congressional committees'' for ''designated congressional committees'' in heading and in text.

Subsec. (c)(7)(C)(i)(I). Pub. L. 113–5, §401(a)(5)(A), inserted ''including advanced research and development,'' after ''as may reasonably be required,''.

Subsec. (c)(7)(C)(ii)(III). Pub. L. 113–5, §401(a)(5)(B)(i), substituted ''10 years'' for ''eight years''.

Subsec. (c)(7)(C)(ii)(IX). Pub. L. 113–5, §401(a)(5)(B)(ii), added subcl. (IX) and struck out former subcl. (IX). Prior to amendment, text read as follows: ''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.''

Subsec. (c)(7)(C)(viii). Pub. L. 113–5, § 401(a)(5)(C), added cl. (viii).

Subsec. (c)(9), (10). Pub. L. 113–5, § 401(b)(1)(B), struck out pars. (9) and (10) which described restrictions on the use of funds and defined ''special reserve fund'' and ''designated congressional committees''.

Subsec. (f)(1). Pub. L. 113–5, § 403(2), substituted ''$533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).'' for ''$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.''

Subsecs. (g), (h). Pub. L. 113–5, § 401(b)(2), added subsecs. (g) and (h).

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].''

FIRST RESPONDER ANTHRAX PREPAREDNESS

Pub. L. 114–268, Dec. 14, 2016, 130 Stat. 1387, provided that:

''SECTION 1. SHORT TITLE.

''This Act may be cited as the 'First Responder Anthrax Preparedness Act'.

''SEC. 2. VOLUNTARY PRE-EVENT ANTHRAX VACCINATION PILOT PROGRAM FOR EMERGENCY RESPONSE PROVIDERS.

''(a) PILOT PROGRAM.—

''(1) ESTABLISHMENT.—The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall carry out a pilot program to provide eligible anthrax vaccines from the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) that will be nearing the end of their labeled dates of use at the time such vaccines are made available to States for administration to emergency response providers who would be at high risk of exposure to anthrax if such an attack should occur and who voluntarily consent to such administration.

''(2) DETERMINATION.—The Secretary of Health and Human Services shall determine whether an anthrax vaccine is eligible to be provided to the Secretary of Homeland Security for the pilot program described in paragraph (1) based on—

''(A) a determination that the vaccine is not otherwise allotted for other purposes;

''(B) a determination that the provision of the vaccine will not reduce, or otherwise adversely affect, the capability to meet projected requirements for this product during a public health emergency, including a significant reduction of available quantities of vaccine in the Strategic National Stockpile; and

''(C) such other considerations as determined appropriate by the Secretary of Health and Human Services.

''(3) PRELIMINARY REQUIREMENTS.—Before implementing the pilot program required under this subsection, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall—

''(A) establish a communication platform for the pilot program;

''(B) develop and deliver education and training for the pilot program;

''(C) conduct economic analysis of the pilot program, including a preliminary estimate of total costs and expected benefits;

''(D) create a logistical platform for the anthrax vaccine request process under the pilot program;

''(E) establish goals and desired outcomes for the pilot program; and

''(F) establish a mechanism to reimburse the Secretary of Health and Human Services for—

''(i) the costs of shipment and transportation of such vaccines provided to the Secretary of Homeland Security from the Strategic National Stockpile under such pilot program, including staff time directly supporting such shipment and transportation; and

''(ii) the amount, if any, by which the warehousing costs of the Strategic National Stockpile are increased in order to operate such pilot program.

''(4) LOCATION.—

''(A) IN GENERAL.—In carrying out the pilot program required under this subsection, the Secretary of Homeland Security shall select not fewer than 2 nor more than 5 States for voluntary participation in the pilot program.

''(B) REQUIREMENT.—Each State that participates in the pilot program under this subsection shall ensure that such participation is consistent with the All-Hazards Public Health Emergency Preparedness and Response Plan of the State developed under section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a).

''(5) GUIDANCE FOR SELECTION.—To ensure that participation in the pilot program under this subsection strategically increases State and local response readiness in the event of an anthrax release, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall provide guidance to participating States and units of local government on identifying emergency response providers who are at high risk of exposure to anthrax.

''(6) DISTRIBUTION OF INFORMATION.—The Secretary of Homeland Security shall require that each State that participates in the pilot program under this subsection submit a written certification to the Secretary of Homeland Security stating that each emergency response provider within the State that participates in the pilot program is provided with disclosures and educational materials designated by the Secretary of Health and Human Services, which may include—

''(A) materials regarding the associated benefits and risks of any vaccine provided under the pilot program, and of exposure to anthrax;

''(B) additional material consistent with the Centers for Disease Control and Prevention's clinical guidance; and

''(C) notice that the Federal Government is not obligated to continue providing anthrax vaccine after the date on which the pilot program ends.

''(7) MEMORANDUM OF UNDERSTANDING.—Before implementing the pilot program under this subsection, the Secretary of Homeland Security shall enter into a memorandum of understanding with the Secretary of Health and Human Services to—

''(A) define the roles and responsibilities of each Department for the pilot program; and

''(B) establish other performance metrics and policies for the pilot program, as appropriate.

''(8) REPORT.—

''(A) IN GENERAL.—Notwithstanding subsection (c), not later than 1 year after the date on which the initial vaccines are administered under this section, and annually thereafter until 1 year after the completion of the pilot program under this section, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall submit to the Committee on Homeland Security and the Committee on Energy and Commerce of the House of Representatives and the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the progress and results of the pilot program, including—

''(i) a detailed tabulation of the costs to administer the program, including—

''(I) total costs for management and administration;

''(II) total costs to ship vaccines;

''(III) total number of full-time equivalents allocated to the program; and

''(IV) total costs to the Strategic National Stockpile;

''(ii) the number and percentage of eligible emergency response providers, as determined by each pilot location, that volunteer to participate;

''(iii) the degree to which participants complete the vaccine regimen;

''(iv) the total number of doses of vaccine administered; and

''(v) recommendations to improve initial and recurrent participation in the pilot program.

''(B) FINAL REPORT.—The final report required under subparagraph (A) shall—

''(i) consider whether the pilot program required under this subsection should continue after the date described in subsection (c); and

''(ii) include—

''(I) an analysis of the costs and benefits of continuing the program to provide anthrax vaccines to emergency response providers;

''(II) an explanation of the economic, health, and other risks and benefits of administering vaccines through the pilot program rather than post-event treatment; and

''(III) in the case of a recommendation under clause (i) to continue the pilot program after the date described in subsection (c), a plan under which the pilot program could be continued.

''(b) DEADLINE FOR IMPLEMENTATION.—Not later than 1 year after the date of enactment of this Act [Dec. 14, 2016], the Secretary of Homeland Security shall begin implementing the pilot program under this section.

''(c) SUNSET.—The authority to carry out the pilot program under this section shall expire on the date that is 5 years after the date of enactment of this Act [Dec. 14, 2016].''

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, 42 U.S.C. 247d–6b], 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. Repealed. Pub. L. 113–5, title II, § 205, Mar. 13, 2013, 127 Stat. 179

Section, Pub. L. 108–276, § 5, July 21, 2004, 118 Stat. 860, related to reports regarding authorities under the Project BioShield Act of 2004.

§ 247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term ''loss'' means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) Rebuttable presumption

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) Declaration by Secretary

(1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) Effective period of declaration

(A) Flexibility of period

The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) Additional time to be specified

In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) Additional period for certain strategic national stockpile countermeasures

With respect to a covered countermeasure that is in the stockpile under section 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) 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), 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 sub-

mit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term ''willful misconduct'' shall, for purposes of subsection (d), denote an act or omission that is taken—

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(B) Rule of construction

The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) Authority to promulgate regulatory definition

(A) In general

The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as ''willful misconduct'' for purposes of subsection (d).

(B) Factors to be considered

In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) Temporal scope of regulations

The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) Initial rulemaking

Within 180 days after 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), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) Defense for acts or omissions taken pursuant to Secretary's declaration

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in ''willful misconduct'' as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) Exclusion for regulated activity of manufacturer or distributor

(A) In general

If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this 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) if—

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) Definitions

For purposes of this paragraph, the following terms have the following meanings:

(i) Enforcement action

The term ''enforcement action'' means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [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.

[1] So in original. Probably should be chapter ''V''.

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity

In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement

(i) In general

The complaint shall include a verification, made by affidavit of the plaintiff

under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief

Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required

In an action under subsection (d), the plaintiff shall file with the complaint—

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court

Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28 and paragraph (3) of subsection (b) of section 2284 of title 28 shall not apply to actions under subsection (d).

(6) Civil discovery

(A) Timing

In an action under subsection (d), no discovery shall be allowed—

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard

Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits

(A) In general

In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation

No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined

For purposes of this paragraph, the term ''collateral source benefit'' means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term ''noneconomic damages'' means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d),

the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28 (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, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b].

(2) Covered person

The term ''covered person'', when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor

The term ''distributor'' means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer

The term ''manufacturer'' includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person

The term ''person'' includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) Program planner

The term ''program planner'' means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) Qualified pandemic or epidemic product

The term ''qualified pandemic or epidemic product'' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),[2]

[2] So in original. A third closing parenthesis probably should appear.

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;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [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, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b].

(8) Qualified person

The term ''qualified person'', when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) Security countermeasure

The term ''security countermeasure'' has the meaning given such term in section 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; amended Pub. L. 113–5, title IV, § 402(g)(2), (3), Mar. 13, 2013, 127 Stat. 196.)

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.

AMENDMENTS

2013—Subsec. (i)(1)(C). Pub. L. 113–5, § 402(g)(3)(A), inserted '', 564A, or 564B'' after ''564''.

Subsec. (i)(7)(A)(iii). Pub. L. 113–5, § 402(g)(2), added cl. (iii).

Subsec. (i)(7)(B)(iii). Pub. L. 113–5, § 402(g)(3)(B), inserted '', 564A, or 564B'' after ''564''.

§ 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), 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 de-

termination 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), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 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).

(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) 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) 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), 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) are States, political subdivisions of States, and public or private non-profit organizations.

(c) Specific criteria

In making grants under subsection (a), the Secretary shall take into account the following factors:

(1) Whether the eligible entity involved is proximate to, and collaborates with, a major research university with expertise in scientific training, identification of biological agents, medicine, and life sciences.

(2) Whether the entity is proximate to, and collaborates with, a laboratory that has expertise in the identification of biological agents.

(3) Whether the entity demonstrates, in the application for the program, support and participation of State and local governments and research institutions in the conduct of the program.

(4) Whether the entity is proximate to, and collaborates with, or is, an academic medical center that has the capacity to serve an uninsured or underserved population, and is equipped to educate medical personnel.

(5) Such other factors as the Secretary determines to be appropriate.

(d) Duration of award

The period during which payments are made under a grant under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.

(e) Supplement not supplant

Grants under subsection (a) shall be used to supplement, and not supplant, other Federal, State, or local public funds provided for the activities described in such subsection.

(f) Government Accountability Office report

Not later than 180 days after the conclusion of the demonstration programs carried out under subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Commerce and the Committee on Appropriations of the House of Representatives, a report that describes the ability of grantees under such subsection to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel involved with the various responsibilities and capabilities needed to deal with bioterrorist threats.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section $6,000,000 for fiscal year 2001, and such sums as may be necessary through fiscal year 2006.

(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) 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).

(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 $5,000,000 for each of fiscal years 2014 through 2018.

(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; Pub. L. 113–5, title II, § 203(b)(1), Mar. 13, 2013, 127 Stat. 175.)

AMENDMENTS

2013—Subsec. (k). Pub. L. 113–5 substituted ''$5,000,000 for each of fiscal years 2014 through 2018'' for ''$2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011''.

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), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(b) Corresponding reduction in payments

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

(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) 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 improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

The term ''security countermeasure'' has the meaning given such term in section 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, including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section.

(4) Duties

(A) Collaboration

To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

(B) Support advanced research and development

To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of this title) 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, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies.

(E) Medical countermeasures innovation partner

(i) In general

To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

(ii) Eligibility

(I) In general

To be eligible to enter into an agreement under clause (i) an entity shall—

(aa) be an independent, nonprofit entity;

(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

(cc) have experience in promoting novel technology innovation;

(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

(gg) not be within the Department of Health and Human Services.

(II) Partnering experience

In selecting an entity with which to enter into an agreement under clause (i),

the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

(iii) Not agency

An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5.

(iv) Direction

Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

(II) develop a description of work to be performed by the entity under the agreement;

(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

(V) ensure, as a condition of the agreement that the entity—

(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

(cc) provides monthly accounting on the use of funds provided under such agreement; and

(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

(v) Supplement not supplant

Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

(vi) No establishment of entity

To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

(vii) Transparency and oversight

Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

(viii) Independent evaluation

Not later than 4 years after December 13, 2016, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

(ix) Sunset

This subparagraph shall have no force or effect after September 30, 2022.

(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[1] 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 1702(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 authori-

[1] See References in Text note below.

ties, 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 6101 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 3304(a)(3) of title 41.

(G) Government purpose

In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(6) At-risk individuals

In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

(7) Personnel authorities

(A) Specially qualified scientific and professional personnel

(i) In general

In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5 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 is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2014 through 2018, such amounts to remain available until expended.

(e) Inapplicability of certain provisions

(1) Disclosure

(A) In general

The Secretary shall withhold from disclosure under section 552 of title 5 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 12 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.

(f) Independent evaluation

(1) In general

Not later than 180 days after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) Report

Not later than 1 year after March 13, 2013, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives; and

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents.

(July 1, 1944, ch. 373, title III, § 319L, as added Pub. L. 109–417, title IV, § 401, Dec. 19, 2006, 120 Stat. 2865; amended Pub. L. 113–5, title IV, § 402(a)–(d), (f), Mar. 13, 2013, 127 Stat. 194, 195; Pub. L. 114–255, div. A, title III, §§ 3082(b), 3084, Dec. 13, 2016, 130 Stat. 1141.)

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)(B)(iii), (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 was formerly set out as a note under section 2371 of Title 10, Armed Forces, prior to repeal by Pub. L. 114–92, div. A, title VIII, § 815(c), Nov. 25, 2015, 129 Stat. 896. See section 2371b of Title 10.

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.

CODIFICATION

In subsec. (c)(5)(A)(ii)(II), ''section 1702(c) of title 41'' substituted for ''section 16(c) of the Office of Federal

Procurement Policy Act (41 U.S.C. 414(c))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(C), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(F), ''section 3304(a)(3) of title 41'' substituted for ''section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

Subsec. (c)(3). Pub. L. 114–255, § 3082(b), inserted '', including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section'' before period at end.

Subsec. (c)(4)(E). Pub. L. 114–255, § 3084, added subpar. (E).

2013—Subsec. (c)(4)(B)(iii). Pub. L. 113–5, § 402(a)(1), inserted ''(which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 262 of this title)'' after ''research and development''.

Subsec. (c)(4)(D)(iii). Pub. L. 113–5, § 402(a)(2), substituted ''vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies'' for ''and vaccine manufacturing technologies''.

Subsec. (c)(5)(G). Pub. L. 113–5, § 402(b), added subpar. (G).

Subsec. (d)(2). Pub. L. 113–5, § 402(c), amended par. (2) generally. Prior to amendment, text read as follows: ''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.''

Subsec. (e)(1)(C). Pub. L. 113–5, § 402(d), substituted ''12 years'' for ''7 years''.

Subsec. (f). Pub. L. 113–5, § 402(f), added subsec. (f).

§ 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;

(ii) one such member shall be an individual from an organization representing healthcare consumers;

(iii) one such member shall be an individual with pediatric subject matter expertise; and

(iv) one such member shall be a State, tribal, territorial, or local public health official.

Nothing in this paragraph shall preclude a member of the Board from satisfying two or more of the requirements described in subparagraph (D).

(3) Term of appointment

A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) Duties

The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b);

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities; and

(D) provide any recommendation, finding, or report provided to the Secretary under this paragraph to the appropriate committees of Congress.

(6) Meetings

(A) Initial meeting

Not later than one year after 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; amended Pub. L. 113–5, title IV, § 404, Mar. 13, 2013, 127 Stat. 197.)

AMENDMENTS

2013—Subsec. (a)(2). Pub. L. 113–5, § 404(1)(B), inserted concluding provisions.

Subsec. (a)(2)(D)(iii), (iv). Pub. L. 113–5, § 404(1)(A), added cls. (iii) and (iv).

Subsec. (a)(5)(D). Pub. L. 113–5, § 404(2), added subpar. (D).

§ 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-Determination and Education Assistance Act [25 U.S.C. 5301 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.

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

(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, which is classified principally to chapter 46 (§ 5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 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.

§ 247d–9. Dental education for parents of newborns

The Secretary shall develop and implement, through entities that fund or provide perinatal care services to targeted low-income children under a State child health plan under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], a program to deliver oral health educational materials that inform new parents about risks for, and prevention of, early childhood caries and the need for a dental visit within their newborn's first year of life.

(Pub. L. 111–3, title V, § 501(c), Feb. 4, 2009, 123 Stat. 87.)

REFERENCES IN TEXT

The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XXI of the Act is classified generally to subchapter XXI (§ 1397aa 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.

CODIFICATION

Section was enacted as part of the Children's Health Insurance Program Reauthorization Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective Apr. 1, 2009, and applicable to child health assistance and medical assistance provided on or after that date, with certain exceptions, see section 3 of Pub. L. 111–3, set out as a note under section 1396 of this title.

DEFINITION OF ''SECRETARY''

''Secretary'' as meaning the Secretary of Health and Human Services, see section 1(c)(3) of Pub. L. 111–3, set out as a note under section 1396 of this title.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

CODIFICATION

Pub. L. 95–626, title I, § 113(a)(1), Nov. 10, 1978, 92 Stat. 3562, struck out heading ''Subpart I—General Provisions''.

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), 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) 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). 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.

AMENDMENTS

2002—Subsec. (a)(1). Pub. L. 107–220 substituted ''National Hansen's Disease Programs Center'' for ''Gillis W. Long Hansen's Disease Center''.

1997—Pub. L. 105–78 amended section catchline and text generally, substituting present provisions for former provisions which related to: in subsec. (a), care and treatment; and in subsec. (b), payments to Board of Health of Hawaii.

1985—Pub. L. 99–117 substituted ''Hansen's disease program'' for ''Receipt, apprehension, detention, treatment, and release of lepers'' in section catchline.

Subsec. (a). Pub. L. 99–117 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: ''The Service shall, in accordance with regulations, receive into any hospital of the Service suitable for his accommodation any person afflicted with leprosy who presents himself for care, detention, or treatment, or who may be apprehended under subsection (b) of this section or section 264 of this title, and any person afflicted with leprosy duly consigned to the care of the Service by the proper health authority of any State. The Surgeon General is authorized, upon the request of any health authority, to send for any person within the jurisdiction of such authority who is afflicted with leprosy and to convey such person to the appropriate hospital for detention and treatment. When the transportation of any such person is undertaken for the protection of the public health the expense of such removal shall be met from funds available for the maintenance of hospitals of the Service. Such funds shall also be available, subject to regulations, for transportation of recovered indigent leper patients to their homes, including subsistence allowance while traveling. When so provided in appropriations available for any fiscal year for the maintenance of hospitals of the Service, the Surgeon General is authorized and directed to make payments to the Board of Health of Hawaii for the care and treatment in its facilities of persons afflicted with leprosy at a per diem rate, determined from time to time by the Surgeon General, which shall, subject to the availability of appropriations, be approximately equal to the per diem operating cost per patient of such facilities, except that such per diem rate shall not be greater than the comparable per diem operating cost per patient at the National Leprosarium, Carville, Louisiana.''

Subsec. (b). Pub. L. 99–117 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''The Surgeon General may provide by regulation for the apprehension, detention, treatment, and release of persons being treated by the Service for leprosy.''

1979—Subsec. (a). Pub. L. 96–32 substituted ''apprehended under subsection (b) of this section or section 264 of this title'' for ''apprehended under section 256 or 264 of this title''.

1978—Pub. L. 95–626 designated existing provisions as subsec. (a) and added subsec. (b).

1960—Pub. L. 86–624 struck out '', Territory, or the District of Columbia'' after ''proper health authority of any State'', and substituted ''Board of Health of Hawaii'' for ''Board of Health of the Territory of Hawaii''.

1952—Act June 25, 1952, provided for payments to Hawaiian Board of Health for expenditures made by them in care and treatment of patients.

1948—Act June 25, 1948, authorized payment of travel expenses of indigent leper patients.

CHANGE OF NAME

Pub. L. 107–220, §§ 1(b), 2, Aug. 21, 2002, 116 Stat. 1332, provided that:

''(b) PUBLIC LAW 105–78.—References in section 211 of Public Law 105–78 [amending this section and enacting provisions set out as a note under this section], and in deeds, agreements, or other documents under such section, to the Gillis W. Long Hansen's Disease Center shall be deemed to be references to the National Hansen's Disease Programs Center.

''SEC. 2. OTHER REFERENCES.

''Any reference in a law, map, regulation, document, paper, or other record of the United States to the Gillis W. Long Hansen's Disease Center shall be deemed to be a reference to the 'National Hansen's Disease Programs Center' ''.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

RELOCATION OF NATIONAL HANSEN'S DISEASE PROGRAMS CENTER

Pub. L. 105–78, title II, § 211(a)–(g), Nov. 13, 1997, 111 Stat. 1489, as amended by Pub. L. 107–220, § 1(b), Aug. 21, 2002, 116 Stat. 1332, provided that:

''(a) The Secretary of Health and Human Services may in accordance with this section provide for the relocation of the Federal facility known as the National Hansen's Disease Programs Center (located in the vicinity of Carville, in the State of Louisiana), including the relocation of the patients of the Center.

''(b)(1) Subject to paragraph (2), in relocating the Center the Secretary may on behalf of the United States transfer to the State of Louisiana, without charge, title to the real property and improvements that as of the date of the enactment of this Act [Nov. 13, 1997] constitute the Center. Such real property is a parcel consisting of approximately 330 acres. The exact acreage and legal description used for purposes of the transfer shall be in accordance with a survey satisfactory to the Secretary.

''(2) Any conveyance under paragraph (1) is not effective unless the deed or other instrument of conveyance contains the conditions specified in subsection (d); the instrument specifies that the United States and the State of Louisiana agree to such conditions; and the instrument specifies that, if the State engages in a material breach of the conditions, title to the real property and improvements involved reverts to the United States at the election of the Secretary.

''(c)(1) With respect to Federal equipment and other items of Federal personal property that are in use at the Center as of the date of the enactment of this Act [Nov. 13, 1997], the Secretary may, subject to paragraph (2), transfer to the State such items as the Secretary determines to be appropriate, if the Secretary makes the transfer under subsection (b).

''(2) A transfer of equipment or other items may be made under paragraph (1) only if the State agrees that, during the 30-year period beginning on the date on which the transfer under subsection (b) is made, the items will be used exclusively for purposes that promote the health or education of the public, except that the Secretary may authorize such exceptions as the Secretary determines to be appropriate.

''(d) For purposes of subsection (b)(2), the conditions specified in this subsection with respect to a transfer of title are the following:

''(1) During the 30-year period beginning on the date on which the transfer is made, the real property and improvements referred to in subsection (b)(1) (referred to in this subsection as the 'transferred property') will be used exclusively for purposes that promote the health or education of the public, with such incidental exceptions as the Secretary may approve.

''(2) For purposes of monitoring the extent to which the transferred property is being used in accordance with paragraph (1), the Secretary will have access to such documents as the Secretary determines to be necessary, and the Secretary may require the advance approval of the Secretary for such contracts, conveyances of real or personal property, or other transactions as the Secretary determines to be necessary.

''(3) The relocation of patients from the transferred property will be completed not later than 3 years after the date on which the transfer is made, except to the extent the Secretary determines that relocating particular patients is not feasible. During the period of relocation, the Secretary will have unrestricted access to the transferred property, and after such period will have such access as may be necessary with respect to the patients who pursuant to the preceding sentence are not relocated.

''(4)(A) With respect to projects to make repairs and energy-related improvements at the transferred property, the Secretary will provide for the completion of all such projects for which contracts have been awarded and appropriations have been made as of the date on which the transfer is made.

''(B) If upon completion of the projects referred to in subparagraph (A) there are any unobligated balances of amounts appropriated for the projects, and the sum of such balances is in excess of $100,000—

''(i) the Secretary will transfer the amount of such excess to the State; and

''(ii) the State will expend such amount for the purposes referred to in paragraph (1), which may include the renovation of facilities at the transferred property.

''(5)(A) The State will maintain the cemetery located on the transferred property, will permit individuals who were long-term-care patients of the Center to be buried at the cemetery, and will permit members of the public to visit the cemetery.

''(B) The State will permit the Center to maintain a museum on the transferred property, and will permit members of the public to visit the museum.

''(C) In the case of any waste products stored at the transferred property as of the date of the transfer, the Federal Government will after the transfer retain title to and responsibility for the products, and the State will not require that the Federal Government remove the products from the transferred property.

''(6) In the case of each individual who as of the date of the enactment of this Act [Nov. 13, 1997] is a Federal employee at the transferred property with facilities management or dietary duties:

''(A) The State will offer the individual an employment position with the State, the position with the State will have duties similar to the duties the individual performed in his or her most recent position at the transferred property, and the position with the State will provide compensation and benefits that are similar to the compensation and benefits provided for such most recent position, subject to the concurrence of the Governor of the State.

''(B) If the individual becomes an employee of the State pursuant to subparagraph (A), the State will make payments in accordance with subsection (e)(2)(B) (relating to disability), as applicable with respect to the individual.

''(7) The Federal Government may, consistent with the intended uses by the State of the transferred property, carry out at such property activities regarding at-risk youth.

''(8) Such additional conditions as the Secretary determines to be necessary to protect the interests of the United States.

''(e)(1) This subsection applies if the transfer under subsection (b) is made.

''(2) In the case of each individual who as of the date of the enactment of this Act [Nov. 13, 1997] is a Federal employee at the Center with facilities management or dietary duties, and who becomes an employee of the State pursuant to subsection (d)(6)(A):

''(A) The provisions of subchapter III of chapter 83 of title 5, United States Code, or of chapter 84 of such title, whichever are applicable, that relate to disability shall be considered to remain in effect with respect to the individual (subject to subparagraph (C)) until the earlier of—

''(i) the expiration of the 2-year period beginning on the date on which the transfer under subsection (b) is made; or

''(ii) the date on which the individual first meets all conditions for coverage under a State program for payments during retirement by reason of disability.

''(B) The payments to be made by the State pursuant to subsection (d)(6)(B) with respect to the individual are payments to the Civil Service Retirement and Disability Fund, if the individual is receiving Federal disability coverage pursuant to subparagraph (A). Such payments are to be made in a total amount equal to that portion of the normal-cost percentage (determined through the use of dynamic assumptions) of the basic pay of the individual that is allocable to such coverage and is paid for service performed during the period for which such coverage is in effect. Such amount is to be determined in accordance with chapter 84 of such title 5, is to be paid at such time and in such manner as mutually agreed by the State and the Office of Personnel Management, and is in lieu of individual or agency contributions otherwise required.

''(C) In the determination pursuant to subparagraph (A) of whether the individual is eligible for Federal disability coverage (during the applicable period of time under such subparagraph), service as an employee of the State after the date of the transfer under subsection (b) shall be counted toward the service requirement specified in the first sentence of section 8337(a) or 8451(a)(1)(A) of such title 5 (whichever is applicable).

''(3) In the case of each individual who as of the date of the enactment of this Act is a Federal employee with a position at the Center and is, for duty at the Center, receiving the pay differential under section 208(e) of the Public Health Service Act [42 U.S.C. 210(e)] or under section 5545(d) of title 5, United States Code:

''(A) If as of the date of the transfer under subsection (b) the individual is eligible for an annuity under section 8336 or 8412 of title 5, United States Code, then once the individual separates from the service and thereby becomes entitled to receive the annuity, the pay differential shall be included in the computation of the annuity if the individual separated from the service not later than the expiration of the 90-day period beginning on the date of the transfer.

''(B) If the individual is not eligible for such an annuity as of the date of the transfer under subsection (b) but subsequently does become eligible, then once the individual separates from the service and thereby becomes entitled to receive the annuity, the pay differential shall be included in the computation of the annuity if the individual separated from the service not later than the expiration of the 90-day period beginning on the date on which the individual first became eligible for the annuity.

''(C) For purposes of this paragraph, the individual is eligible for the annuity if the individual meets all conditions under such section 8336 or 8412 to be entitled to the annuity, except the condition that the individual be separated from the service.

''(4) With respect to individuals who as of the date of the enactment of this Act are Federal employees with positions at the Center and are not, for duty at the cen-

ter, receiving the pay differential under section 208(e) of the Public Health Service Act [42 U.S.C. 210(e)] or under section 5545(d) of title 5, United States Code:

''(A) During the calendar years 1997 and 1998, the Secretary may in accordance with this paragraph provide to any such individual a voluntary separation incentive payment. The purpose of such payments is to avoid or minimize the need for involuntary separations under a reduction in force with respect to the Center.

''(B) During calendar year 1997, any payment under subparagraph (A) shall be made under section 663 of the Treasury, Postal Service, and General Government Appropriations Act, 1997 (as contained in section 101(f) of division A of Public Law 104–208) [5 U.S.C. 5597 note], except that, for purposes of this subparagraph, subsection (b) of such section 663 does not apply.

''(C) During calendar year 1998, such section 663 applies with respect to payments under subparagraph (A) to the same extent and in the same manner as such section applied with respect to the payments during fiscal year 1997, and for purposes of this subparagraph, the reference in subsection (c)(2)(D) of such section 663 to December 31, 1997, is deemed to be a reference to December 31, 1998.

''(f) The following provisions apply if under subsection (a) the Secretary makes the decision to relocate the Center:

''(1) The site to which the Center is relocated shall be in the vicinity of Baton Rouge, in the State of Louisiana.

''(2) The facility involved shall continue to be designated as the National Hansen's Disease Programs Center.

''(3) The Secretary shall make reasonable efforts to inform the patients of the Center with respect to the planning and carrying out of the relocation.

''(4) In the case of each individual who as of October 1, 1996, was a patient of the Center and is considered by the Director of the Center to be a long-term-care patient (referred to in this subsection as an 'eligible patient'), the Secretary shall continue to provide for the long-term care of the eligible patient, without charge, for the remainder of the life of the patient.

''(5)(A) For purposes of paragraph (4), an eligible patient who is legally competent has the following options with respect to support and maintenance and other nonmedical expenses:

''(i) For the remainder of his or her life, the patient may reside at the Center.

''(ii) For the remainder of his or her life, the patient may receive payments each year at an annual rate of $33,000 (adjusted in accordance with subparagraphs (C) and (D)), and may not reside at the Center. Payments under this clause are in complete discharge of the obligation of the Federal Government under paragraph (4) for support and maintenance and other nonmedical expenses of the patient.

''(B) The choice by an eligible patient of the option under clause (i) of subparagraph (A) may at any time be revoked by the patient, and the patient may instead choose the option under clause (ii) of such subparagraph. The choice by an eligible patient of the option under such clause (ii) is irrevocable.

''(C) Payments under subparagraph (A)(ii) shall be made on a monthly basis, and shall be pro rated as applicable. In 1999 and each subsequent year, the monthly amount of such payments shall be increased by a percentage equal to any percentage increase taking effect under section 215(i) of the Social Security Act [42 U.S.C. 415(i)] (relating to a cost-of-living increase) for benefits under title II of such Act [42 U.S.C. 401 et seq.] (relating to Federal old-age, survivors, and disability insurance benefits). Any such percentage increase in monthly payments under subparagraph (A)(ii) shall take effect in the same month as the percentage increase under such section 215(i) takes effect.

''(D) With respect to the provision of outpatient and inpatient medical care for Hansen's disease and related complications to an eligible patient:

''(i) The choice the patient makes under subparagraph (A) does not affect the responsibility of the Secretary for providing to the patient such care at or through the Center.

''(ii) If the patient chooses the option under subparagraph (A)(ii) and receives inpatient care at or through the Center, the Secretary may reduce the amount of payments under such subparagraph, except to the extent that reimbursement for the expenses of such care is available to the provider of the care through the program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or the program under title XIX of such Act [42 U.S.C. 1396 et seq.]. Any such reduction shall be made on the basis of the number of days for which the patient received the inpatient care.

''(6) The Secretary shall provide to each eligible patient such information and time as may be necessary for the patient to make an informed decision regarding the options under paragraph (5)(A).

''(7) After the date of the enactment of this Act [Nov. 13, 1997], the Center may not provide long-term care for any individual who as of such date was not receiving such care as a patient of the Center.

''(8) If upon completion of the projects referred to in subsection (d)(4)(A) there are unobligated balances of amounts appropriated for the projects, such balances are available to the Secretary for expenses relating to the relocation of the Center, except that, if the sum of such balances is in excess of $100,000, such excess is available to the State in accordance with subsection (d)(4)(B). The amounts available to the Secretary pursuant to the preceding sentence are available until expended.

''(g) For purposes of this section:

''(1) The term 'Center' means the National Hansen's Disease Programs Center.

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

''(3) The term 'State' means the State of Louisiana.''

§ 248. Control and management of hospitals; furnishing prosthetic and orthopedic devices; transfer of patients; disposal of articles produced by patients; disposal of money and effects of deceased patients; payment of burial expenses

The Surgeon General, pursuant to regulations, shall—

(a) Control, manage, and operate all institutions, hospitals, and stations of the Service, including minor repairs and maintenance, and provide for the care, treatment, and hospitalization of patients, including the furnishing of prosthetic and orthopedic devices; and from time to time, with the approval of the President, select suitable sites for and establish such additional institutions, hospitals, and stations in the States and possessions of the United States as in his judgment are necessary to enable the Service to discharge its functions and duties;

(b) Provide for the transfer of Public Health Service patients, in the care of attendants where necessary, between hospitals and stations operated by the Service or between such hospitals and stations and other hospitals and stations in which Public Health Service patients may be received, and the payment of expenses of such transfer;

(c) Provide for the disposal of articles produced by patients in the course of their curative treatment, either by allowing the patient to re-

tain such articles or by selling them and depositing the money received therefor to the credit of the appropriation from which the materials for making the articles were purchased;

(d) Provide for the disposal of money and effects, in the custody of the hospitals or stations, of deceased patients; and

(e) Provide, to the extent the Surgeon General determines that other public or private funds are not available therefor, for the payment of expenses of preparing and transporting the remains of, or the payment of reasonable burial expenses for, any patient dying in a hospital or station.

(July 1, 1944, ch. 373, title III, § 321, 58 Stat. 695; June 25, 1948, ch. 654, § 2, 62 Stat. 1017; Pub. L. 95–622, title II, § 266, Nov. 9, 1978, 92 Stat. 3437.)

AMENDMENTS

1978—Subsec. (a). Pub. L. 95–622 struck out '', and tobacco'' after ''orthopedic devices''.

1948—Subsec. (a). Act June 25, 1948, § 2(a), amended subsec. (a) generally, continuing authority of Service to furnish tobacco to patients being treated by it.

Subsec. (e). Act June 25, 1948, § 2(b), added subsec. (e).

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§ 248a. Closing or transfer of hospitals; reduction of services; Congressional authorization required

(a) Except as provided in subsection (b), the Secretary of Health and Human Services shall take such action as may be necessary to assure that the hospitals of the Public Health Service, located in Seattle, Washington, Boston, Massachusetts, San Francisco, California, Galveston, Texas, New Orleans, Louisiana, Baltimore, Maryland, Staten Island, New York, and Norfolk, Virginia, shall continue—

(1) in operation as hospitals of the Public Health Service,

(2) to provide for all categories of individuals entitled or authorized to receive care and treatment at hospitals or other stations of the Public Health Service inpatient, outpatient, and other health care services in like manner as such services were provided on January 1, 1973, to such categories of individuals at the hospitals of the Public Health Service referred to in the matter preceding paragraph (1) and at a level and range at least as great as the level and range of such services which were provided (or authorized to be provided) by such hospitals on such date, and

(3) to conduct at such hospitals a level and range of other health-related activities (including training and research activities) which is not less than the level and range of such activities which were being conducted on January 1, 1973, at such hospitals.

(b)(1) The Secretary may—

(A) close or transfer control of a hospital of the Public Health Service to which subsection (a) applies,

(B) reduce the level and range of health care services provided at such a hospital from the level and range required by subsection (a)(2) or change the manner in which such services are provided at such a hospital from the manner required by such subsection, or

(C) reduce the level and range of the other health-related activities conducted at such hospital from the level and range required by subsection (a)(3),

if Congress by law (enacted after November 16, 1973) specifically authorizes such action.

(2) Any recommendation submitted to the Congress for legislation to authorize an action described in paragraph (1) with respect to a hospital of the Public Health Service shall be accompanied by a copy of the written, unqualified approval of the proposed action submitted to the Secretary by each (A) section 314(a) State health planning agency whose section 314(a) plan covers (in whole or in part) the area in which such hospital is located or which is served by such hospital, and (B) section 314(b) areawide health planning agency whose section 314(b) plan covers (in whole or in part) such area.

(3) For purposes of this subsection, the term ''section 314(a) State health planning agency'' means the agency of a State which administers or supervises the administration of a State's health planning functions under a State plan approved under section 314(a) of the Public Health Service Act (referred to in paragraph (2) as a ''section 314(a) plan''); and the term ''section 314(b) areawide health planning agency'' means a public or nonprofit private agency or organization which has developed a comprehensive regional, metropolitan, or other local area plan or plans referred to in section 314(b) of that Act (referred to in paragraph (2) as a ''section 314(b) plan'').

(Pub. L. 93–155, title VIII, § 818(a), (b), Nov. 16, 1973, 87 Stat. 622; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

Section 314 of the Public Health Service Act, referred to in subsec. (b)(2), (3), is classified to section 246 of this title.

CODIFICATION

Section was enacted as part of the Department of Defense Appropriation Authorization Act, 1974, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Provisions similar to those comprising this section were contained in Pub. L. 92–585, § 3, Oct. 27, 1972, 86 Stat. 1292, setting out procedure to be followed in closing or transferring control of hospitals or other health care delivery facilities of Public Health Service, prior to repeal by Pub. L. 93–155, § 818(c).

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

§ 248b. Transfer or financial self-sufficiency of public health service hospitals and clinics

(a) Deadline for closure, transfer, or financial self-sufficiency

The Secretary of Health and Human Services (hereinafter in this subtitle referred to as the ''Secretary'') shall, in accordance with this section and notwithstanding section 248a of this title, provide for the closure, transfer, or financial self-sufficiency of all hospitals and other stations of the Public Health Service (hereinafter in this subtitle referred to as the ''Service'') not later than September 30, 1982.

(b) Proposals for transfer or financial self-sufficiency

Not later than July 1, 1981, the Secretary shall notify each Service hospital and other station, and the chief executive officer of each State and of each locality in which such a hospital or other station is located, that the Secretary will accept proposals for the transfer of each such hospital and station from the Service to a public (including Federal) or nonprofit private entity or for the achievement of financial self-sufficiency of each such hospital and station not later than September 30, 1982. No such proposal shall be considered by the Secretary if it is submitted later than September 1, 1981.

(c) Evaluation of proposals

The Secretary shall evaluate promptly each proposal submitted under subsection (b) with respect to a hospital or other station and determine, not later than September 30, 1981, whether or not under such proposal the hospital or station—

(1) will be maintained as a general health care facility providing a range of services to the population within its service area,

(2) will continue to make services available to existing patient populations, and

(3) has a reasonable expectation of financial viability and, in the case of a hospital or station that is not proposed to be transferred, of financial self-sufficiency.

Paragraph (1) shall not apply in the case of a proposal for the transfer of a discrete, minor, freestanding part of a hospital or station to a local public entity for the purpose of continuing the provision of services to refugees.

(d) Rejection or approval of proposal

(1) If the Secretary determines that a proposal for a hospital or other station does not meet the standards of subsection (c) or if there is no proposal submitted under subsection (b) with respect to a hospital or other station, the Secretary shall provide for the closure of the hospital or station by not later than October 31, 1981.

(2) If the Secretary determines that a proposal for a hospital or other station meets the standards of subsection (c), the Secretary shall take such steps, within the amounts available through appropriations, as may be necessary and proper—

(A) to operate (or participate or assist in the operation of) the hospital or station by the Service until the transfer is accomplished or financial self-sufficiency is achieved,

(B) to bring the hospital or station into compliance with applicable licensure, accreditation, and local medical practice standards, and

(C) to provide for such other legal, administrative, personnel, and financial arrangements (including allowing payments made with respect to services provided by the hospital or station to be made directly to that hospital or station) as may be necessary to effect a timely and orderly transfer of such hospital or station (including the land, building, and equipment thereof) from the Service, or for the financial self-sufficiency of the hospital or station, not later than September 30, 1982.

(e) Establishment of identifiable administrative unit

There is established, within the Office of the Assistant Secretary for Health of the Department of Health and Human Services, an identifiable administrative unit which shall have direct responsibility and authority for overseeing the activities under this section.

(f) Finding of financial self-sufficiency

For purposes of this section, a hospital or station cannot be found to be financially self-sufficient if the hospital or station is relying, in whole or in part, on direct appropriated funds for its continued operations.

(Pub. L. 97–35, title IX, § 987, Aug. 13, 1981, 95 Stat. 603.)

REFERENCES IN TEXT

This subtitle, referred to in subsec. (a), is subtitle J of title IX of Pub. L. 97–35, §§ 985 to 988, Aug. 13, 1981, 95 Stat. 602, which enacted this section, amended sections 201, 249, and 254e of this title, and enacted provisions set out as notes under this section and section 249 of this title. For complete classification of this subtitle to the Code, see Tables.

Section 248a of this title, referred to in subsec. (a), was in the original ''section 818 of Public Law 93–155'', meaning section 818 of Pub. L. 93–155, title VIII, Nov. 16, 1973, 87 Stat. 622, which enacted section 248a of this title and repealed section 3 of Pub. L. 92–585, Oct. 27, 1972, 86 Stat. 1292.

CODIFICATION

Section was enacted as part of the Omnibus Budget Reconciliation Act of 1981, and not as part of the Public Health Service Act which comprises this chapter.

CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSE

Pub. L. 97–35, title IX, § 985, Aug. 13, 1981, 95 Stat. 602, provided that:

''(a) Congress finds that—

''(1) because of national budgetary considerations, it has become necessary to terminate Federal appropriations for Public Health Service hospitals and clinics,

''(2) with proper planning and coordination, some of these hospitals and clinics could be transferred to State, local, or private control or become financially self-sufficient and continue to provide effective and efficient health care to individuals in the areas in which they are located,

''(3) a precipitous closure of these hospitals and clinics will preclude the possibility of such orderly transfer to entities which are willing and able to take over operations at such facilities and will cause unnecessary and costly hardships on the patients and staffs at such facilities and on the communities in which the facilities are located, and

''(4) it is in the national interest, consistent with sound budgetary considerations, to assist in the orderly and prompt transfer of such operations to State, local, or private operation or in the achievement of financial self-sufficiency where feasible.

''(b) The purposes of this subtitle [enacting this section, amending sections 201, 249, and 254e of this title, and enacting provisions set out as notes under section 249 of this title] are—

''(1) to provide for the prompt and orderly closure by October 31, 1981, of Public Health Service hospitals and clinics which cannot reasonably be transferred to State, local, or private operation or become financially self-sufficient and for the transfer or achievement of financial self-sufficiency by September 30, 1982, of those hospitals and clinics which can be so transferred or which can achieve such financial self-sufficiency, and

''(2) to provide for transitional assistance for merchant seamen whose entitlement to receive free care through Public Health Service hospitals and clinics is repealed and who are hospitalized at the end of fiscal year 1981 and require continuing hospitalization.''

§§ 248c, 248d. Repealed. Pub. L. 104–201, div. A, title VII, § 727(a)(1), (2), Sept. 23, 1996, 110 Stat. 2596

Section 248c, Pub. L. 97–99, title IX, § 911, Dec. 23, 1981, 95 Stat. 1386; Pub. L. 98–94, title XII, § 1252(g), formerly § 1252(f), Sept. 24, 1983, 97 Stat. 699, renumbered § 1252(g), Pub. L. 101–510, div. A, title VII, § 718(b)(1), Nov. 5, 1990, 104 Stat. 1586; Pub. L. 98–557, § 17(f)(1), Oct. 30, 1984, 98 Stat. 2868, related to continued use of former Public Health Service facilities.

Section 248d, Pub. L. 98–94, title XII, § 1252, Sept. 24, 1983, 97 Stat. 698; Pub. L. 98–557, § 17(f)(2), Oct. 30, 1984, 98 Stat. 2868; Pub. L. 99–661, div. A, title VII, § 706, Nov. 14, 1986, 100 Stat. 3905; Pub. L. 100–456, div. A, title VI, § 645, Sept. 29, 1988, 102 Stat. 1988; Pub. L. 101–510, div. A, title VII, § 718(a), (b), Nov. 5, 1990, 104 Stat. 1586, 1587; Pub. L. 102–25, title VII, § 705(h), Apr. 6, 1991, 105 Stat. 121; Pub. L. 103–160, div. A, title VII, § 717(a), Nov. 30, 1993, 107 Stat. 1693; Pub. L. 104–106, div. A, title VII, §§ 721, 722, 727, title XV, § 1502(c)(8), Feb. 10, 1996, 110 Stat. 377, 380, 508, related to Public Health Service facilities providing medical care for dependents, members, and former members of uniformed services.

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1997, see section 727(b) of Pub. L. 104–201, set out in an Inclusion of Certain Designated Providers in Uniformed Services Health Care Delivery System note under section 1073 of Title 10, Armed Forces.

EQUITABLE IMPLEMENTATION OF UNIFORM COST SHARING REQUIREMENTS FOR UNIFORMED SERVICES TREATMENT FACILITIES

Pub. L. 104–106, div. A, title VII, § 726, Feb. 10, 1996, 110 Stat. 379, provided that the uniform managed care benefit fee and copayment schedule developed by Secretary of Defense for use in all managed care initiatives of military health service system be extended to managed care program of Uniformed Services Treatment Facility only after the later of the implementation of the TRICARE regional program covering service area of Facility or Oct. 1, 1996, and provided for evaluation of such extension by Comptroller General, prior to repeal by Pub. L. 104–201, div. A, title VII, § 727(a)(4), Sept. 23, 1996, 110 Stat. 2596.

MANAGED-CARE DELIVERY AND REIMBURSEMENT MODEL FOR THE UNIFORMED SERVICES TREATMENT FACILITIES

Pub. L. 101–510, div. A, title VII, § 718(c), Nov. 5, 1990, 104 Stat. 1587, as amended by Pub. L. 102–484, div. A, title VII, § 716, Oct. 23, 1992, 106 Stat. 2438; Pub. L. 103–160, div. A, title VII, § 718, Nov. 30, 1993, 107 Stat. 1694; Pub. L. 104–106, div. A, title VII, §§ 724(a), 725, Feb. 10, 1996, 110 Stat. 378, provided that not later than Nov. 5, 1990, the Secretary of Defense was to begin operation of a managed-care delivery and reimbursement model to continue to use Uniformed Services Treatment Facilities in the military health services system, prior to repeal by Pub. L. 104–201, div. A, title VII, § 727(a)(3), Sept. 23, 1996, 110 Stat. 2596.

§ 249. Medical care and treatment of quarantined and detained persons

(a) Persons entitled to treatment

Any person when detained in accordance with quarantine laws, or, at the request of the Immigration and Naturalization Service, any person detained by that Service, may be treated and cared for by the Public Health Service.

(b) Temporary treatment in emergency cases

Persons not entitled to treatment and care at institutions, hospitals, and stations of the Service may, in accordance with regulations of the Surgeon General, be admitted thereto for temporary treatment and care in case of emergency.

(c) Authorization for outside treatment

Persons whose care and treatment is authorized by subsection (a) may, in accordance with regulations, receive such care and treatment at the expense of the Service from public or private medical or hospital facilities other than those of the Service, when authorized by the officer in charge of the station at which the application is made.

(July 1, 1944, ch. 373, title III, § 322, 58 Stat. 696; June 25, 1948, ch. 654, § 3, 62 Stat. 1018; Aug. 8, 1956, ch. 1036, § 3, 70 Stat. 1120; Pub. L. 88–424, Aug. 13, 1964, 78 Stat. 398; Pub. L. 90–174, § 10(c), Dec. 5, 1967, 81 Stat. 541; Pub. L. 97–35, title IX, § 986(a), (b)(1), (2), Aug. 13, 1981, 95 Stat. 603.)

AMENDMENTS

1981—Subsec. (a). Pub. L. 97–35, § 986(a), (b)(2), redesignated subsec. (c) as (a). Former subsec. (a), which related to persons entitled to medical, etc., treatment and hospitalization, was struck out.

Subsec. (b). Pub. L. 97–35, § 986(a), (b)(2), redesignated subsec. (d) as (b). Former subsec. (b), which related to treatment for seamen on foreign-flag vessels, was struck out.

Subsec. (c). Pub. L. 97–35, § 986(b)(1), (2), redesignated subsec. (e) as (c), substituted ''subsection (a)'' for ''subsection (c)'', and struck out ''entitled to care and treatment under subsection (a) of this section and persons'' after ''Persons''. Former subsec. (c) redesignated (a).

Subsecs. (d), (e). Pub. L. 97–35, § 986(b)(2), redesignated subsecs. (d) and (e) as (b) and (c), respectively.

1967—Subsec. (a)(7). Pub. L. 90–174 substituted provision for entitlement to treatment and hospitalization of seamen-trainees, while participating in maritime training programs to develop or enhance their employability in maritime industry, for provision for such entitlement of employees and noncommissioned officers in field service of Public Health Service when injured or taken sick in line of duty.

1964—Subsec. (a)(8). Pub. L. 88–424 added par. (8).

1948—Subsec. (e). Act June 25, 1948, permitted Service to provide for care and treatment of individuals detained in accordance with our quarantine laws.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title IX, §986(c), Aug. 13, 1981, 95 Stat. 603, provided that: ''The amendments and repeals made by this section [amending this section and sections 201 and 254e of this title] shall take effect on October 1, 1981.''

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

Functions of all other officers of Department of Justice and functions of all agencies and employees of such Department transferred, with a few exceptions, to Attorney General, with power vested in him to authorize their performance or the performance of any of his functions by any of such officers, agencies, and employees, by sections 1 and 2 of Reorg. Plan No. 2 of 1950, eff. May 24, 1950, 15 F.R. 3173, 64 Stat. 1261, which were repealed by Pub. L. 89–554, §8(a), Sept. 6, 1966, 80 Stat. 662. Immigration and Naturalization Service, referred to in this section, was a bureau in Department of Justice.

ABOLITION OF IMMIGRATION AND NATURALIZATION SERVICE AND TRANSFER OF FUNCTIONS

For abolition of Immigration and Naturalization Service, transfer of functions, and treatment of related references, see note set out under section 1551 of Title 8, Aliens and Nationality.

CONTINUED CARE FOR MERCHANT SEAMEN HOSPITALIZED IN PUBLIC HEALTH SERVICE HOSPITALS

Pub. L. 97–35, title IX, §988, Aug. 13, 1981, 95 Stat. 604, provided that:

''(a) The Secretary shall provide, by contract or other arrangement with a Federal entity and without charge but subject to subsection (b), for the continuation of inpatient hospital services (and outpatient services related to the condition of hospitalization) to any individual who—

''(1) on September 30, 1981, is receiving inpatient hospital services at a Public Health Service hospital on the basis of the entitlement contained in section 322(a) of the Public Health Service Act (42 U.S.C. 249(a)), as such section was in effect on such date, for treatment of a condition,

''(2) requires continued hospitalization after such date for treatment of that condition (or requires outpatient services related to such condition), and

''(3) the Secretary determines has no other source of inpatient hospital services available for continued treatment of that condition.

''(b) Services may not be provided under subsection (a) to an individual after the earlier of—

''(1) September 30, 1982,

''(2) the end of the first 60-day consecutive period (beginning after September 30, 1981) during the entire period of which the individual is not an inpatient of a hospital.

''(c) Notwithstanding any other provision of law, the head of any Federal department or agency which provides, under other authority of law and through federal facilities, inpatient hospital services or outpatient services, or both, is authorized to provide inpatient hospital services (and related outpatient services) to individuals under contract or other arrangement with the Secretary pursuant to this section.''

FOREIGN SEAMEN

Section 810(c), formerly §710(c), of act July 1, 1944, as renumbered by acts Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; July 30, 1956, ch. 779, §3(b), 70 Stat. 721, which gave foreign seamen the same benefits as accorded seamen employed on United States vessels under subsec. (a)(1) of this section, was repealed effective Jan. 25, 1948, by Joint Res. July 25, 1947, ch. 327, §2(b), 61 Stat. 451.

§ 250. Medical care and treatment of Federal prisoners

The Service shall supervise and furnish medical treatment and other necessary medical, psychiatric, and related technical and scientific services, authorized by section 4005 of title 18, in penal and correctional institutions of the United States.

(July 1, 1944, ch. 373, title III, §323, 58 Stat. 697.)

CODIFICATION

''Section 4005 of title 18'' substituted in text for ''the Act of May 13, 1930, as amended (U.S.C., 1940 edition, title 18, secs. 751, 752)'' on authority of act June 25, 1948, ch. 645, 62 Stat. 684, the first section of which enacted Title 18, Crimes and Criminal Procedure.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

§ 250a. Transfer of appropriations

The Attorney General may transfer to the Department of Health and Human Services such amounts as may be necessary for direct expenditures by that Department for medical relief for inmates of Federal penal and correctional institutions.

(Pub. L. 115–31, div. B, title II, May 5, 2017, 131 Stat. 198.)

CODIFICATION

Section was enacted as part of the appropriation act cited as the credit to this section, and not as part of the Public Health Service Act which comprises this chapter.

Section was formerly classified to section 341h of title 5 prior to the general revision and enactment of Title 5, Government Organization and Employees, by Pub. L. 89–554, §1, Sept. 6, 1966, 80 Stat. 378.

PRIOR PROVISIONS

Provisions similar to those in this section were contained in the following prior appropriation acts:

Pub. L. 114–113, div. B, title II, Dec. 18, 2015, 129 Stat. 2302.

Pub. L. 113–235, div. B, title II, Dec. 16, 2014, 128 Stat. 2188.

Pub. L. 113–76, div. B, title II, Jan. 17, 2014, 128 Stat. 57.

Pub. L. 113–6, div. B, title II, Mar. 26, 2013, 127 Stat. 248.

Pub. L. 112–55, div. B, title II, Nov. 18, 2011, 125 Stat. 610.

Pub. L. 111–117, div. B, title II, Dec. 16, 2009, 123 Stat. 3129.

Pub. L. 111–8, div. B, title II, Mar. 11, 2009, 123 Stat. 576.

Pub. L. 110–161, div. B, title II, Dec. 26, 2007, 121 Stat. 1905.

Pub. L. 109–108, title I, Nov. 22, 2005, 119 Stat. 2297.
Pub. L. 108–447, div. B, title I, Dec. 8, 2004, 118 Stat. 2860.
Pub. L. 108–199, div. B, title I, Jan. 23, 2004, 118 Stat. 53.
Pub. L. 108–7, div. B, title I, Feb. 20, 2003, 117 Stat. 58.
Pub. L. 107–77, title I, Nov. 28, 2001, 115 Stat. 757.
Pub. L. 106–553, § 1(a)(2) [title I], Dec. 21, 2000, 114 Stat. 2762, 2762A–60.
Pub. L. 106–113, div. B, § 1000(a)(1) [title I], Nov. 29, 1999, 113 Stat. 1535, 1501A–13.
Pub. L. 105–277, div. A, § 101(b) [title I], Oct. 21, 1998, 112 Stat. 2681–50, 2681–60.
Pub. L. 105–119, title I, Nov. 26, 1997, 111 Stat. 2449.
Pub. L. 104–208, div. A, title I, § 101(a) [title I], Sept. 30, 1996, 110 Stat. 3009, 3009–11.
Pub. L. 104–134, title I, § 101[(a)] [title I], Apr. 26, 1996, 110 Stat. 1321, 1321–9; renumbered title I, Pub. L. 104–140, § 1(a), May 2, 1996, 110 Stat. 1327.
Pub. L. 103–317, title I, Aug. 26, 1994, 108 Stat. 1732.
Pub. L. 103–121, title I, Oct. 27, 1993, 107 Stat. 1161.
Pub. L. 102–395, title I, Oct. 6, 1992, 106 Stat. 1836.
Pub. L. 102–140, title I, Oct. 28, 1991, 105 Stat. 790.
Pub. L. 101–515, title II, Nov. 5, 1990, 104 Stat. 2114.
Pub. L. 101–162, title II, Nov. 21, 1989, 103 Stat. 1000.
Pub. L. 100–459, title II, Oct. 1, 1988, 102 Stat. 2196.
Pub. L. 100–202, § 101(a) [title II], Dec. 22, 1987, 101 Stat. 1329, 1329–13.
Pub. L. 99–500, § 101(b) [title II], Oct. 18, 1986, 100 Stat. 1783–39, 1783–49, and Pub. L. 99–591, § 101(b) [title II], Oct. 30, 1986, 100 Stat. 3341–39, 3341–49.
Pub. L. 99–180, title II, Dec. 13, 1985, 99 Stat. 1144.
Pub. L. 98–411, title II, Aug. 30, 1984, 98 Stat. 1556.
Pub. L. 98–166, title II, Nov. 28, 1983, 97 Stat. 1084.
Pub. L. 97–377, § 101(d) [S. 2956, title II], Dec. 21, 1982, 96 Stat. 1866.
Pub. L. 97–92, § 101(h) [incorporating Pub. L. 96–536, § 101*o*; H.R. 7584, title II], Dec. 15, 1981, 95 Stat. 1190.
Pub. L. 96–536, § 101*o* [H.R. 7584, title II], Dec. 16, 1980, 94 Stat. 3169.
Pub. L. 96–68, title II, Sept. 24, 1979, 93 Stat. 421.
Pub. L. 95–431, title II, Oct. 10, 1978, 92 Stat. 1028.
Pub. L. 95–86, title II, Aug. 2, 1977, 91 Stat. 427.
Pub. L. 94–362, title II, July 14, 1976, 90 Stat. 945.
Pub. L. 94–121, title II, Oct. 21, 1975, 89 Stat. 620.
Pub. L. 93–433, title II, Oct. 5, 1974, 88 Stat. 1194.
Pub. L. 93–162, title II, Nov. 27, 1973, 87 Stat. 643.
Pub. L. 92–544, title II, Oct. 25, 1972, 86 Stat. 1116.
Pub. L. 92–77, title II, Aug. 10, 1971, 85 Stat. 253.
Pub. L. 91–472, title II, Oct. 21, 1970, 84 Stat. 1047.
Pub. L. 91–153, title II, Dec. 24, 1969, 83 Stat. 410.
Pub. L. 90–470, title II, Aug. 9, 1968, 82 Stat. 675.
Pub. L. 90–133, title II, Nov. 8, 1967, 81 Stat. 418.
Pub. L. 89–797, title II, Nov. 8, 1966, 80 Stat. 1487.
Pub. L. 89–164, title II, Sept. 2, 1965, 79 Stat. 628.
Pub. L. 88–527, title II, Aug. 31, 1964, 78 Stat. 719.
Pub. L. 88–245, title II, Dec. 30, 1963, 77 Stat. 783.
Pub. L. 87–843, title II, Oct. 18, 1962, 76 Stat. 1088.
Pub. L. 87–264, title II, Sept. 21, 1961, 75 Stat. 553.
Pub. L. 86–678, title II, Aug. 31, 1960, 74 Stat. 563.
Pub. L. 86–84, title II, July 13, 1959, 73 Stat. 189.
Pub. L. 85–474, title II, June 30, 1958, 72 Stat. 252.
Pub. L. 85–49, title II, June 11, 1957, 71 Stat. 62.
June 20, 1956, ch. 414, title II, 70 Stat. 307.
July 7, 1955, ch. 279, title II, 69 Stat. 273.

§ 251. Medical examination and treatment of Federal employees; medical care at remote stations

(a) The Surgeon General is authorized to provide at institutions, hospitals, and station of the Service medical, surgical, and hospital services and supplies for persons entitled to treatment under subchapter I of Chapter 81 of title 5 and extensions thereof. The Surgeon General may also provide for making medical examinations of—

(1) employees of the Federal Government for retirement purposes;

(2) employees in the Federal classified service, and applicants for appointment, as requested by the Director of the Office of Personnel Management for the purpose of promoting health and efficiency;

(3) seamen for purposes of qualifying for certificates of service; and

(4) employees eligible for benefits under the Longshore and Harbor Workers' Compensation Act, as amended [33 U.S.C. 901 et seq.], as requested by any deputy commissioner thereunder.

(b) The Secretary is authorized to provide medical, surgical, and dental treatment and hospitalization and optometric care for Federal employees (as defined in section 8901(1) of title 5) and their dependents at remote medical facilities of the Public Health Service where such care and treatment are not otherwise available. Such employees and their dependents who are not entitled to this care and treatment under any other provision of law shall be charged for it at rates established by the Secretary to reflect the reasonable cost of providing the care and treatment. Any payments pursuant to the preceding sentence shall be credited to the applicable appropriation to the Public Health Service for the year in which such payments are received.

(July 1, 1944, ch. 373, title III, § 324, 58 Stat. 697; Pub. L. 90–174, § 10(a), (b), Dec. 5, 1967, 81 Stat. 540; 1978 Reorg. Plan No. 2, § 102, eff. Jan. 1, 1979, 43 F.R. 36037, 92 Stat. 3783; Pub. L. 97–468, title VI, § 615(b)(4), Jan. 14, 1983, 96 Stat. 2578; Pub. L. 98–426, § 27(d)(2), Sept. 28, 1984, 98 Stat. 1654.)

REFERENCES IN TEXT

The Longshore and Harbor Workers' Compensation Act, as amended, referred to in subsec. (a)(4), is act Mar. 4, 1927, ch. 509, 44 Stat. 1424, as amended, which is classified generally to chapter 18 (§ 901 et seq.) of Title 33, Navigation and Navigable Waters. For complete classification of this Act to the Code, see section 901 of Title 33 and Tables.

CODIFICATION

In subsec. (a), ''subchapter I of chapter 81 of title 5'' substituted for ''United States Employees' Compensation Act'' on authority of Pub. L. 89–554, § 7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1984—Subsec. (a)(4). Pub. L. 98–426 substituted ''Longshore and Harbor Workers' Compensation Act'' for ''Longshoremen's and Harbor Workers' Compensation Act''.

1983—Subsec. (a)(1). Pub. L. 97–468 struck out ''employees of the Alaska Railroad and'' before ''employees of the Federal Government''.

1967—Subsec. (a). Pub. L. 90–174, § 10(a), designated existing provisions as subsec. (a) and redesignated cls. (a) to (d) as cls. (1) to (4), respectively.

Subsec. (b). Pub. L. 90–174, § 10(b), added subsec. (b).

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–426 effective Sept. 28, 1984, see section 28(e)(1) of Pub. L. 98–426, set out as a note under section 901 of Title 33, Navigation and Navigable Waters.

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by Pub. L. 97–468 effective on date of transfer of Alaska Railroad to the State [Jan. 5, 1985],

pursuant to section 1203 of Title 45, Railroads, see section 615(b) of Pub. L. 97–468.

TRANSFER OF FUNCTIONS

''Director of the Office of Personnel Management'' substituted for ''Civil Service Commission'' in subsec. (a)(2), pursuant to Reorg. Plan No. 2 of 1978, §102, 43 F.R. 36037, 92 Stat. 3783, set out under section 1101 of Title 5, Government Organization and Employees, which transferred all functions vested by statute in United States Civil Service Commission to Director of Office of Personnel Management (except as otherwise specified), effective Jan. 1, 1979, as provided by section 1–102 of Ex. Ord. No. 12107, Dec. 28, 1978, 44 F.R. 1055, set out under section 1101 of Title 5.

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

§ 252. Medical examination of aliens

The Surgeon General shall provide for making, at places within the United States or in other countries, such physical and mental examinations of aliens as are required by the immigration laws, subject to administrative regulations prescribed by the Attorney General and medical regulations prescribed by the Surgeon General with the approval of the Secretary.

(July 1, 1944, ch. 373, title III, §325, 58 Stat. 697; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

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.

ABOLITION OF IMMIGRATION AND NATURALIZATION SERVICE AND TRANSFER OF FUNCTIONS

For abolition of Immigration and Naturalization Service, transfer of functions, and treatment of related references, see note set out under section 1551 of Title 8, Aliens and Nationality.

§ 253. Medical services to Coast Guard, National Oceanic and Atmospheric Administration, and Public Health Service

(a) Persons entitled to medical services

Subject to regulations of the President—

(1) commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard on active duty, including those on shore duty and those on detached duty; and Regular, and temporary members of the United States Coast Guard Reserve when on active duty;

(2) commissioned officers, ships' officers, and members of the crews of vessels of the National Oceanic and Atmospheric Administration on active duty, including those on shore duty and those on detached duty; and

(3) commissioned officers of the Regular or Reserve Corps of the Public Health Service on active duty;

shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service. The Surgeon General may detail commissioned officers for duty aboard vessels of the Coast Guard or the National Oceanic and Atmospheric Administration.

(b) Health care for involuntarily separated officers and dependents

(1) The Secretary may provide health care for an officer of the Regular or Reserve Corps involuntarily separated from the Service, and for any dependent of such officer, if—

(A) the officer or dependent was receiving health care at the expense of the Service at the time of separation; and

(B) the Secretary finds that the officer or dependent is unable to obtain appropriate insurance for the conditions for which the officer or dependent was receiving health care.

(2) Health care may be provided under paragraph (1) for a period of not more than one year from the date of separation of the officer from the Service.

(c) Examination of personnel of Service assigned to Coast Guard or National Oceanic and Atmospheric Administration

The Service shall provide all services referred to in subsection (a) required by the Coast Guard or National Oceanic and Atmospheric Administration and shall perform all duties prescribed by statute in connection with the examinations to determine physical or mental condition for purposes of appointment, enlistment, and reenlistment, promotion and retirement, and officers of the Service assigned to duty on Coast Guard or National Oceanic and Atmospheric Administration vessels may extend aid to the crews of American vessels engaged in deep-sea fishing.

(July 1, 1944, ch. 373, title III, §326, 58 Stat. 697; June 7, 1956, ch. 374, §306(3), 70 Stat. 254; Pub. L. 86–415, §5(d), Apr. 8, 1960, 74 Stat. 34; Pub. L. 88–71, §2, July 19, 1963, 77 Stat. 83; 1965 Reorg. Plan No. 2, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318; 1970 Reorg. Plan No. 4, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090; Pub. L. 99–117, §5, Oct. 7, 1985, 99 Stat. 492.)

AMENDMENTS

1985—Subsec. (b). Pub. L. 99–117 added subsec. (b).

1963—Subsec. (b). Pub. L. 88–71, §2(a), repealed subsec. (b) which provided for treatment of dependents of personnel. See section 253a(b) of this title.

Subsec. (c). Pub. L. 88–71, §2(b), inserted ''or Coast and Geodetic Survey'' after ''Coast Guard'' in two places.

1960—Subsec. (a). Pub. L. 86–415 struck out provisions which authorized medical, surgical, and dental care and hospitalization for retired personnel of Coast Guard, Coast and Geodetic Survey, and Public Health Service.

1956—Subsec. (b). Act June 7, 1956, repealed subsec. (b) except insofar as it related to dependent members of families of ships' officers and members of crews of vessels of Coast and Geodetic Survey.

CHANGE OF NAME

Coast and Geodetic Survey consolidated with Weather Bureau to form a new agency in Department of Commerce to be known as Environmental Science Services Administration, and commissioned officers of Survey transferred to ESSA, by Reorg. Plan No. 2 of 1965, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 4 of 1970, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090, abolished Environmental Science Services Administration, established National Oceanic and Atmospheric Administration, and redesignated Commissioned Officer Corps of ESSA as Commissioned Officer Corps of NOAA. For further details, see Transfer of Functions note set out under section 851 of Title 33, Navigation and Navigable Waters.

EFFECTIVE DATE OF 1956 AMENDMENT

Amendment by act June 7, 1956, effective six months after June 7, 1956, see section 307 of act June 7, 1956.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

§ 253a. Medical services to retired personnel of National Oceanic and Atmospheric Administration

(a) Eligibility

Subject to regulations of the President, retired ships' officers and retired members of the crews of vessels of the National Oceanic and Atmospheric Administration shall be entitled to medical, surgical, and dental treatment and hospitalization by the Public Health Service if the ships' officer or crew member, (1) was on active duty as a vessel employee of the National Oceanic and Atmospheric Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee was continuous from that date until retirement, or (2) was retired as a vessel employee of the National Oceanic and Atmospheric Administration on or before July 1, 1963, or on July 19, 1963, whichever is later.

(b) Treatment of dependents of personnel

Subject to regulations of the President, dependent members of families (as defined in such regulations) of ships' officers and members of crews of vessels of the National Oceanic and Atmospheric Administration, whether such, ships' officers and members of crew are on active duty or retired, shall be furnished medical advice and outpatient treatment by the Public Health Service and, if suitable accommodations are available, they shall also be furnished hospitalization by the Public Health Service if the ships' officer or crew member (1) was on active duty as a vessel employee of the National Oceanic and Atmospheric Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee has been continuous from that time, or (2) was on active duty as a vessel employee of the National Oceanic and Atmospheric Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee was continuous from that time until retirement, or (3) was retired as a vessel employee of the National Oceanic and Atmospheric Administration on or before July 1, 1963, or on July 19, 1963, whichever is later. When dependent members of families are hospitalized, a per diem charge, at such uniform rate as may be prescribed from time to time for the hospitalization of dependents of members of the uniformed services at hospitals of the uniformed services pursuant to section 1078(a) of title 10 shall be made.

(c) Identification

The National Oceanic and Atmospheric Administration shall furnish proper identification to those persons entitled to medical treatment under the provisions of this section.

(Pub. L. 88–71, §1, July 19, 1963, 77 Stat. 83; 1965 Reorg. Plan No. 2, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318; 1970 Reorg. Plan No. 4, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090; Pub. L. 98–498, title III, §310(b), (c), Oct. 19, 1984, 98 Stat. 2306, 2307.)

CODIFICATION

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

AMENDMENTS

1984—Subsec. (a). Pub. L. 98–498, §310(b), substituted ''by the Public Health Service if'' for ''at facilities of the Public Health Service: *Provided*, That''.

Subsec. (b). Pub. L. 98–498, §310(c), struck out ''at its hospitals and relief stations'' before ''and, if suitable accommodations'' and substituted ''by the Public Health Service if'' for ''at hospitals of the Public Health Service: *Provided*, That''.

CHANGE OF NAME

Coast and Geodetic Survey consolidated with Weather Bureau to form a new agency in Department of Commerce to be known as Environmental Science Services Administration, and commissioned officers of Survey transferred to ESSA, by Reorg. Plan No. 2 of 1965, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 4 of 1970, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090, abolished Environmental

Science Services Administration, established National Oceanic and Atmospheric Administration, and redesignated Commissioned Officer Corps of ESSA as Commissioned Officer Corps of NOAA. For further details, see Transfer of Functions note set out under section 851 of Title 33, Navigation and Navigable Waters.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

EX. ORD. NO. 11160. REGULATIONS RELATING TO MEDICAL CARE FOR RETIRED PERSONNEL OF COAST AND GEODETIC SURVEY [NOW NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION] AND THEIR DEPENDENTS

Ex. Ord. No. 11160, July 6, 1964, 29 F.R. 9315, provided:

By virtue of the authority vested in me by the first section of the Act of July 19, 1963 (Public Law 88–71, 77 Stat. 83, 42 U.S.C. 253a), and as President of the United States, I hereby prescribe the following regulations relating to the medical care of certain retired personnel of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] and dependents of Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] ships' officers and crew members, both active and retired.

SECTION 1. *Definitions.* As used in these regulations, the term:

(1) ''Retired ships' officer and retired crew member'' means a noncommissioned ships' officer or crew member of a vessel of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] who either was on active duty as a vessel employee on July 19, 1963, and whose employment as such vessel employee was continuous from that date until the date of his retirement, or who had retired as a vessel employee on or before July 19, 1963.

(2) ''Active duty ships' officer and active duty crew member'' means a noncommissioned ships' officer or crew member on active duty as a vessel employee of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] on July 19, 1963, and whose employment as such vessel employee has been continuous from that time.

(3) ''Dependent members of families'', with respect to active duty or retired ships' officers or crew members, means:

(A) the lawful wife;

(B) the unmarried legitimate child, including an adopted child or stepchild, who has not passed his twenty-first birthday; and

(C) the father or mother, if in fact dependent upon such active duty or retired ships' officer or crew member for over one-half of his or her support.

(4) ''Relief stations'' means Public Health Service outpatient clinics and outpatient offices.

(5) ''Outpatient clinic'' means a full-time outpatient medical facility, operated in Federally owned or leased space under the supervision of a commissioned medical officer or a full-time civil service medical officer (formerly known as a Second-Class Relief Station).

(6) ''Outpatient office'' means a part-time outpatient facility serving all classes of legal beneficiaries, located in other than Federal space, and in the charge of a local private physician under contract to the Service to provide medical care on an annual or fee basis (formerly known as a Third-Class Relief Station).

SEC. 2. *Persons entitled to treatment.* The following persons shall be entitled to medical care under these regulations:

(1) Retired ships' officers and retired crew members of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration];

(2) Dependent members of families of persons described in paragraph (1) of this section;

(3) Dependent members of families of active duty ships' officers and crew members of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration].

SEC. 3. *Application for treatment; evidence of eligibility.* Persons entitled to medical care under Section 2 of these regulations, when applying to Public Health Service medical care facilities for medical care, shall produce proper identification, as issued to them by the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration], and such identification shall be accepted as evidence of eligibility for such medical care by the Service.

SEC. 4. *Extent of treatment; retired ships' officers and crew members.* Subject to the limitation imposed by paragraph (2) of this section, retired ships' officers and crew members entitled to medical care under these regulations shall be furnished:

(1) Medical, surgical, and dental treatment at hospitals, outpatient clinics, and outpatient offices of the Service, and hospitalization at hospitals of the Service. The Service will not be responsible for defraying the cost of hospitalization, medical services, and supplies procured elsewhere.

(2) Dental treatment shall be furnished to the extent that facilities and services at hospitals and outpatient clinics of the Service having full-time dental officers on duty are available to provide such treatment. At other Service facilities, dental treatment shall be limited to emergency measures necessary to relieve pain.

SEC. 5. *Extent of treatment; dependent members of families; charges.* (a) Dependent members of families shall be furnished medical advice and outpatient treatment at hospitals, outpatient clinics, and outpatient offices of the Service and, if suitable accommodations are available, shall be furnished hospitalization at hospitals of the Service. The Service will not be responsible for defraying the cost of hospitalization, medical services, and supplies procured elsewhere.

(b) For the purpose of this section—

(1) Medical advice and outpatient treatment may include such services and supplies as the Medical Officer in Charge may deem to be necessary for reasonable and adequate treatment.

(2) Hospitalization shall be furnished when, in the opinion of the Medical Officer in Charge, suitable accommodations are available and the condition of the patient is such as to require hospitalization. When hospitalization is authorized, it may include such services and supplies as the Medical Officer in Charge may deem to be necessary for reasonable and adequate treatment.

(c) Charges shall be made for hospitalization of dependent members of families at the same per diem rate as is prescribed for dependents of members of the uniformed services pursuant to section 1078(a) of Title 10 of the United States Code.

(d) Dental treatment may be furnished to the extent that facilities and services at hospitals and outpatient clinics of the Service having full-time dental officers are available to provide such treatment. Dental care will not be furnished under any circumstances in private facilities at the expense of the Service.

SEC. 6. *Prior orders.* Executive Order No. 9703 of March 12, 1946, prescribing regulations relating to medical care of certain personnel of the Coast Guard, Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration], Public Health Service, and former Lighthouse Service, is hereby amended to the extent necessary to conform it to the provisions of this order.

LYNDON B. JOHNSON.

§ 253b. Former Lighthouse Service employees; medical service eligibility

Subject to regulations of the President, lightkeepers, assistant lightkeepers, and officers and

crews of vessels of the former Lighthouse Service, including any such persons who subsequent to June 30, 1939, were involuntarily assigned to other civilian duty in the Coast Guard, who were entitled to medical relief at hospitals and other stations of the Public Health Service prior to July 1, 1944, and who retired under the provisions of section 763 of title 33, shall be entitled to medical, surgical, and dental treatment and hospitalization at hospitals and other stations of the Public Health Service.

(Pub. L. 93–353, title I, § 108(a), July 23, 1974, 88 Stat. 371.)

CODIFICATION

Section was enacted as a part of Health Services Research, Health Statistics, and Medical Libraries Act of 1974, and also as a part of Health Services Research and Evaluation and Health Statistics Act of 1974, and not as a part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Pub. L. 93–353, title I, § 108(b), July 23, 1974, 88 Stat. 371, provided that: ''Subsection (a) [enacting this section] shall be effective from December 28, 1973.''

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§ 254. Interdepartmental work

Nothing contained in this part shall affect the authority of the Service to furnish any materials, supplies, or equipment, or perform any work of services, requested in accordance with sections 1535 and 1536 of title 31, or the authority of any other executive department to furnish any materials, supplies, or equipment, or perform any work or services, requested by the Department of Health and Human Services for the Service in accordance with that section.

(July 1, 1944, ch. 373, title III, § 327, 58 Stat. 697; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

CODIFICATION

''Sections 1535 and 1536 of title 31'' substituted in text for ''section 7 of the Act of May 21, 1920, as amended (U.S.C., 1940 edition, title 31, sec. 686)'' on authority of Pub. L. 97–258, § 4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

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.

§ 254a. Sharing of medical care facilities and resources

(a) Definitions

For purposes of this section—

(1) the term ''specialized health resources'' means health care resources (whether equipment, space, or personnel) which, because of cost, limited availability, or unusual nature, are either unique in the health care community or are subject to maximum utilization only through mutual use;

(2) the term ''hospital'', unless otherwise specified, includes (in addition to other hospitals) any Federal hospital.

(b) Statement of purpose; agreements or arrangements; reciprocity; reimbursement; credits

For the purpose of maintaining or improving the quality of care in Public Health Service facilities and to provide a professional environment therein which will help to attract and retain highly qualified and talented health personnel, to encourage mutually beneficial relationships between Public Health Service facilities and hospitals and other health facilities in the health care community, and to promote the full utilization of hospitals and other health facilities and resources, the Secretary may—

(1) enter into agreements or arrangements with schools of medicine, schools of osteopathic medicine, and with other health professions schools, agencies, or institutions, for such interchange or cooperative use of facilities and services on a reciprocal or reimbursable basis, as will be of benefit to the training or research programs of the participating agencies; and

(2) enter into agreements or arrangements with hospitals and other health care facilities for the mutual use or the exchange of use of specialized health resources, and providing for reciprocal reimbursement.

Any reimbursement pursuant to any such agreement or arrangement shall be based on charges covering the reasonable cost of such utilization, including normal depreciation and amortization costs of equipment. Any proceeds to the Government under this subsection shall be credited to the applicable appropriation of the Public Health Service for the year in which such proceeds are received.

(July 1, 1944, ch. 373, title III, § 327A, formerly § 328, as added Pub. L. 90–174, § 7, Dec. 5, 1967, 81 Stat. 539; renumbered § 327A, Pub. L. 95–626, title I, § 113(a)(2), Nov. 10, 1978, 92 Stat. 3562; amended Pub. L. 100–607, title VI, § 629(a)(1), Nov. 4, 1988, 102 Stat. 3146.)

AMENDMENTS

1988—Subsec. (b)(1). Pub. L. 100–607 inserted ''schools of osteopathic medicine,'' after ''schools of medicine,'' and ''professions'' after ''health''.

AVAILABILITY OF APPROPRIATIONS FOR EXPENSES OF SHARING MEDICAL CARE FACILITIES AND RESOURCES

Pub. L. 102–394, title II, § 204, Oct. 6, 1992, 106 Stat. 1811, provided that: ''Funds advanced to the National Institutes of Health Management Fund from appropriations in this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be available for the expenses of sharing medical care facilities and resources pursuant to section 327A of the Public Health Service Act [42 U.S.C. 254a].''

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title II, § 204, Nov. 26, 1991, 105 Stat. 1126.

Pub. L. 101–517, title II, § 204, Nov. 5, 1990, 104 Stat. 2208.

Pub. L. 101–166, title II, § 205, Nov. 21, 1989, 103 Stat. 1177.

Pub. L. 100–202, § 101(h) [title II, § 205], Dec. 22, 1987, 101 Stat. 1329–256, 1329–274.

Pub. L. 99–500, § 101(i) [H.R. 5233, title II, § 205], Oct. 18, 1986, 100 Stat. 1783–287, and Pub. L. 99–591, § 101(i) [H.R. 5233, title II, § 205], Oct. 30, 1986, 100 Stat. 3341–287.

Pub. L. 99–178, title II, § 205, Dec. 12, 1985, 99 Stat. 1119.

Pub. L. 98–619, title II, § 205, Nov. 8, 1984, 98 Stat. 3321.

Pub. L. 98–139, title II, § 205, Oct. 31, 1983, 97 Stat. 887.

Pub. L. 97–377, title I, § 101(e)(1) [title II, § 205], Dec. 21, 1982, 96 Stat. 1878, 1894.

PART D—PRIMARY HEALTH CARE

CODIFICATION

Pub. L. 95–626, title I, § 113(a)(3), Nov. 10, 1978, 92 Stat. 3562, added heading ''Part D—Primary Health Care''.

SUBPART I—HEALTH CENTERS

CODIFICATION

Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626, substituted ''Health Centers'' for ''Primary Health Centers'' in subpart heading.

Pub. L. 95–626, title I, § 113(a)(3), Nov. 10, 1978, 92 Stat. 3562, added heading ''Subpart I—Primary Health Centers''.

§ 254b. Health centers

(a) "Health center" defined

(1) In general

For purposes of this section, the term ''health center'' means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements—

(A) required primary health services (as defined in subsection (b)(1)); and

(B) as may be appropriate for particular centers, additional health services (as defined in subsection (b)(2)) necessary for the adequate support of the primary health services required under subparagraph (A);

for all residents of the area served by the center (hereafter referred to in this section as the ''catchment area'').

(2) Limitation

The requirement in paragraph (1) to provide services for all residents within a catchment area shall not apply in the case of a health center receiving a grant only under subsection (g), (h), or (i).

(b) Definitions

For purposes of this section:

(1) Required primary health services

(A) In general

The term ''required primary health services'' means—

(i) basic health services which, for purposes of this section, shall consist of—

(I) health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physician assistants, nurse practitioners, and nurse midwives;

(II) diagnostic laboratory and radiologic services;

(III) preventive health services, including—

(aa) prenatal and perinatal services;

(bb) appropriate cancer screening;

(cc) well-child services;

(dd) immunizations against vaccine-preventable diseases;

(ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol;

(ff) pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;

(gg) voluntary family planning services; and

(hh) preventive dental services;

(IV) emergency medical services; and

(V) pharmaceutical services as may be appropriate for particular centers;

(ii) referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services (including substance abuse and mental health services);

(iii) patient case management services (including counseling, referral, and follow-up services) and other services designed to assist health center patients in establishing eligibility for and gaining access to Federal, State, and local programs that provide or financially support the provision of medical, social, housing, educational, or other related services;

(iv) services that enable individuals to use the services of the health center (including outreach and transportation services and, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals); and

(v) education of patients and the general population served by the health center regarding the availability and proper use of health services.

(B) Exception

With respect to a health center that receives a grant only under subsection (g), the Secretary, upon a showing of good cause, shall—

(i) waive the requirement that the center provide all required primary health services under this paragraph; and

(ii) approve, as appropriate, the provision of certain required primary health services only during certain periods of the year.

(2) Additional health services

The term ''additional health services'' means services that are not included as required primary health services and that are appropriate to meet the health needs of the population served by the health center involved. Such term may include—

(A) behavioral and mental health and substance abuse services;

(B) recuperative care services;

(C) environmental health services, including—

(i) the detection and alleviation of unhealthful conditions associated with—

(I) water supply;

(II) chemical and pesticide exposures;

(III) air quality; or

(IV) exposure to lead;

(ii) sewage treatment;

(iii) solid waste disposal;

(iv) rodent and parasitic infestation;

(v) field sanitation;

(vi) housing; and

(vii) other environmental factors related to health; and

(D) in the case of health centers receiving grants under subsection (g), special occupation-related health services for migratory and seasonal agricultural workers, including—

(i) screening for and control of infectious diseases, including parasitic diseases; and

(ii) injury prevention programs, including prevention of exposure to unsafe levels of agricultural chemicals including pesticides.

(3) Medically underserved populations

(A) In general

The term ''medically underserved population'' means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.

(B) Criteria

In carrying out subparagraph (A), the Secretary shall prescribe criteria for determining the specific shortages of personal health services of an area or population group. Such criteria shall—

(i) take into account comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of a population group or residents of an area, the ability of the residents of an area or of a population group to pay for health services and their accessibility to them, and the availability of health professionals to residents of an area or to a population group.

(C) Limitation

The Secretary may not designate a medically underserved population in a State or terminate the designation of such a population unless, prior to such designation or termination, the Secretary provides reasonable notice and opportunity for comment and consults with—

(i) the chief executive officer of such State;

(ii) local officials in such State; and

(iii) the organization, if any, which represents a majority of health centers in such State.

(D) Permissible designation

The Secretary may designate a medically underserved population that does not meet the criteria established under subparagraph (B) if the chief executive officer of the State in which such population is located and local officials of such State recommend the designation of such population based on unusual local conditions which are a barrier to access to or the availability of personal health services.

(c) Planning grants

(1) In general

(A) Centers

The Secretary may make grants to public and nonprofit private entities for projects to plan and develop health centers which will serve medically underserved populations. A project for which a grant may be made under this subsection may include the cost of the acquisition and lease of buildings and equipment (including the costs of amortizing the principal of, and paying the interest on, loans) and shall include—

(i) an assessment of the need that the population proposed to be served by the health center for which the project is undertaken has for required primary health services and additional health services;

(ii) the design of a health center program for such population based on such assessment;

(iii) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project;

(iv) initiation and encouragement of continuing community involvement in the development and operation of the project; and

(v) proposed linkages between the center and other appropriate provider entities, such as health departments, local hospitals, and rural health clinics, to provide better coordinated, higher quality, and more cost-effective health care services.

(B) Managed care networks and plans

The Secretary may make grants to health centers that receive assistance under this section to enable the centers to plan and develop a managed care network or plan. Such a grant may only be made for such a center if—

(i) the center has received grants under subsection (e)(1)(A) for at least 2 consecutive years preceding the year of the grant under this subparagraph or has otherwise demonstrated, as required by the Secretary, that such center has been providing primary care services for at least the 2 consecutive years immediately preceding such year; and

(ii) the center provides assurances satisfactory to the Secretary that the provision of such services on a prepaid basis, or under another managed care arrangement, will not result in the diminution of the level or quality of health services provided to the medically underserved population served prior to the grant under this subparagraph.

(C) Practice management networks

The Secretary may make grants to health centers that receive assistance under this section to enable the centers to plan and develop practice management networks that will enable the centers to—

(i) reduce costs associated with the provision of health care services;

(ii) improve access to, and availability of, health care services provided to individuals served by the centers;

(iii) enhance the quality and coordination of health care services; or

(iv) improve the health status of communities.

(D) Use of funds

The activities for which a grant may be made under subparagraph (B) or (C) may include the purchase or lease of equipment, which may include data and information systems (including paying for the costs of amortizing the principal of, and paying the interest on, loans for equipment), the provision of training and technical assistance related to the provision of health care services on a prepaid basis or under another managed care arrangement, and other activities that promote the development of practice management or managed care networks and plans.

(2) Limitation

Not more than two grants may be made under this subsection for the same project, except that upon a showing of good cause, the Secretary may make additional grant awards.

(3) Recognition of high poverty

(A) In general

In making grants under this subsection, the Secretary may recognize the unique needs of high poverty areas.

(B) High poverty area defined

For purposes of subparagraph (A), the term ''high poverty area'' means a catchment area which is established in a manner that is consistent with the factors in subsection (k)(3)(J), and the poverty rate of which is greater than the national average poverty rate as determined by the Bureau of the Census.

(d) Loan guarantee program

(1) Establishment

(A) In general

The Secretary shall establish a program under which the Secretary may, in accordance with this subsection and to the extent that appropriations are provided in advance for such program, guarantee up to 90 percent of the principal and interest on loans made by non-Federal lenders to health centers, funded under this section, for the costs of developing and operating managed care networks or plans described in subsection (c)(1)(B), or practice management networks described in subsection (c)(1)(C).

(B) Use of funds

Loan funds guaranteed under this subsection may be used—

(i) to establish reserves for the furnishing of services on a pre-paid basis;

(ii) for costs incurred by the center or centers, otherwise permitted under this section, as the Secretary determines are necessary to enable a center or centers to develop, operate, and own the network or plan; or

(iii) to refinance an existing loan (as of the date of refinancing) to the center or centers, if the Secretary determines—

(I) that such refinancing will be beneficial to the health center and the Federal Government; or

(II) that the center (or centers) can demonstrate an ability to repay the refinanced loan equal to or greater than the ability of the center (or centers) to repay the original loan on the date the original loan was made.

(C) Publication of guidance

Prior to considering an application submitted under this subsection, the Secretary shall publish guidelines to provide guidance on the implementation of this section. The Secretary shall make such guidelines available to the universe of parties affected under this subsection, distribute such guidelines to such parties upon the request of such parties, and provide a copy of such guidelines to the appropriate committees of Congress.

(D) Provision directly to networks or plans

At the request of health centers receiving assistance under this section, loan guarantees provided under this paragraph may be made directly to networks or plans that are at least majority controlled and, as applicable, at least majority owned by those health centers.

(E) Federal credit reform

The requirements of the Federal Credit Reform Act of 1990 (2 U.S.C. 661 et seq.) shall apply with respect to loans refinanced under subparagraph (B)(iii).

(2) Protection of financial interests

(A) In general

The Secretary may not approve a loan guarantee for a project under this subsection unless the Secretary determines that—

(i) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such percent per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States, except that the Secretary may not require as security any center asset that is, or may be, needed by the center or centers involved to provide health services;

(ii) the loan would not be available on reasonable terms and conditions without the guarantee under this subsection; and

(iii) amounts appropriated for the program under this subsection are sufficient to provide loan guarantees under this subsection.

(B) Recovery of payments

(i) In general

The United States shall be entitled to recover from the applicant for a loan guarantee under this subsection the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery (subject to appropriations remaining available to permit such a waiver) and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made. Amounts recovered under this clause shall be credited as reimbursements to the financing account of the program.

(ii) Modification of terms and conditions

To the extent permitted by clause (iii) and subject to the requirements of section 504(e) of the Credit Reform Act of 1990 (2 U.S.C. 661c(e)), any terms and conditions applicable to a loan guarantee under this subsection (including terms and conditions imposed under clause (iv)) may be modified or waived by the Secretary to the extent the Secretary determines it to be consistent with the financial interest of the United States.

(iii) Incontestability

Any loan guarantee made by the Secretary under this subsection shall be incontestable—

(I) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee; and

(II) as to any person (or successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(iv) Further terms and conditions

Guarantees of loans under this subsection shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this section will be achieved.

(3) Loan origination fees

(A) In general

The Secretary shall collect a loan origination fee with respect to loans to be guaranteed under this subsection, except as provided in subparagraph (C).

(B) Amount

The amount of a loan origination fee collected by the Secretary under subparagraph (A) shall be equal to the estimated long term cost of the loan guarantees involved to the Federal Government (excluding administrative costs), calculated on a net present value basis, after taking into account any appropriations that may be made for the purpose of offsetting such costs, and in accordance with the criteria used to award loan guarantees under this subsection.

(C) Waiver

The Secretary may waive the loan origination fee for a health center applicant who demonstrates to the Secretary that the applicant will be unable to meet the conditions of the loan if the applicant incurs the additional cost of the fee.

(4) Defaults

(A) In general

Subject to the requirements of the Credit Reform Act of 1990[1] (2 U.S.C. 661 et seq.), the Secretary may take such action as may be necessary to prevent a default on a loan guaranteed under this subsection, including the waiver of regulatory conditions, deferral of loan payments, renegotiation of loans, and the expenditure of funds for technical and consultative assistance, for the temporary payment of the interest and principal on such a loan, and for other purposes. Any such expenditure made under the preceding sentence on behalf of a health center or centers shall be made under such terms and conditions as the Secretary shall prescribe, including the implementation of such organizational, operational, and financial reforms as the Secretary determines are appropriate and the disclosure of such financial or other information as the Secretary may require to determine the extent of the implementation of such reforms.

(B) Foreclosure

The Secretary may take such action, consistent with State law respecting foreclosure

[1] See References in Text note below.

procedures and, with respect to reserves required for furnishing services on a prepaid basis, subject to the consent of the affected States, as the Secretary determines appropriate to protect the interest of the United States in the event of a default on a loan guaranteed under this subsection, except that the Secretary may only foreclose on assets offered as security (if any) in accordance with paragraph (2)(A)(i).

(5) Limitation

Not more than one loan guarantee may be made under this subsection for the same network or plan, except that upon a showing of good cause the Secretary may make additional loan guarantees.

(6) Authorization of appropriations

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

(e) Operating grants

(1) Authority

(A) In general

The Secretary may make grants for the costs of the operation of public and nonprofit private health centers that provide health services to medically underserved populations.

(B) Entities that fail to meet certain requirements

The Secretary may make grants, for a period of not to exceed 2 years, for the costs of the operation of public and nonprofit private entities which provide health services to medically underserved populations but with respect to which the Secretary is unable to make each of the determinations required by subsection (k)(3).

(C) Operation of networks and plans

The Secretary may make grants to health centers that receive assistance under this section, or at the request of the health centers, directly to a network or plan (as described in subparagraphs (B) and (C) of subsection (c)(1)) that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under this section, for the costs associated with the operation of such network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment).

(2) Use of funds

The costs for which a grant may be made under subparagraph (A) or (B) of paragraph (1) may include the costs of acquiring and leasing buildings and equipment (including the costs of amortizing the principal of, and paying interest on, loans), and the costs of providing training related to the provision of required primary health services and additional health services and to the management of health center programs.

(3) Construction

The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings or constructing new buildings (including the costs of amortizing the principal of, and paying the interest on, loans) for projects approved prior to October 1, 1996.

(4) Limitation

Not more than two grants may be made under subparagraph (B) of paragraph (1) for the same entity.

(5) Amount

(A) In general

The amount of any grant made in any fiscal year under subparagraphs (A) and (B) of paragraph (1) to a health center shall be determined by the Secretary, but may not exceed the amount by which the costs of operation of the center in such fiscal year exceed the total of—

(i) State, local, and other operational funding provided to the center; and

(ii) the fees, premiums, and third-party reimbursements, which the center may reasonably be expected to receive for its operations in such fiscal year.

(B) Networks and plans

The total amount of grant funds made available for any fiscal year under paragraph (1)(C) and subparagraphs (B) and (C) of subsection (c)(1) to a health center or to a network or plan shall be determined by the Secretary, but may not exceed 2 percent of the total amount appropriated under this section for such fiscal year.

(C) Payments

Payments under grants under subparagraph (A) or (B) of paragraph (1) shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary and adjustments may be made for overpayments or underpayments.

(D) Use of nongrant funds

Nongrant funds described in clauses (i) and (ii) of subparagraph (A), including any such funds in excess of those originally expected, shall be used as permitted under this section, and may be used for such other purposes as are not specifically prohibited under this section if such use furthers the objectives of the project.

(f) Infant mortality grants

(1) In general

The Secretary may make grants to health centers for the purpose of assisting such centers in—

(A) providing comprehensive health care and support services for the reduction of—

(i) the incidence of infant mortality; and

(ii) morbidity among children who are less than 3 years of age; and

(B) developing and coordinating service and referral arrangements between health centers and other entities for the health management of pregnant women and children described in subparagraph (A).

(2) Priority

In making grants under this subsection the Secretary shall give priority to health centers

providing services to any medically underserved population among which there is a substantial incidence of infant mortality or among which there is a significant increase in the incidence of infant mortality.

(3) Requirements

The Secretary may make a grant under this subsection only if the health center involved agrees that—

(A) the center will coordinate the provision of services under the grant to each of the recipients of the services;

(B) such services will be continuous for each such recipient;

(C) the center will provide follow-up services for individuals who are referred by the center for services described in paragraph (1);

(D) the grant will be expended to supplement, and not supplant, the expenditures of the center for primary health services (including prenatal care) with respect to the purpose described in this subsection; and

(E) the center will coordinate the provision of services with other maternal and child health providers operating in the catchment area.

(g) Migratory and seasonal agricultural workers

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of—

(A) migratory agricultural workers, seasonal agricultural workers, and members of the families of such migratory and seasonal agricultural workers who are within a designated catchment area; and

(B) individuals who have previously been migratory agricultural workers but who no longer meet the requirements of subparagraph (A) of paragraph (3) because of age or disability and members of the families of such individuals who are within such catchment area.

(2) Environmental concerns

The Secretary may enter into grants or contracts under this subsection with public and private entities to—

(A) assist the States in the implementation and enforcement of acceptable environmental health standards, including enforcement of standards for sanitation in migratory agricultural worker and seasonal agricultural worker labor camps, and applicable Federal and State pesticide control standards; and

(B) conduct projects and studies to assist the several States and entities which have received grants or contracts under this section in the assessment of problems related to camp and field sanitation, exposure to unsafe levels of agricultural chemicals including pesticides, and other environmental health hazards to which migratory agricultural workers and seasonal agricultural workers, and members of their families, are exposed.

(3) Definitions

For purposes of this subsection:

(A) Migratory agricultural worker

The term ''migratory agricultural worker'' means an individual whose principal employment is in agriculture, who has been so employed within the last 24 months, and who establishes for the purposes of such employment a temporary abode.

(B) Seasonal agricultural worker

The term ''seasonal agricultural worker'' means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(C) Agriculture

The term ''agriculture'' means farming in all its branches, including—

(i) cultivation and tillage of the soil;

(ii) the production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in or on, the land; and

(iii) any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in clause (ii).

(h) Homeless population

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of homeless individuals, including grants for innovative programs that provide outreach and comprehensive primary health services to homeless children and youth and children and youth at risk of homelessness.

(2) Required services

In addition to required primary health services (as defined in subsection (b)(1)), an entity that receives a grant under this subsection shall be required to provide substance abuse services as a condition of such grant.

(3) Supplement not supplant requirement

A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(4) Temporary continued provision of services to certain former homeless individuals

If any grantee under this subsection has provided services described in this section under the grant to a homeless individual, such grantee may, notwithstanding that the individual is no longer homeless as a result of becoming a resident in permanent housing, expend the grant to continue to provide such services to the individual for not more than 12 months.

(5) Definitions

For purposes of this section:

(A) Homeless individual

The term ''homeless individual'' means an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations and an individual who is a resident in transitional housing.

(B) Substance abuse

The term ''substance abuse'' has the same meaning given such term in section 290cc–34(4)[1] of this title.

(C) Substance abuse services

The term ''substance abuse services'' includes detoxification, risk reduction, outpatient treatment, residential treatment, and rehabilitation for substance abuse provided in settings other than hospitals.

(i) Residents of public housing

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of residents of public housing (such term, for purposes of this subsection, shall have the same meaning given such term in section 1437a(b)(1) of this title) and individuals living in areas immediately accessible to such public housing.

(2) Supplement not supplant

A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(3) Consultation with residents

The Secretary may not make a grant under paragraph (1) unless, with respect to the residents of the public housing involved, the applicant for the grant—

(A) has consulted with the residents in the preparation of the application for the grant; and

(B) agrees to provide for ongoing consultation with the residents regarding the planning and administration of the program carried out with the grant.

(j) Access grants

(1) In general

The Secretary may award grants to eligible health centers with a substantial number of clients with limited English speaking proficiency to provide translation, interpretation, and other such services for such clients with limited English speaking proficiency.

(2) Eligible health center

In this subsection, the term ''eligible health center'' means an entity that—

(A) is a health center as defined under subsection (a);

(B) provides health care services for clients for whom English is a second language; and

(C) has exceptional needs with respect to linguistic access or faces exceptional challenges with respect to linguistic access.

(3) Grant amount

The amount of a grant awarded to a center under this subsection shall be determined by the Administrator. Such determination of such amount shall be based on the number of clients for whom English is a second language that is served by such center, and larger grant amounts shall be awarded to centers serving larger numbers of such clients.

(4) Use of funds

An eligible health center that receives a grant under this subsection may use funds received through such grant to—

(A) provide translation, interpretation, and other such services for clients for whom English is a second language, including hiring professional translation and interpretation services; and

(B) compensate bilingual or multilingual staff for language assistance services provided by the staff for such clients.

(5) Application

An eligible health center desiring a grant under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including—

(A) an estimate of the number of clients that the center serves for whom English is a second language;

(B) the ratio of the number of clients for whom English is a second language to the total number of clients served by the center;

(C) a description of any language assistance services that the center proposes to provide to aid clients for whom English is a second language; and

(D) a description of the exceptional needs of such center with respect to linguistic access or a description of the exceptional challenges faced by such center with respect to linguistic access.

(6) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, in addition to any funds authorized to be appropriated or appropriated for health centers under any other subsection of this section, such sums as may be necessary for each of fiscal years 2002 through 2006.

(k) Applications

(1) Submission

No grant may be made under this section unless an application therefore is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe.

(2) Description of need

An application for a grant under subparagraph (A) or (B) of subsection (e)(1) for a health center shall include—

(A) a description of the need for health services in the catchment area of the center;

(B) a demonstration by the applicant that the area or the population group to be served by the applicant has a shortage of personal health services; and

(C) a demonstration that the center will be located so that it will provide services to the greatest number of individuals residing in the catchment area or included in such population group.

Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under subsection (b)(3) or on any other criteria which the Secretary may prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services. In considering an application for a grant under subparagraph (A) or (B) of subsection (e)(1), the Secretary may require as a condition to the approval of such application an assurance that the applicant will provide any health service defined under paragraphs (1) and (2) of subsection (b) that the Secretary finds is needed to meet specific health needs of the area to be served by the applicant. Such a finding shall be made in writing and a copy shall be provided to the applicant.

(3) Requirements

Except as provided in subsection (e)(1)(B), the Secretary may not approve an application for a grant under subparagraph (A) or (B) of subsection (e)(1) unless the Secretary determines that the entity for which the application is submitted is a health center (within the meaning of subsection (a)) and that—

(A) the required primary health services of the center will be available and accessible in the catchment area of the center promptly, as appropriate, and in a manner which assures continuity;

(B) the center has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the center;

(C) the center will have an ongoing quality improvement system that includes clinical services and management, and that maintains the confidentiality of patient records;

(D) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(E) the center—

(i)(I) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan; and

(II) has or will have a contractual or other arrangement with the State agency administering the program under title XXI of such Act (42 U.S.C. 1397aa et seq.) with respect to individuals who are State children's health insurance program beneficiaries; or

(ii) has made or will make every reasonable effort to enter into arrangements described in subclauses (I) and (II) of clause (i);

(F) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.], or to assistance for medical expenses under any other public assistance program or private health insurance program;

(G) the center—

(i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay;

(ii) has made and will continue to make every reasonable effort—

(I) to secure from patients payment for services in accordance with such schedules; and

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;

(iii)(I) will assure that no patient will be denied health care services due to an individual's inability to pay for such services; and

(II) will assure that any fees or payments required by the center for such services will be reduced or waived to enable the center to fulfill the assurance described in subclause (I); and

(iv) has submitted to the Secretary such reports as the Secretary may require to determine compliance with this subparagraph;

(H) the center has established a governing board which except in the case of an entity operated by an Indian tribe or tribal or Indian organization under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.] or an urban Indian organization under the Indian Health Care Improvement Act (25 U.S.C. 1651 et seq.)—

(i) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center;

(ii) meets at least once a month, selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center, and, except in

the case of a governing board of a public center (as defined in the second sentence of this paragraph), establishes general policies for the center; and

(iii) in the case of an application for a second or subsequent grant for a public center, has approved the application or if the governing body has not approved the application, the failure of the governing body to approve the application was unreasonable;

except that, upon a showing of good cause the Secretary shall waive, for the length of the project period, all or part of the requirements of this subparagraph in the case of a health center that receives a grant pursuant to subsection (g), (h), (i), or (p);

(I) the center has developed—

(i) an overall plan and budget that meets the requirements of the Secretary; and

(ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to—

(I) the costs of its operations;

(II) the patterns of use of its services;

(III) the availability, accessibility, and acceptability of its services; and

(IV) such other matters relating to operations of the applicant as the Secretary may require;

(J) the center will review periodically its catchment area to—

(i) ensure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate;

(ii) ensure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs; and

(iii) ensure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation;

(K) in the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, the center has—

(i) developed a plan and made arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals; and

(ii) identified an individual on its staff who is fluent in both that language and in English and whose responsibilities shall include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences;

(L) the center, has developed an ongoing referral relationship with one or more hospitals; and

(M) the center encourages persons receiving or seeking health services from the center to participate in any public or private (including employer-offered) health programs or plans for which the persons are eligible, so long as the center, in complying with this subparagraph, does not violate the requirements of subparagraph (G)(iii)(I).

For purposes of subparagraph (H), the term ''public center'' means a health center funded (or to be funded) through a grant under this section to a public agency.

(4) Approval of new or expanded service applications

The Secretary shall approve applications for grants under subparagraph (A) or (B) of subsection (e)(1) for health centers which—

(A) have not received a previous grant under such subsection; or

(B) have applied for such a grant to expand their services;

in such a manner that the ratio of the medically underserved populations in rural areas which may be expected to use the services provided by such centers to the medically underserved populations in urban areas which may be expected to use the services provided by such centers is not less than two to three or greater than three to two.

(*l*) Technical assistance

The Secretary shall establish a program through which the Secretary shall provide (either through the Department of Health and Human Services or by grant or contract) technical and other assistance to eligible entities to assist such entities to meet the requirements of subsection (k)(3). Services provided through the program may include necessary technical and nonfinancial assistance, including fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the entities of the variety of resources available under this subchapter and how those resources can be best used to meet the health needs of the communities served by the entities.

(m) Memorandum of agreement

In carrying out this section, the Secretary may enter into a memorandum of agreement with a State. Such memorandum may include, where appropriate, provisions permitting such State to—

(1) analyze the need for primary health services for medically underserved populations within such State;

(2) assist in the planning and development of new health centers;

(3) review and comment upon annual program plans and budgets of health centers, including comments upon allocations of health care resources in the State;

(4) assist health centers in the development of clinical practices and fiscal and administrative systems through a technical assistance

plan which is responsive to the requests of health centers; and

(5) share information and data relevant to the operation of new and existing health centers.

(n) Records

(1) In general

Each entity which receives a grant under subsection (e) shall establish and maintain such records as the Secretary shall require.

(2) Availability

Each entity which is required to establish and maintain records under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(*o*) Delegation of authority

The Secretary may delegate the authority to administer the programs authorized by this section to any office, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

(p) Special consideration

In making grants under this section, the Secretary shall give special consideration to the unique needs of sparsely populated rural areas, including giving priority in the awarding of grants for new health centers under subsections (c) and (e), and the granting of waivers as appropriate and permitted under subsections (b)(1)(B)(i) and (k)(3)(G).

(q) Audits

(1) In general

Each entity which receives a grant under this section shall provide for an independent annual financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant and such other funds received by or allocated to the project for which such grant was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with generally accepted accounting principles. Each audit shall evaluate—

(A) the entity's implementation of the guidelines established by the Secretary respecting cost accounting,

(B) the processes used by the entity to meet the financial and program reporting requirements of the Secretary, and

(C) the billing and collection procedures of the entity and the relation of the procedures to its fee schedule and schedule of discounts and to the availability of health insurance and public programs to pay for the health services it provides.

A report of each such audit shall be filed with the Secretary at such time and in such manner as the Secretary may require.

(2) Records

Each entity which receives a grant under this section shall establish and maintain such records as the Secretary shall by regulation require to facilitate the audit required by paragraph (1). The Secretary may specify by regulation the form and manner in which such records shall be established and maintained.

(3) Availability of records

Each entity which is required to establish and maintain records or to provide for and[2] audit under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(4) Waiver

The Secretary may, under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an entity.

(r) Authorization of appropriations

(1) General amounts for grants

For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there is authorized to be appropriated the following:

(A) For fiscal year 2010, $2,988,821,592.

(B) For fiscal year 2011, $3,862,107,440.

(C) For fiscal year 2012, $4,990,553,440.

(D) For fiscal year 2013, $6,448,713,307.

(E) For fiscal year 2014, $7,332,924,155.

(F) For fiscal year 2015, $8,332,924,155.

(G) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(i) one plus the average percentage increase in costs incurred per patient served; and

(ii) one plus the average percentage increase in the total number of patients served.

(2) Special provisions

(A) Public centers

The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sentence of subsection (k)(3)) the governing boards of which (as described in subsection (k)(3)(H)) do not establish general policies

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

for such centers, an amount which exceeds 5 percent of the amounts appropriated under this section for that fiscal year. For purposes of applying the preceding sentence, the term ''public centers'' shall not include health centers that receive grants pursuant to subsection (h) or (i).

(B) Distribution of grants

For fiscal year 2002 and each of the following fiscal years, the Secretary, in awarding grants under this section, shall ensure that the proportion of the amount made available under each of subsections (g), (h), and (i), relative to the total amount appropriated to carry out this section for that fiscal year, is equal to the proportion of the amount made available under that subsection for fiscal year 2001, relative to the total amount appropriated to carry out this section for fiscal year 2001.

(3) Funding report

The Secretary shall annually prepare and submit to the appropriate committees of Congress a report concerning the distribution of funds under this section that are provided to meet the health care needs of medically underserved populations, including the homeless, residents of public housing, and migratory and seasonal agricultural workers, and the appropriateness of the delivery systems involved in responding to the needs of the particular populations. Such report shall include an assessment of the relative health care access needs of the targeted populations and the rationale for any substantial changes in the distribution of funds.

(4) Rule of construction with respect to rural health clinics

(A) In general

Nothing in this section shall be construed to prevent a community health center from contracting with a Federally certified rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act [42 U.S.C. 1395x(aa)(2)]), a low-volume hospital (as defined for purposes of section 1886 of such Act [42 U.S.C. 1395ww]), a critical access hospital, a sole community hospital (as defined for purposes of section 1886(d)(5)(D)(iii) of such Act), or a medicare-dependent share hospital (as defined for purposes of section 1886(d)(5)(G)(iv) of such Act) for the delivery of primary health care services that are available at the clinic or hospital to individuals who would otherwise be eligible for free or reduced cost care if that individual were able to obtain that care at the community health center. Such services may be limited in scope to those primary health care services available in that clinic or hospitals.[3]

(B) Assurances

In order for a clinic or hospital to receive funds under this section through a contract with a community health center under subparagraph (A), such clinic or hospital shall establish policies to ensure—

(i) nondiscrimination based on the ability of a patient to pay; and

(ii) the establishment of a sliding fee scale for low-income patients.

(s) Demonstration program for individualized wellness plans

(1) In general

The Secretary shall establish a pilot program to test the impact of providing at-risk populations who utilize community health centers funded under this section an individualized wellness plan that is designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(2) Agreements

The Secretary shall enter into agreements with not more than 10 community health centers funded under this section to conduct activities under the pilot program under paragraph (1).

(3) Wellness plans

(A) In general

An individualized wellness plan prepared under the pilot program under this subsection may include one or more of the following as appropriate to the individual's identified risk factors:

(i) Nutritional counseling.

(ii) A physical activity plan.

(iii) Alcohol and smoking cessation counseling and services.

(iv) Stress management.

(v) Dietary supplements that have health claims approved by the Secretary.

(vi) Compliance assistance provided by a community health center employee.

(B) Risk factors

Wellness plan risk factors shall include—

(i) weight;

(ii) tobacco and alcohol use;

(iii) exercise rates;

(iv) nutritional status; and

(v) blood pressure.

(C) Comparisons

Individualized wellness plans shall make comparisons between the individual involved and a control group of individuals with respect to the risk factors described in subparagraph (B).

(4) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, such sums as may be necessary.

(July 1, 1944, ch. 373, title III, § 330, as added Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626; amended Pub. L. 107–251, title I, § 101, Oct. 26, 2002, 116 Stat. 1622; Pub. L. 108–163, § 2(a), Dec. 6, 2003, 117 Stat. 2020; Pub. L. 110–355, § 2(a), (c)(1), Oct. 8, 2008, 122 Stat. 3988, 3992; Pub. L. 111–148, title IV, § 4206, title V, § 5601, Mar. 23, 2010, 124 Stat. 576, 676.)

REFERENCES IN TEXT

The Federal Credit Reform Act of 1990, referred to in subsec. (d)(1)(E), is title V of Pub. L. 93–344, as added by

[3] So in original. Probably should be ''hospital''.

Pub. L. 101–508, title XIII, §13201(a), Nov. 5, 1990, 104 Stat. 1388–609, which is classified generally to subchapter III (§661 et seq.) of chapter 17A of Title 2, The Congress. The Credit Reform Act of 1990, referred to in subsec. (d)(4)(A), probably means the Federal Credit Reform Act of 1990. For complete classification of this Act to the Code, see Short Title note set out under section 621 of Title 2 and Tables.

Section 290cc–34 of this title, referred to in subsec. (h)(5)(B), was subsequently amended, and no longer defines the term ''substance abuse''.

The Social Security Act, referred to in subsec. (k)(3)(E)(i), (F), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 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 Indian Self-Determination Act, referred to in subsec. (k)(3)(H), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (k)(3)(H), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, which is classified principally to chapter 18 (§1601 et seq.) of Title 25. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

PRIOR PROVISIONS

A prior section 254a–1, act July 1, 1944, ch. 373, title III, §328, as added Nov. 10, 1978, Pub. L. 95–626, title I, §114, 92 Stat. 3563; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to hospital-affiliated primary care centers, prior to repeal by Pub. L. 99–117, §12(c), Oct. 7, 1985, 99 Stat. 495.

A prior section 254b, act July 1, 1944, ch. 373, title III, §329, formerly §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592; amended Aug. 5, 1965, Pub. L. 89–109, §3, 79 Stat. 436; Oct. 15, 1968, Pub. L. 90–574, title II, §201, 82 Stat. 1006; Mar. 12, 1970, Pub. L. 91–209, 84 Stat. 52; June 18, 1973, Pub. L. 93–45, title I, §105, 87 Stat. 91; renumbered §319, July 23, 1974, Pub. L. 93–353, title I, §102(d), 88 Stat. 362; amended July 29, 1975, Pub. L. 94–63, title IV, §401(a), title VII, §701(c), 89 Stat. 334, 352; Apr. 22, 1976, Pub. L. 94–278, title VIII, §801(a), 90 Stat. 414; Aug. 1, 1977, Pub. L. 95–83, title III, §303, 91 Stat. 388; renumbered §329 and amended Nov. 10, 1978, Pub. L. 95–626, title I, §§102(a), 103(a)–(g)(1)(B), (2), (h), (i), 92 Stat. 3551–3555; July 10, 1979, Pub. L. 96–32, §6(a), 93 Stat. 83; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Aug. 13, 1981, Pub. L. 97–35, title IX, §930, 95 Stat. 569; Dec. 21, 1982, Pub. L. 97–375, title I, §107(b), 96 Stat. 1820; Apr. 24, 1986, Pub. L. 99–280, §§6, 7, 100 Stat. 400, 401; Aug. 10, 1988, Pub. L. 100–386, §2, 102 Stat. 919; Nov. 6, 1990, Pub. L. 101–527, §9(b), 104 Stat. 2333; Oct. 27, 1992, Pub. L. 102–531, title III, §309(a), 106 Stat. 3499, related to migrant health centers, prior to the general amendment of this subpart by Pub. L. 104–299, §2.

Another prior section 254b, act July 1, 1944, ch. 373, title III, §329, as added Dec. 31, 1970, Pub. L. 91–623, §2, 84 Stat. 1868; amended Nov. 18, 1971, Pub. L. 92–157, title II, §203, 85 Stat. 462; Oct. 27, 1972, Pub. L. 92–585, §2, 86 Stat. 1290; July 29, 1975, Pub. L. 94–63, title VIII, §§801–803, 89 Stat. 353, 354; Oct. 12, 1976, Pub. L. 94–484, title I, §101(b), 90 Stat. 2244, related to establishment of National Health Service Corps, assignment of personnel and statement of purpose, prior to repeal by Pub. L. 94–484, title IV, §407(b)(1), Oct. 12, 1976, 90 Stat. 2268. See section 254d et seq. of this title.

A prior section 330 of act July 1, 1944, was classified to section 254c of this title prior to the general amendment of this subpart by Pub. L. 104–299.

AMENDMENTS

2010—Subsec. (r)(1). Pub. L. 111–148, §5601(a), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: ''For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there are authorized to be appropriated—

''(A) $2,065,000,000 for fiscal year 2008;

''(B) $2,313,000,000 for fiscal year 2009;

''(C) $2,602,000,000 for fiscal year 2010;

''(D) $2,940,000,000 for fiscal year 2011; and

''(E) $3,337,000,000 for fiscal year 2012.''

Subsec. (r)(4). Pub. L. 111–148, §5601(b), added par. (4).

Subsec. (s). Pub. L. 111–148, §4206, added subsec. (s).

2008—Subsec. (c)(3). Pub. L. 110–355, §2(c)(1), added par. (3).

Subsec. (r)(1). Pub. L. 110–355, §2(a), amended par. (1) generally. Prior to amendment, text read as follows: ''For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d) of this section, there are authorized to be appropriated $1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006.''

2003—Subsec. (c)(1)(B). Pub. L. 108–163, §2(a)(2)(A), substituted ''plan.'' for ''plan..'' in introductory provisions.

Subsec. (d)(1)(B)(iii)(I). Pub. L. 108–163, §2(a)(2)(B), inserted ''or'' at end.

Subsec. (e)(3) to (5). Pub. L. 108–163, §2(a)(1)(A), amended pars. (3) to (5) to read as if subpar. (C) of the second par. (4) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (j). Pub. L. 108–163, §2(a)(2)(E), added subsec. (j) identical to the subsec. (j) appearing in the amendment by section 101(8)(C) of Pub. L. 107–251. See 2002 Amendment notes below. Former subsec. (j) redesignated (k).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (j) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (j)(3)(H). Pub. L. 108–163, §2(a)(1)(B), amended subpar. (H) to read as if subpar. (C) of par. (7) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (k). Pub. L. 108–163, §2(a)(2)(C), (D), redesignated subsec. (j) as (k) and struck out heading and text of former subsec. (k). Text read as follows: ''The Secretary may provide (either through the Department of Health and Human Services or by grant or contract) all necessary technical and other nonfinancial assistance (including fiscal and program management assistance and training in such management) to any public or private nonprofit entity to assist entities in developing plans for, or operating as, health centers, and in meeting the requirements of subsection (j)(2) of this section.''

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (k) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (*l*). Pub. L. 108–163, §2(a)(2)(H), inserted ''(either through the Department of Health and Human Services or by grant or contract)'' after ''shall provide'' and substituted ''(k)(3)'' for ''(*l*)(3)''.

Pub. L. 108–163, §2(a)(2)(G), added subsec. (*l*) identical to the subsec. (m) appearing in the amendment by section 101(9) of Pub. L. 107–251. See 2002 Amendment notes below. Former subsec. (*l*) redesignated (r).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (*l*) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsecs. (m) to (*o*). Pub. L. 108–163, §2(a)(1)(C), amended subsecs. (m) to (*o*) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (p). Pub. L. 108–163, §2(a)(2)(I), substituted ''(k)(3)(G)'' for ''(j)(3)(G)''.

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (p) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (q). Pub. L. 108–163, §2(a)(1)(C), amended subsec. (q) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (r). Pub. L. 108–163, §2(a)(2)(F), redesignated subsec. (*l*) as (r).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (r) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (r)(1). Pub. L. 108–163, §2(a)(2)(J)(i), substituted ''$1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006'' for ''$802,124,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 through 2001''.

Subsec. (r)(2)(A). Pub. L. 108–163, §2(a)(2)(J)(ii), substituted ''(k)(3)'' for ''(j)(3)'' and ''(k)(3)(H)'' for ''(j)(3)(G)(ii)''.

Subsec. (r)(2)(B). Pub. L. 108–163, §2(a)(2)(J)(iii), added subpar. (B) identical to the subpar. (B) appearing in the amendment by section 101(11)(B)(ii) of Pub. L. 107–251 and struck out heading and text of former subpar. (B) relating to distribution of grants for fiscal years 1997 through 1999. See 2002 Amendment note below.

Subsec. (s). Pub. L. 108–163, §2(a)(1)(C), amended subsec. (s) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

2002—Subsec. (b)(1)(A)(i)(III)(bb). Pub. L. 107–251, §101(1)(A), substituted ''appropriate cancer screening'' for ''screening for breast and cervical cancer''.

Subsec. (b)(1)(A)(ii). Pub. L. 107–251, §101(1)(B), inserted ''(including specialty referral when medically indicated)'' after ''medical services''.

Subsec. (b)(1)(A)(iii). Pub. L. 107–251, §101(1)(C), inserted ''housing,'' after ''social,''.

Subsec. (b)(2)(A). Pub. L. 107–251, §101(2)(C), added subpar. (A). Former subpar. (A) redesignated (C).

Subsec. (b)(2)(A)(i). Pub. L. 107–251, §101(2)(A), substituted ''associated with—'' and subcls. (I) to (IV) for ''associated with water supply;''.

Subsec. (b)(2)(B) to (D). Pub. L. 107–251, §101(2)(B), (C), added subpar. (B) and redesignated former subpars. (A) and (B) as (C) and (D), respectively.

Subsec. (c)(1)(B). Pub. L. 107–251, §101(3)(A)(iii), struck out concluding provisions which read as follows: ''Any such grant may include the acquisition and lease of buildings and equipment which may include data and information systems (including the costs of amortizing the principal of, and paying the interest on, loans), and providing training and technical assistance related to the provision of health services on a prepaid basis or under another managed care arrangement, and for other purposes that promote the development of managed care networks and plans.''

Pub. L. 107–251, §101(3)(A)(ii), in introductory provisions, substituted ''managed care network or plan.'' for ''network or plan for the provision of health services, which may include the provision of health services on a prepaid basis or through another managed care arrangement, to some or to all of the individuals which the centers serve''.

Pub. L. 107–251, §101(3)(A)(i), substituted ''Managed care'' for ''Comprehensive service delivery'' in heading.

Subsec. (c)(1)(C), (D). Pub. L. 107–251, §101(3)(B), added subpars. (C) and (D).

Subsec. (d). Pub. L. 107–251, §101(4)(A), substituted ''Loan guarantee program'' for ''Managed care loan guarantee program'' in heading.

Subsec. (d)(1)(A). Pub. L. 107–251, §101(4)(B)(i), substituted ''up to 90 percent of the principal and interest on loans made by non-Federal lenders to health centers, funded under this section, for the costs of developing and operating managed care networks or plans described in subsection (c)(1)(B), or practice management networks described in subsection (c)(1)(C)'' for ''the principal and interest on loans made by non-Federal lenders to health centers funded under this section for the costs of developing and operating managed care networks or plans''.

Subsec. (d)(1)(B)(iii). Pub. L. 107–251, §101(4)(B)(ii), added cl. (iii).

Subsec. (d)(1)(D), (E). Pub. L. 107–251, §101(4)(B)(iii), added subpars. (D) and (E).

Subsec. (d)(6) to (8). Pub. L. 107–251, §101(4)(C), redesignated par. (8) as (6) and struck out headings and text of former pars. (6) and (7) which related to annual reports and program evaluation, respectively.

Subsec. (e)(1)(B). Pub. L. 107–251, §101(4)(A)(i), substituted ''subsection (k)(3)'' for ''subsection (j)(3)''.

Subsec. (e)(1)(C). Pub. L. 107–251, §101(4)(A)(ii), added subpar. (C).

Subsec. (e)(3). Pub. L. 107–251, §101(4)(C), redesignated par. (4), relating to limitation, as (3).

Subsec. (e)(4). Pub. L. 107–251, §101(4)(C), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (e)(5). Pub. L. 107–251, §101(4)(B), (C), redesignated par. (5) as (4), inserted ''subparagraphs (A) and (B) of'' after ''any fiscal year under'' in subpar. (A), added subpar. (B), and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (g)(2)(A). Pub. L. 107–251, §101(5)(A)(i), inserted ''and seasonal agricultural worker'' after ''migratory agricultural worker''.

Subsec. (g)(2)(B). Pub. L. 107–251, §101(5)(A)(ii), substituted ''and seasonal agricultural workers, and members of their families,'' for ''and members of their families''.

Subsec. (g)(3)(A). Pub. L. 107–251, §101(5)(B), struck out ''on a seasonal basis'' after ''in agriculture''.

Subsec. (h)(1). Pub. L. 107–251, §101(6)(A), substituted ''homeless children and youth and children and youth at risk of homelessness'' for ''homeless children and children at risk of homelessness''.

Subsec. (h)(4). Pub. L. 107–251, §101(6)(B)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (h)(5). Pub. L. 107–251, §101(6)(B)(i), (C), redesignated par. (4) as (5) and substituted '', risk reduction, outpatient treatment, residential treatment, and rehabilitation'' for ''and residential treatment'' in subpar. (C).

Subsec. (j). Pub. L. 107–251, §101(8)(C), added subsec. (j) relating to access grants.

Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (j)(3)(E)(i). Pub. L. 107–251, §101(7)(A)(i), designated existing provisions as subcl. (I) and added subcl. (II).

Subsec. (j)(3)(E)(ii). Pub. L. 107–251, §101(7)(A)(ii), substituted ''arrangements described in subclauses (I) and (II) of clause (i)'' for ''such an arrangement''.

Subsec. (j)(3)(G)(iii), (iv). Pub. L. 107–251, §101(7)(B), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (j)(3)(H). Pub. L. 107–251, §101(7)(C), substituted ''or (q)'' for ''or (p)'' in concluding provisions.

Subsec. (j)(3)(M). Pub. L. 107–251, §101(7)(D)–(F), added subpar. (M).

Subsec. (k). Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (*l*). Pub. L. 107–251, §101(8)(A), redesignated subsec. (*l*) as (s).

Subsec. (m). Pub. L. 107–251, §101(9), which directed striking subsec. (m) (as redesignated by paragraph (9)(B)) and adding a new subsec. (m), could not be executed. The new subsec. (m) to be added read as follows: ''(m) TECHNICAL ASSISTANCE.—The Secretary shall establish a program through which the Secretary shall provide technical and other assistance to eligible entities to assist such entities to meet the requirements of subsection (*l*)(3). Services provided through the program may include necessary technical and nonfinancial assistance, including fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the entities of the variety of resources available under this subchapter and how those

resources can be best used to meet the health needs of the communities served by the entities.''

Pub. L. 107–251, § 101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsecs. (n) to (p). Pub. L. 107–251, § 101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (q). Pub. L. 107–251, § 101(10), which directed the substitution of ''(*l*)(3)(G)'' for ''(j)(3)(G)'' in subsec. (q) ''(as redesignated by paragraph (9)(B))'', could not be executed.

Pub. L. 107–251, § 101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (r). Pub. L. 107–251, § 101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (s). Pub. L. 107–251, § 101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (*o*), and (p) through (s), respectively, could not be executed.

Subsec. (s)(1). Pub. L. 107–251, § 101(11)(A), substituted ''$1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006'' for ''$802,124,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 through 2001''.

Subsec. (s)(2)(A). Pub. L. 107–251, § 101(11)(B)(i), substituted ''(*l*)(3)'' for ''(j)(3)'' and ''(*l*)(3)(H)'' for ''(j)(3)(G)(ii)''.

Subsec. (s)(2)(B). Pub. L. 107–251, § 101(11)(B)(ii), added subpar. (B) and struck out heading and text of former subpar. (B) relating to distribution of grants for fiscal years 1997 through 1999.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–355, § 2(c)(2), Oct. 8, 2008, 122 Stat. 3992, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to grants made on or after January 1, 2009.''

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments 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

Section effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as an Effective Date of 1996 Amendment note under section 233 of this title.

SAVINGS PROVISION FOR CURRENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

Pub. L. 104–299, § 3(b), Oct. 11, 1996, 110 Stat. 3644, provided that: ''The Secretary of Health and Human Services shall ensure the continued funding of grants made, or contracts or cooperative agreements entered into, under subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) (as such subpart existed on the day prior to the date of enactment of this Act [Oct. 11, 1996]), until the expiration of the grant period or the term of the contract or cooperative agreement. Such funding shall be continued under the same terms and conditions as were in effect on the date on which the grant, contract or cooperative agreement was awarded, subject to the availability of appropriations.''

NEGOTIATED RULEMAKING FOR DEVELOPMENT OF METHODOLOGY AND CRITERIA FOR DESIGNATING MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONS SHORTAGE AREAS

Pub. L. 111–148, title V, § 5602, Mar. 23, 2010, 124 Stat. 677, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall establish, through a negotiated rulemaking process under subchapter 3 [III] of chapter 5 of title 5, United States Code, a comprehensive methodology and criteria for designation of—

''(A) medically underserved populations in accordance with section 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3));

''(B) health professions shortage areas under section 332 of the Public Health Service Act (42 U.S.C. 254e).

''(2) FACTORS TO CONSIDER.—In establishing the methodology and criteria under paragraph (1), the Secretary—

''(A) shall consult with relevant stakeholders who will be significantly affected by a rule (such as national, State and regional organizations representing affected entities), State health offices, community organizations, health centers and other affected entities, and other interested parties; and

''(B) shall take into account—

''(i) the timely availability and appropriateness of data used to determine a designation to potential applicants for such designations;

''(ii) the impact of the methodology and criteria on communities of various types and on health centers and other safety net providers;

''(iii) the degree of ease or difficulty that will face potential applicants for such designations in securing the necessary data; and

''(iv) the extent to which the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services.

''(b) PUBLICATION OF NOTICE.—In carrying out the rulemaking process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act [Mar. 23, 2010].

''(c) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subsection (b), and for purposes of this subsection, the 'target date for publication', as referred to in section 564(a)(5) of title 5, United Sates [sic] Code, shall be July 1, 2010.

''(d) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

''(1) the appointment of a negotiated rulemaking committee under section 565(a) of title 5, United States Code, by not later than 30 days after the end of the comment period provided for under section 564(c) of such title; and

''(2) the nomination of a facilitator under section 566(c) of such title 5 by not later than 10 days after the date of appointment of the committee.

''(e) PRELIMINARY COMMITTEE REPORT.—The negotiated rulemaking committee appointed under subsection (d) shall report to the Secretary, by not later than April 1, 2010, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this section through such other methods as the Secretary may provide.

''(f) FINAL COMMITTEE REPORT.—If the committee is not terminated under subsection (e), the rulemaking committee shall submit a report containing a proposed rule by not later than one month before the target publication date.

''(g) INTERIM FINAL EFFECT.—The Secretary shall publish a rule under this section in the Federal Register by not later than the target publication date.

Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 90 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications for such designations pursuant to such rules and consistent with this section.

''(h) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date.''

STUDIES RELATING TO COMMUNITY HEALTH CENTERS

Pub. L. 110–355, §2(b)(1)–(3), Oct. 8, 2008, 122 Stat. 3988, 3989, provided that:

''(1) DEFINITIONS.—For purposes of this subsection—

''(A) the term 'community health center' means a health center receiving assistance under section 330 of the Public Health Service Act (42 U.S.C. 254b); and

''(B) the term 'medically underserved population' has the meaning given that term in such section 330.

''(2) SCHOOL-BASED HEALTH CENTER STUDY.—

''(A) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Oct. 8, 2008], the Comptroller General of the United States shall issue a study of the economic costs and benefits of school-based health centers and the impact on the health of students of these centers.

''(B) CONTENT.—In conducting the study under subparagraph (A), the Comptroller General of the United States shall analyze—

''(i) the impact that Federal funding could have on the operation of school-based health centers;

''(ii) any cost savings to other Federal programs derived from providing health services in school-based health centers;

''(iii) the effect on the Federal Budget and the health of students of providing Federal funds to school-based health centers and clinics, including the result of providing disease prevention and nutrition information;

''(iv) the impact of access to health care from school-based health centers in rural or underserved areas; and

''(v) other sources of Federal funding for school-based health centers.

''(3) HEALTH CARE QUALITY STUDY.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Oct. 8, 2008], the Secretary of Health and Human Services (referred to in this Act [see Short Title of 2008 Amendment note set out under section 201 of this title] as the 'Secretary'), acting through the Administrator of the Health Resources and Services Administration, and in collaboration with the Agency for Healthcare Research and Quality, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes agency efforts to expand and accelerate quality improvement activities in community health centers.

''(B) CONTENT.—The report under subparagraph (A) shall focus on—

''(i) Federal efforts, as of the date of enactment of this Act, regarding health care quality in community health centers, including quality data collection, analysis, and reporting requirements;

''(ii) identification of effective models for quality improvement in community health centers, which may include models that—

''(I) incorporate care coordination, disease management, and other services demonstrated to improve care;

''(II) are designed to address multiple, co-occurring diseases and conditions;

''(III) improve access to providers through non-traditional means, such as the use of remote monitoring equipment;

''(IV) target various medically underserved populations, including uninsured patient populations;

''(V) increase access to specialty care, including referrals and diagnostic testing; and

''(VI) enhance the use of electronic health records to improve quality;

''(iii) efforts to determine how effective quality improvement models may be adapted for implementation by community health centers that vary by size, budget, staffing, services offered, populations served, and other characteristics determined appropriate by the Secretary;

''(iv) types of technical assistance and resources provided to community health centers that may facilitate the implementation of quality improvement interventions;

''(v) proposed or adopted methodologies for community health center evaluations of quality improvement interventions, including any development of new measures that are tailored to safety-net, community-based providers;

''(vi) successful strategies for sustaining quality improvement interventions in the long-term; and

''(vii) partnerships with other Federal agencies and private organizations or networks as appropriate, to enhance health care quality in community health centers.

''(C) DISSEMINATION.—The Administrator of the Health Resources and Services Administration shall establish a formal mechanism or mechanisms for the ongoing dissemination of agency initiatives, best practices, and other information that may assist health care quality improvement efforts in community health centers.''

GUARANTEE STUDY

Pub. L. 107–251, title V, §501, Oct. 26, 2002, 116 Stat. 1664, as amended by Pub. L. 108–163, §2(n)(2), Dec. 6, 2003, 117 Stat. 2023, provided that: ''The Secretary of Health and Human Services shall conduct a study regarding the ability of the Department of Health and Human Services to provide for guarantees of solvency for managed care networks or plans involving health centers receiving funding under section 330 of the Public Health Service Act [42 U.S.C. 254b]. The Secretary shall prepare and submit a report to the appropriate Committees of Congress regarding such ability not later than 2 years after the date of enactment of the Health Care Safety Net Amendments of 2002 [Oct. 26, 2002].''

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Pub. L. 104–299, §4(c), Oct. 11, 1996, 110 Stat. 3645, provided that: ''Whenever any reference is made in any provision of law, regulation, rule, record, or document to a community health center, migrant health center, public housing health center, or homeless health center, such reference shall be considered a reference to a health center.''

LEGISLATIVE PROPOSAL FOR CHANGES CONFORMING TO PUB. L. 104–299

Pub. L. 104–299, §4(e), Oct. 11, 1996, 110 Stat. 3645, provided that: ''After consultation with the appropriate committees of the Congress, the Secretary of Health and Human Services shall prepare and submit to the Congress a legislative proposal in the form of an implementing bill containing technical and conforming amendments to reflect the changes made by this Act [see Short Title of 1996 Amendments note set out under section 201 of this title].''

MEDICARE DEMONSTRATION TO TEST MEDICAL HOMES IN FEDERALLY QUALIFIED HEALTH CENTERS

Memorandum of President of the United States, Dec. 9, 2009, 74 F.R. 66207, provided:

Memorandum for the Secretary of Health And Human Services

My Administration is committed to building a high-quality, efficient health care system and improving access to health care for all Americans. Health centers are a vital part of the health care delivery system. For more than 40 years, health centers have served populations with limited access to health care, treating all patients regardless of ability to pay. These include low-income populations, the uninsured, individuals with limited English proficiency, migrant and seasonal farm workers, individuals and families experiencing homelessness, and individuals living in public housing. There are over 1,100 health centers across the country, delivering care at over 7,500 sites. These centers served more than 17 million patients in 2008 and are estimated to serve more than 20 million patients in 2010.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) provided $2 billion for health centers, including $500 million to expand health centers' services to over 2 million new patients by opening new health center sites, adding new providers, and improving hours of operations. An additional $1.5 billion is supporting much-needed capital improvements, including funding to buy equipment, modernize clinic facilities, expand into new facilities, and adopt or expand the use of health information technology and electronic health records.

One of the key benefits health centers provide to the communities they serve is quality primary health care services. Health centers use interdisciplinary teams to treat the ''whole patient'' and focus on chronic disease management to reduce the use of costlier providers of care, such as emergency rooms and hospitals.

Federally qualified health centers provide an excellent environment to demonstrate the further improvements to health care that may be offered by the medical homes approach. In general, this approach emphasizes the patient's relationship with a primary care provider who coordinates the patient's care and serves as the patient's principal point of contact for care. The medical homes approach also emphasizes activities related to quality improvement, access to care, communication with patients, and care management and coordination. These activities are expected to improve the quality and efficiency of care and to help avoid preventable emergency and inpatient hospital care. Demonstration programs establishing the medical homes approach have been recommended by the Medicare Payment Advisory Commission, an independent advisory body to the Congress.

Therefore, I direct you to implement a Medicare Federally Qualified Health Center Advanced Primary Care Practice demonstration, pursuant to your statutory authority to conduct experiments and demonstrations on changes in payments and services that may improve the quality and efficiency of services to beneficiaries. Health centers participating in this demonstration must have shown their ability to provide comprehensive, coordinated, integrated, and accessible health care.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§ 254b–1. State grants to health care providers who provide services to a high percentage of medically underserved populations or other special populations

(a) In general

A State may award grants to health care providers who treat a high percentage, as determined by such State, of medically underserved populations or other special populations in such State.

(b) Source of funds

A grant program established by a State under subsection (a) may not be established within a department, agency, or other entity of such State that administers the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), and no Federal or State funds allocated to such Medicaid program, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), or the TRICARE program under chapter 55 of title 10 may be used to award grants or to pay administrative costs associated with a grant program established under subsection (a).

(Pub. L. 111–148, title V, § 5606, as added Pub. L. 111–148, title X, § 10501(k), Mar. 23, 2010, 124 Stat. 999.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 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.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254b–2. Community health centers and the National Health Service Corps Fund

(a) Purpose

It is the purpose of this section to establish a Community Health Center Fund (referred to in this section as the ''CHC Fund''), to be administered through the Office of the Secretary of the Department of Health and Human Services to provide for expanded and sustained national investment in community health centers under section 254b of this title and the National Health Service Corps.

(b) Funding

There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—

(1) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the community health center program under section 254b of this title—

(A) $1,000,000,000 for fiscal year 2011;

(B) $1,200,000,000 for fiscal year 2012;

(C) $1,500,000,000 for fiscal year 2013;

(D) $2,200,000,000 for fiscal year 2014;

(E) $3,600,000,000 for each of fiscal years 2015 through 2017; and

(F) $550,000,000 for the period of the first and second quarters of fiscal year 2018; [1]

(2) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the National Health Service Corps—

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

(A) $290,000,000 for fiscal year 2011;
(B) $295,000,000 for fiscal year 2012;
(C) $300,000,000 for fiscal year 2013;
(D) $305,000,000 for fiscal year 2014;
(E) $310,000,000 for each of fiscal years 2015 through 2017; and
(F) $65,000,000 for period of the first and second quarters of fiscal year 2018.

(c) Construction

There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, $1,500,000,000 to be available for fiscal years 2011 through 2015 to be used by the Secretary of Health and Human Services for the construction and renovation of community health centers.

(d) Use of fund

The Secretary of Health and Human Services shall transfer amounts in the CHC Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for community health centers and the National Health Service Corps.

(e) Availability

Amounts appropriated under subsections (b) and (c) shall remain available until expended.

(Pub. L. 111–148, title X, §10503, Mar. 23, 2010, 124 Stat. 1004; Pub. L. 111–152, title II, §2303, Mar. 30, 2010, 124 Stat. 1083; Pub. L. 114–10, title II, §221(a), Apr. 16, 2015, 129 Stat. 154; Pub. L. 115–96, div. C, title I, §3101(a), (b), Dec. 22, 2017, 131 Stat. 2048.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2017—Subsec. (b)(1)(F). Pub. L. 115–96, §3101(a), added subpar. (F).
Subsec. (b)(2)(F). Pub. L. 115–96, §3101(b), added subpar. (F).
2015—Subsec. (b)(1)(E), (2)(E). Pub. L. 114–10 substituted ''for each of fiscal years 2015 through 2017'' for ''for fiscal year 2015''.
2010—Subsec. (b)(1)(A). Pub. L. 111–152, §2303(1), substituted ''1,000,000,000'' for ''700,000,000''.
Subsec. (b)(1)(B). Pub. L. 111–152, §2303(2), substituted ''1,200,000,000'' for ''800,000,000''.
Subsec. (b)(1)(C). Pub. L. 111–152, §2303(3), substituted ''1,500,000,000'' for ''1,000,000,000''.
Subsec. (b)(1)(D). Pub. L. 111–152, §2303(4), substituted ''2,200,000,000'' for ''1,600,000,000''.
Subsec. (b)(1)(E). Pub. L. 111–152, §2303(5), substituted ''3,600,000,000'' for ''2,900,000,000''.

§ 254c. Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs

(a) Purpose

The purpose of this section is to provide grants for expanded delivery of health care services in rural areas, for the planning and implementation of integrated health care networks in rural areas, and for the planning and implementation of small health care provider quality improvement activities.

(b) Definitions

(1) Director

The term ''Director'' means the Director specified in subsection (d).

(2) Federally qualified health center; rural health clinic

The terms ''Federally qualified health center'' and ''rural health clinic'' have the meanings given the terms in section 1395x(aa) of this title.

(3) Health professional shortage area

The term ''health professional shortage area'' means a health professional shortage area designated under section 254e of this title.

(4) Medically underserved community

The term ''medically underserved community'' has the meaning given the term in section 295p(6) of this title.

(5) Medically underserved population

The term ''medically underserved population'' has the meaning given the term in section 254b(b)(3) of this title.

(c) Program

The Secretary shall establish, under section 241 of this title, a small health care provider quality improvement grant program.

(d) Administration

(1) Programs

The rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs established under section 241 of this title shall be administered by the Director of the Office of Rural Health Policy of the Health Resources and Services Administration, in consultation with State offices of rural health or other appropriate State government entities.

(2) Grants

(A) In general

In carrying out the programs described in paragraph (1), the Director may award grants under subsections (e), (f), and (g) to expand access to, coordinate, and improve the quality of essential health care services, and enhance the delivery of health care, in rural areas.

(B) Types of grants

The Director may award the grants—
(i) to promote expanded delivery of health care services in rural areas under subsection (e);
(ii) to provide for the planning and implementation of integrated health care networks in rural areas under subsection (f); and
(iii) to provide for the planning and implementation of small health care provider quality improvement activities under subsection (g).

(e) Rural health care services outreach grants

(1) Grants

The Director may award grants to eligible entities to promote rural health care services

outreach by expanding the delivery of health care services to include new and enhanced services in rural areas. The Director may award the grants for periods of not more than 3 years.

(2) Eligibility

To be eligible to receive a grant under this subsection for a project, an entity—

(A) shall be a rural public or rural nonprofit private entity;

(B) shall represent a consortium composed of members—

(i) that include 3 or more health care providers; and

(ii) that may be nonprofit or for-profit entities; and

(C) shall not previously have received a grant under this subsection for the same or a similar project, unless the entity is proposing to expand the scope of the project or the area that will be served through the project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) a description of the manner in which the project funded under the grant will meet the health care needs of rural underserved populations in the local community or region to be served;

(C) a description of how the local community or region to be served will be involved in the development and ongoing operations of the project;

(D) a plan for sustaining the project after Federal support for the project has ended;

(E) a description of how the project will be evaluated; and

(F) other such information as the Secretary determines to be appropriate.

(f) Rural health network development grants

(1) Grants

(A) In general

The Director may award rural health network development grants to eligible entities to promote, through planning and implementation, the development of integrated health care networks that have combined the functions of the entities participating in the networks in order to—

(i) achieve efficiencies;

(ii) expand access to, coordinate, and improve the quality of essential health care services; and

(iii) strengthen the rural health care system as a whole.

(B) Grant periods

The Director may award such a rural health network development grant for implementation activities for a period of 3 years. The Director may also award such a rural health network development grant for planning activities for a period of 1 year, to assist in the development of an integrated health care network, if the proposed participants in the network do not have a history of collaborative efforts and a 3-year grant would be inappropriate.

(2) Eligibility

To be eligible to receive a grant under this subsection, an entity—

(A) shall be a rural public or rural nonprofit private entity;

(B) shall represent a network composed of participants—

(i) that include 3 or more health care providers; and

(ii) that may be nonprofit or for-profit entities; and

(C) shall not previously have received a grant under this subsection (other than a grant for planning activities) for the same or a similar project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of—

(i) the history of collaborative activities carried out by the participants in the network;

(ii) the degree to which the participants are ready to integrate their functions; and

(iii) how the local community or region to be served will benefit from and be involved in the activities carried out by the network;

(D) a description of how the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the integration activities carried out by the network;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(g) Small health care provider quality improvement grants

(1) Grants

The Director may award grants to provide for the planning and implementation of small health care provider quality improvement activities. The Director may award the grants for periods of 1 to 3 years.

(2) Eligibility

To be eligible for a grant under this subsection, an entity—

(A)(i) shall be a rural public or rural nonprofit private health care provider or provider of health care services, such as a critical access hospital or a rural health clinic; or

(ii) shall be another rural provider or network of small rural providers identified by the Secretary as a key source of local care; and

(B) shall not previously have received a grant under this subsection for the same or a similar project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of the manner in which the project funded under the grant will assure continuous quality improvement in the provision of services by the entity;

(D) a description of how the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the activities carried out by the entity;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(4) Expenditures for small health care provider quality improvement grants

In awarding a grant under this subsection, the Director shall ensure that the funds made available through the grant will be used to provide services to residents of rural areas. The Director shall award not less than 50 percent of the funds made available under this subsection to providers located in and serving rural areas.

(h) General requirements

(1) Prohibited uses of funds

An entity that receives a grant under this section may not use funds provided through the grant—

(A) to build or acquire real property; or

(B) for construction.

(2) Coordination with other agencies

The Secretary shall coordinate activities carried out under grant programs described in this section, to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar grant programs, to maximize the effect of public dollars in funding meritorious proposals.

(3) Preference

In awarding grants under this section, the Secretary shall give preference to entities that—

(A) are located in health professional shortage areas or medically underserved communities, or serve medically underserved populations; or

(B) propose to develop projects with a focus on primary care, and wellness and prevention strategies.

(i) Report

Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsections (e), (f), and (g).

(j) Authorization of appropriations

There are authorized to be appropriated to carry out this section $45,000,000 for each of fiscal years 2008 through 2012.

(July 1, 1944, ch. 373, title III, §330A, as added Pub. L. 104–299, §3(a), Oct. 11, 1996, 110 Stat. 3642; amended Pub. L. 107–251, title II, §201, Oct. 26, 2002, 116 Stat. 1628; Pub. L. 108–163, §2(b), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 110–355, §4, Oct. 8, 2008, 122 Stat. 3994.)

PRIOR PROVISIONS

A prior section 254c, act July 1, 1944, ch. 373, title III, §330, as added July 29, 1975, Pub. L. 94–63, title V, §501(a), 89 Stat. 342; amended Apr. 22, 1976, Pub. L. 94–278, title VIII, §801(b), 90 Stat. 415; Aug. 1, 1977, Pub. L. 95–83, title III, §304, 91 Stat. 388; Nov. 10, 1978, Pub. L. 95–626, title I, §104(a)–(d)(3)(B), (4), (5), (e), (f), 92 Stat. 3556–3559; July 10, 1979, Pub. L. 96–32, §§6(b)–(d), 7(c), 93 Stat. 83, 84; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Oct. 19, 1980, Pub. L. 96–470, title I, §106(e), 94 Stat. 2238; Aug. 13, 1981, Pub. L. 97–35, title IX, §§903(a), 905, 906, 95 Stat. 561, 562; Jan. 4, 1983, Pub. L. 97–414, §8(e), 96 Stat. 2060; Apr. 24, 1986, Pub. L. 99–280, §§2–4, 100 Stat. 399, 400; Aug. 10, 1988, Pub. L. 100–386, §§3, 4, 102 Stat. 921, 923; Nov. 4, 1988, Pub. L. 100–607, title I, §163(3), 102 Stat. 3062; Dec. 19, 1989, Pub. L. 101–239, title VI, §6103(e)(5), 103 Stat. 2207; Nov. 6, 1990, Pub. L. 101–527, §9(a), 104 Stat. 2332; Oct. 27, 1992, Pub. L. 102–531, title III, §309(b), 106 Stat. 3500, related to community health centers, prior to the general amendment of this subpart by Pub. L. 104–299, §2.

AMENDMENTS

2008—Subsec. (j). Pub. L. 110–355 substituted ''$45,000,000 for each of fiscal years 2008 through 2012.'' for ''$40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.''

2003—Subsec. (b)(4). Pub. L. 108–163 substituted ''section 295p(6)'' for ''section 295p''.

2002—Pub. L. 107–251 amended section generally. Prior to amendment, section related to a rural health outreach, network development, and telemedicine grant program, and in subsec. (a), provided for administration by the Office of Rural Health Policy; in subsec. (b), set out the objectives of grants; in subsec. (c), set out eligibility requirements; in subsec. (d), described preferred characteristics of applicant networks; in subsec. (e), specified permitted uses of grant funds; in subsec. (f), limited the duration of grants; and in subsec. (g), authorized 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.

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as an Effective Date of 1996 Amendment note under section 233 of this title.

RURAL ACCESS TO EMERGENCY DEVICES

Pub. L. 106–505, title IV, subtitle B, Nov. 13, 2000, 114 Stat. 2340, provided that:

''SEC. 411. SHORT TITLE.

''This subtitle may be cited as the 'Rural Access to Emergency Devices Act' or the 'Rural AED Act'.

''SEC. 412. FINDINGS.

''Congress makes the following findings:

''(1) Heart disease is the leading cause of death in the United States.

''(2) The American Heart Association estimates that 250,000 Americans die from sudden cardiac arrest each year.

''(3) A cardiac arrest victim's chance of survival drops 10 percent for every minute that passes before his or her heart is returned to normal rhythm.

''(4) Because most cardiac arrest victims are initially in ventricular fibrillation, and the only treatment for ventricular fibrillation is defibrillation, prompt access to defibrillation to return the heart to normal rhythm is essential.

''(5) Lifesaving technology, the automated external defibrillator, has been developed to allow trained lay rescuers to respond to cardiac arrest by using this simple device to shock the heart into normal rhythm.

''(6) Those people who are likely to be first on the scene of a cardiac arrest situation in many communities, particularly smaller and rural communities, lack sufficient numbers of automated external defibrillators to respond to cardiac arrest in a timely manner.

''(7) The American Heart Association estimates that more than 50,000 deaths could be prevented each year if defibrillators were more widely available to designated responders.

''(8) Legislation should be enacted to encourage greater public access to automated external defibrillators in communities across the United States.

''SEC. 413. GRANTS.

''(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Rural Health Outreach Office of the Health Resources and Services Administration, shall award grants to community partnerships that meet the requirements of subsection (b) to enable such partnerships to purchase equipment and provide training as provided for in subsection (c).

''(b) COMMUNITY PARTNERSHIPS.—A community partnership meets the requirements of this subsection if such partnership—

''(1) is composed of local emergency response entities such as community training facilities, local emergency responders, fire and rescue departments, police, community hospitals, and local non-profit entities and for-profit entities concerned about cardiac arrest survival rates;

''(2) evaluates the local community emergency response times to assess whether they meet the standards established by national public health organizations such as the American Heart Association and the American Red Cross; and

''(3) submits to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) USE OF FUNDS.—Amounts provided under a grant under this section shall be used—

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

''(2) to provide defibrillator and basic life support training in automated external defibrillator usage through the American Heart Association, the American Red Cross, or other nationally recognized training courses.

''(d) REPORT.—Not later than 4 years after the date of the enactment of this Act [Nov. 13, 2000], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether the increased availability of defibrillators has affected survival rates in the communities in which grantees under this section operated. The procedures under which the Secretary obtains data and prepares the report under this subsection shall not impose an undue burden on program participants under this section.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $25,000,000 for fiscal years 2001 through 2003 to carry out this section.''

REPORT ON TELEMEDICINE

Pub. L. 106–129, § 6, Dec. 6, 1999, 113 Stat. 1675, provided that: ''Not later than January 10, 2001, the Secretary of Health and Human Services shall submit to the Congress a report that—

''(1) identifies any factors that inhibit the expansion and accessibility of telemedicine services, including factors relating to telemedicine networks;

''(2) identifies any factors that, in addition to geographical isolation, should be used to determine which patients need or require access to telemedicine care;

''(3) determines the extent to which—

''(A) patients receiving telemedicine service have benefited from the services, and are satisfied with the treatment received pursuant to the services; and

''(B) the medical outcomes for such patients would have differed if telemedicine services had not been available to the patients;

''(4) determines the extent to which physicians involved with telemedicine services have been satisfied with the medical aspects of the services;

''(5) determines the extent to which primary care physicians are enhancing their medical knowledge and experience through the interaction with specialists provided by telemedicine consultations; and

''(6) identifies legal and medical issues relating to State licensing of health professionals that are presented by telemedicine services, and provides any recommendations of the Secretary for responding to such issues.''

§ 254c–1. Grants for health services for Pacific Islanders

(a) Grants

The Secretary of Health and Human Services (hereafter in this section referred to as the ''Secretary'') shall provide grants to, or enter into contracts with, public or private nonprofit agencies that have demonstrated experience in serving the health needs of Pacific Islanders living in the Territory of American Samoa, the Commonwealth of Northern Mariana Islands, the Territory of Guam, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia.

(b) Use of grants or contracts

Grants or contracts made or entered into under subsection (a) shall be used, among other items—

(1) to continue, as a priority, the medical officer training program in Pohnpei, Federated States of Micronesia;

(2) to improve the quality and availability of health and mental health services and sys-

tems, with an emphasis therein on preventive health services and health promotion programs and projects, including improved health data systems;

(3) to improve the quality and availability of health manpower, including programs and projects to train new and upgrade the skills of existing health professionals by—

(A) establishing dental officer, dental assistant, nurse practitioner, or nurse clinical specialist training programs;

(B) providing technical training of new auxiliary health workers;

(C) upgrading the training of currently employed health personnel in special areas of need;

(D) developing long-term plans for meeting health profession needs;

(E) developing or improving programs for faculty enhancement or post-doctoral training; and

(F) providing innovative health professions training initiatives (including scholarships) targeted toward ensuring that residents of the Pacific Basin attend and graduate from recognized health professional programs;

(4) to improve the quality of health services, including laboratory, x-ray, and pharmacy, provided in ambulatory and inpatient settings through quality assurance, standard setting, and other culturally appropriate means;

(5) to improve facility and equipment repair and maintenance systems;

(6) to improve alcohol, drug abuse, and mental health prevention and treatment services and systems;

(7) to improve local and regional health planning systems; and

(8) to improve basic local public health systems, with particular attention to primary care and services to those most in need.

No funds under subsection (b) shall be used for capital construction.

(c) Advisory Council

The Secretary of Health and Human Services shall establish a ''Pacific Health Advisory Council'' which shall consist of 12 members and shall include—

(1) the Directors of the Health Departments for the entities identified in subsection (a); and

(2) 6 members, including a representative of the Rehabilitation Hospital of the Pacific, representing organizations in the State of Hawaii actively involved in the provision of health services or technical assistance to the entities identified in subsection (a). The Secretary shall solicit the advice of the Governor of the State of Hawaii in appointing the 5 Council members in addition to the representative of the Rehabilitation Hospital of the Pacific from the State of Hawaii.

The Secretary shall be responsible for providing sufficient staff support to the Council.

(d) Advisory Council functions

The Council shall meet at least annually to—

(1) recommend priority areas of need for funding by the Public Health Service under this section; and

(2) review progress in addressing priority areas and make recommendations to the Secretary for needed program modifications.

(e) Omitted

(f) Authorization of appropriation

There is authorized to be appropriated to carry out this section $10,000,000 for each of the fiscal years 1991 through 1993.

(Pub. L. 101–527, § 10, Nov. 6, 1990, 104 Stat. 2333.)

CODIFICATION

Section was enacted as part of the Disadvantaged Minority Health Improvement Act of 1990, and not as part of the Public Health Service Act which comprises this chapter.

Subsec. (e) of this section, which required the Secretary, in consultation with the Council, to annually prepare and submit to appropriate committees of Congress a report describing the expenditure of funds authorized to be appropriated under this section, with any recommendations of the Secretary, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 95 of House Document No. 103–7.

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.

§ 254c–1a. Grants to nurse-managed health clinics

(a) Definitions

(1) Comprehensive primary health care services

In this section, the term ''comprehensive primary health care services'' means the primary health services described in section 254b(b)(1) of this title.

(2) Nurse-managed health clinic

The term ''nurse-managed health clinic'' means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

(b) Authority to award grants

The Secretary shall award grants for the cost of the operation of nurse-managed health clinics that meet the requirements of this section.

(c) Applications

To be eligible to receive a grant under this section, an entity shall—

(1) be an NMHC; and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) assurances that nurses are the major providers of services at the NMHC and that at least 1 advanced practice nurse holds an executive management position within the organizational structure of the NMHC;

(B) an assurance that the NMHC will continue providing comprehensive primary health care services or wellness services without regard to income or insurance status of the patient for the duration of the grant period; and

(C) an assurance that, not later than 90 days of receiving a grant under this section, the NMHC will establish a community advisory committee, for which a majority of the members shall be individuals who are served by the NMHC.

(d) Grant amount

The amount of any grant made under this section for any fiscal year shall be determined by the Secretary, taking into account—

(1) the financial need of the NMHC, considering State, local, and other operational funding provided to the NMHC; and

(2) other factors, as the Secretary determines appropriate.

(e) Authorization of appropriations

For the purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for the fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.

(July 1, 1944, ch. 373, title III, § 330A–1, as added Pub. L. 111–148, title V, § 5208(b), Mar. 23, 2010, 124 Stat. 613.)

PURPOSE

Pub. L. 111–148, title V, § 5208(a), Mar. 23, 2010, 124 Stat. 612, provided that: ''The purpose of this section [enacting this section] is to fund the development and operation of nurse-managed health clinics.''

§ 254c–2. Special diabetes programs for type I diabetes

(a) In general

The Secretary, directly or through grants, shall provide for research into the prevention and cure of Type[1] I diabetes.

(b) Funding

(1) Transferred funds

Notwithstanding section 1397dd(a) of this title, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000 is hereby transferred and made available in such fiscal year for grants under this section.

(2) Appropriations

For the purpose of making grants under this section, there is appropriated, out of any funds in the Treasury not otherwise appropriated—

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003;

(C) $150,000,000 for each of fiscal years 2004 through 2017; and

(D) $37,500,000 for the period of the first and second quarters of fiscal year 2018, to remain available until expended.

(July 1, 1944, ch. 373, title III, § 330B, as added Pub. L. 105–33, title IV, § 4921, Aug. 5, 1997, 111 Stat. 574; amended Pub. L. 105–34, title XVI, § 1604(f)(1)(B), (C), Aug. 5, 1997, 111 Stat. 1098; Pub. L. 106–554, § 1(a)(6) [title IX, § 931(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, § 1(a), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 110–173, title III, § 302(a), Dec. 29, 2007, 121 Stat. 2514; Pub. L. 110–275, title III, § 303(a), July 15, 2008, 122 Stat. 2594; Pub. L. 111–309, title I, § 112(1), Dec. 15, 2010, 124 Stat. 3289; Pub. L. 112–240, title VI, § 625(a), Jan. 2, 2013, 126 Stat. 2352; Pub. L. 113–93, title II, § 204(a), Apr. 1, 2014, 128 Stat. 1046; Pub. L. 114–10, title II, § 213(a), Apr. 16, 2015, 129 Stat. 152; Pub. L. 115–96, div. C, title I, § 3102(a), Dec. 22, 2017, 131 Stat. 2049.)

AMENDMENTS

2017—Subsec. (b)(2)(D). Pub. L. 115–96 added subpar. (D).

2015—Subsec. (b)(2)(C). Pub. L. 114–10 substituted ''2017'' for ''2015''.

2014—Subsec. (b)(2)(C). Pub. L. 113–93 substituted ''2015'' for ''2014''.

2013—Subsec. (b)(2)(C). Pub. L. 112–240 substituted ''2014'' for ''2013''.

2010—Subsec. (b)(2)(C). Pub. L. 111–309 substituted ''2013'' for ''2011''.

2008—Subsec. (b)(2)(C). Pub. L. 110–275 substituted ''2011'' for ''2009''.

2007—Subsec. (b)(2)(C). Pub. L. 110–173 substituted ''2009'' for ''2008''.

2002—Subsec. (b)(2)(C). Pub. L. 107–360 added subpar. (C).

2000—Subsec. (b). Pub. L. 106–554 designated existing provisions as par. (1), inserted par. heading, and added par. (2).

1997—Pub. L. 105–34, § 1604(f)(1)(B), amended directory language of Pub. L. 105–33, § 4921, which enacted this section.

Pub. L. 105–34, § 1604(f)(1)(C)(i), struck out ''children with'' before ''type I diabetes'' in section catchline.

Subsec. (a). Pub. L. 105–34, § 1604(f)(1)(C)(ii), amended heading and text of subsec. (a) generally. Prior to amendment, text read as follows: ''The Secretary shall make grants for services for the prevention and treatment of type I diabetes in children, and for research in innovative approaches to such services. Such grants may be made to children's hospitals; grantees under section 254b of this title and other federally qualified health centers; State and local health departments; and other appropriate public or nonprofit private entities.''

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–34, title XVI, § 1604(f)(4), Aug. 5, 1997, 111 Stat. 1099, provided that: ''The provisions of, and amendments made by, this subsection [amending this section and provisions set out as a note under section 5701 of Title 26, Internal Revenue Code] shall take effect immediately after the sections referred to in this subsection [sections 4921, 9302, 11104, and 11201 of Pub. L. 105–33] take effect.''

REPORT ON DIABETES GRANT PROGRAMS

Pub. L. 105–33, title IV, § 4923, Aug. 5, 1997, 111 Stat. 574, as amended by Pub. L. 106–554, § 1(a)(6) [title IX, § 931(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, § 1(c), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 109–482, title I, § 104(b)(3)(C), Jan. 15, 2007, 120 Stat. 3694; Pub. L. 110–275, title III, § 303(c), July 15, 2008, 122 Stat. 2594, provided that:

[1] So in original. Probably should not be capitalized.

''(a) EVALUATION.—The Secretary of Health and Human Services shall conduct an evaluation of the diabetes grant programs established under the amendments made by this chapter [chapter 3 (§§ 4921–4923) of subtitle J of title IV of Pub. L. 105–33, enacting this section and section 254c–3 of this title].

''[(b) Repealed. Pub. L. 109–482, title I, § 104(b)(3)(C), Jan. 15, 2007, 120 Stat. 3694.]''

[Pub. L. 110–275, § 303(c), which directed amendment of section 4923(b) of Pub. L. 105–33 by substituting ''a second interim report'' for ''a final report'' in par. (2) and by adding par. (3) at end to read ''a report on such evaluation not later than January 1, 2011.'', could not be executed because of prior repeal.]

§ 254c–3. Special diabetes programs for Indians

(a) In general

The Secretary shall make grants for providing services for the prevention and treatment of diabetes in accordance with subsection (b).

(b) Services through Indian health facilities

For purposes of subsection (a), services under such subsection are provided in accordance with this subsection if the services are provided through any of the following entities:

(1) The Indian Health Service.

(2) An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self-Determination Act [25 U.S.C. 5321 et seq.].

(3) An urban Indian health program operated by an urban Indian organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(c) Funding

(1) Transferred funds

Notwithstanding section 1397dd(a) of this title, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000, to remain available until expended, is hereby transferred and made available in such fiscal year for grants under this section.

(2) Appropriations

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

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003;

(C) $150,000,000 for each of fiscal years 2004 through 2017; and

(D) $37,500,000 for the first quarter of fiscal year 2018 and $37,500,000 for the second quarter of fiscal year 2018.

(July 1, 1944, ch. 373, title III, § 330C, as added Pub. L. 105–33, title IV, § 4922, Aug. 5, 1997, 111 Stat. 574; amended Pub. L. 105–174, title III, § 3001, May 1, 1998, 112 Stat. 82; Pub. L. 106–554, § 1(a)(6) [title IX, § 931(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, § 1(b), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 110–173, title III, § 302(b), Dec. 29, 2007, 121 Stat. 2515; Pub. L. 110–275, title III, § 303(b), July 15, 2008, 122 Stat. 2594; Pub. L. 111–309, title I, § 112(2), Dec. 15, 2010, 124 Stat. 3289; Pub. L. 112–240, title VI, § 625(b), Jan. 2, 2013, 126 Stat. 2353; Pub. L. 113–93, title II, § 204(b), Apr. 1, 2014, 128 Stat. 1046; Pub. L. 114–10, title II, § 213(b), Apr. 16, 2015, 129 Stat. 152; Pub. L. 115–63, title III, § 301(b), Sept. 29, 2017, 131 Stat. 1172; Pub. L. 115–96, div. C, title I, § 3102(b), Dec. 22, 2017, 131 Stat. 2049.)

REFERENCES IN TEXT

The Indian Self-Determination Act, referred to in subsec. (b)(2), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§ 5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (b)(3), 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.

AMENDMENTS

2017—Subsec. (c)(2)(D). Pub. L. 115–96 inserted ''and $37,500,000 for the second quarter of fiscal year 2018'' before period at end.

Pub. L. 115–63 added subpar. (D).

2015—Subsec. (c)(2)(C). Pub. L. 114–10 substituted ''2017'' for ''2015''.

2014—Subsec. (c)(2)(C). Pub. L. 113–93 substituted ''2015'' for ''2014''.

2013—Subsec. (c)(2)(C). Pub. L. 112–240 substituted ''2014'' for ''2013''.

2010—Subsec. (c)(2)(C). Pub. L. 111–309 substituted ''2013'' for ''2011''.

2008—Subsec. (c)(2)(C). Pub. L. 110–275 substituted ''2011'' for ''2009''.

2007—Subsec. (c)(2)(C). Pub. L. 110–173 substituted ''2009'' for ''2008''.

2002—Subsec. (c)(2)(C). Pub. L. 107–360 added subpar. (C).

2000—Subsec. (c). Pub. L. 106–554 designated existing provisions as par. (1), inserted par. heading, and added par. (2).

1998—Subsec. (c). Pub. L. 105–174 inserted '', to remain available until expended,'' after ''fiscal years 1998 through 2002, $30,000,000''.

FUNDS AVAILABLE UNTIL EXPENDED

Pub. L. 108–7, div. F, title II, Feb. 20, 2003, 117 Stat. 261, provided in part ''That funds appropriated under the Special Diabetes Program for Indians (42 U.S.C. 254c–3(c)) for fiscal year 2003 and thereafter for the purpose of making grants shall remain available until expended''.

§ 254c–4. Centers for strategies on facilitating utilization of preventive health services among various populations

(a) In general

The Secretary, acting through the appropriate agencies of the Public Health Service, shall make grants to public or nonprofit private entities for the establishment and operation of regional centers whose purpose is to develop, evaluate, and disseminate effective strategies, which utilize quality management measures, to assist public and private health care programs and providers in the appropriate utilization of preventive health care services by specific populations.

(b) Research and training

The activities carried out by a center under subsection (a) may include establishing programs of research and training with respect to the purpose described in such subsection, including the development of curricula for training individuals in implementing the strategies developed under such subsection.

(c) Priority regarding infants and children

In carrying out the purpose described in subsection (a), the Secretary shall give priority to various populations of infants, young children, and their mothers.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2000 through 2004.

(July 1, 1944, ch. 373, title III, § 330D, as added Pub. L. 106–129, § 3, Dec. 6, 1999, 113 Stat. 1670.)

§ 254c–5. Epilepsy; seizure disorder

(a) National public health campaign

(1) In general

The Secretary shall develop and implement public health surveillance, education, research, and intervention strategies to improve the lives of persons with epilepsy, with a particular emphasis on children. Such projects may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(2) Certain activities

Activities under paragraph (1) shall include—

(A) expanding current surveillance activities through existing monitoring systems and improving registries that maintain data on individuals with epilepsy, including children;

(B) enhancing research activities on the diagnosis, treatment, and management of epilepsy;

(C) implementing public and professional information and education programs regarding epilepsy, including initiatives which promote effective management of the disease through children's programs which are targeted to parents, schools, daycare providers, patients;

(D) undertaking educational efforts with the media, providers of health care, schools and others regarding stigmas and secondary disabilities related to epilepsy and seizures, and its effects on youth;

(E) utilizing and expanding partnerships with organizations with experience addressing the health and related needs of people with disabilities; and

(F) other activities the Secretary deems appropriate.

(3) Coordination of activities

The Secretary shall ensure that activities under this subsection are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding epilepsy and seizure.

(b) Seizure disorder; demonstration projects in medically underserved areas

(1) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants for the purpose of carrying out demonstration projects to improve access to health and other services regarding seizures to encourage early detection and treatment in children and others residing in medically underserved areas.

(2) Application for grant

A grant may not be awarded under paragraph (1) unless an application therefore is submitted to the Secretary and the Secretary approves such application. Such application shall be submitted in such form and manner and shall contain such information as the Secretary may prescribe.

(c) Definitions

For purposes of this section:

(1) The term ''epilepsy'' refers to a chronic and serious neurological condition characterized by excessive electrical discharges in the brain causing recurring seizures affecting all life activities. The Secretary may revise the definition of such term to the extent the Secretary determines necessary.

(2) The term ''medically underserved'' has the meaning applicable under section 295p(6) 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, § 330E, as added Pub. L. 106–310, div. A, title VIII, § 801, Oct. 17, 2000, 114 Stat. 1124.)

§ 254c–6. Certain services for pregnant women

(a) Infant adoption awareness

(1) In general

The Secretary shall make grants to national, regional, or local adoption organizations for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(2) Best-practices guidelines

(A) In general

A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree that, in providing training under such paragraph, the organization will follow the guidelines developed under subparagraph (B).

(B) Process for development of guidelines

(i) In general

The Secretary shall establish and supervise a process described in clause (ii) in which the participants are—

(I) an appropriate number and variety of adoption organizations that, as a group, have expertise in all models of adoption practice and that represent all members of the adoption triad (birth mother, infant, and adoptive parent); and

(II) affected public health entities.

(ii) Description of process

The process referred to in clause (i) is a process in which the participants described in such clause collaborate to develop best-practices guidelines on the provision of adoption information and referrals to pregnant women on an equal basis with all other courses of action included in non-directive counseling to pregnant women.

(iii) Date certain for development

The Secretary shall ensure that the guidelines described in clause (ii) are developed not later than 180 days after October 17, 2000.

(C) Relation to authority for grants

The Secretary may not make any grant under paragraph (1) before the date on which the guidelines under subparagraph (B) are developed.

(3) Use of grant

(A) In general

With respect to a grant under paragraph (1)—

(i) an adoption organization may expend the grant to carry out the programs directly or through grants to or contracts with other adoption organizations;

(ii) the purposes for which the adoption organization expends the grant may include the development of a training curriculum, consistent with the guidelines developed under paragraph (2)(B); and

(iii) a condition for the receipt of the grant is that the adoption organization agree that, in providing training for the designated staff of eligible health centers, such organization will make reasonable efforts to ensure that the individuals who provide the training are individuals who are knowledgeable in all elements of the adoption process and are experienced in providing adoption information and referrals in the geographic areas in which the eligible health centers are located, and that the designated staff receive the training in such areas.

(B) Rule of construction regarding training of trainers

With respect to individuals who under a grant under paragraph (1) provide training for the designated staff of eligible health centers (referred to in this subparagraph as ''trainers''), subparagraph (A)(iii) may not be construed as establishing any limitation regarding the geographic area in which the trainers receive instruction in being such trainers. A trainer may receive such instruction in a different geographic area than the area in which the trainer trains (or will train) the designated staff of eligible health centers.

(4) Adoption organizations; eligible health centers; other definitions

For purposes of this section:

(A) The term ''adoption organization'' means a national, regional, or local organization—

(i) among whose primary purposes are adoption;

(ii) that is knowledgeable in all elements of the adoption process and on providing adoption information and referrals to pregnant women; and

(iii) that is a nonprofit private entity.

(B) The term ''designated staff'', with respect to an eligible health center, means staff of the center who provide pregnancy or adoption information and referrals (or will provide such information and referrals after receiving training under a grant under paragraph (1)).

(C) The term ''eligible health centers'' means public and nonprofit private entities that provide health services to pregnant women.

(5) Training for certain eligible health centers

A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree to make reasonable efforts to ensure that the eligible health centers with respect to which training under the grant is provided include—

(A) eligible health centers that receive grants under section 300 of this title (relating to voluntary family planning projects);

(B) eligible health centers that receive grants under section 254b of this title (relating to community health centers, migrant health centers, and centers regarding homeless individuals and residents of public housing); and

(C) eligible health centers that receive grants under this chapter for the provision of services in schools.

(6) Participation of certain eligible health clinics

In the case of eligible health centers that receive grants under section 254b or 300 of this title:

(A) Within a reasonable period after the Secretary begins making grants under paragraph (1), the Secretary shall provide eligible health centers with complete information about the training available from organizations receiving grants under such paragraph. The Secretary shall make reasonable efforts to encourage eligible health centers to arrange for designated staff to participate in such training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.

(B) All costs of such centers in obtaining the training shall be reimbursed by the organization that provides the training, using grants under paragraph (1).

(C) Not later than 1 year after October 17, 2000, the Secretary shall submit to the ap-

propriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers. Within a reasonable time after training under this section is initiated, the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers in order to determine the effectiveness of such training and the extent to which such training complies with subsection (a)(1). In preparing the reports required by this subparagraph, the Secretary shall in no respect interpret the provisions of this section to allow any interference in the provider-patient relationship, any breach of patient confidentiality, or any monitoring or auditing of the counseling process or patient records which breaches patient confidentiality or reveals patient identity. The reports required by this subparagraph shall be conducted by the Secretary acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Director of the Agency for Healthcare Research and Quality.

(b) Application for grant

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(c) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 330F, as added Pub. L. 106–310, div. A, title XII, § 1201, Oct. 17, 2000, 114 Stat. 1132.)

§ 254c–7. Special needs adoption programs; public awareness campaign and other activities

(a) Special needs adoption awareness campaign

(1) In general

The Secretary shall, through making grants to nonprofit private entities, provide for the planning, development, and carrying out of a national campaign to provide information to the public regarding the adoption of children with special needs.

(2) Input on planning and development

In providing for the planning and development of the national campaign under paragraph (1), the Secretary shall provide for input from a number and variety of adoption organizations throughout the States in order that the full national diversity of interests among adoption organizations is represented in the planning and development of the campaign.

(3) Certain features

With respect to the national campaign under paragraph (1):

(A) The campaign shall be directed at various populations, taking into account as appropriate differences among geographic regions, and shall be carried out in the language and cultural context that is most appropriate to the population involved.

(B) The means through which the campaign may be carried out include—

(i) placing public service announcements on television, radio, and billboards; and

(ii) providing information through means that the Secretary determines will reach individuals who are most likely to adopt children with special needs.

(C) The campaign shall provide information on the subsidies and supports that are available to individuals regarding the adoption of children with special needs.

(D) The Secretary may provide that the placement of public service announcements, and the dissemination of brochures and other materials, is subject to review by the Secretary.

(4) Matching requirement

(A) In general

With respect to the costs of the activities to be carried out by an entity pursuant to paragraph (1), a condition for the receipt of a grant under such paragraph is that the entity agree to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(B) Determination of amount contributed

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

(b) National resources program

The Secretary shall (directly or through grant or contract) carry out a program that, through toll-free telecommunications, makes available to the public information regarding the adoption of children with special needs. Such information shall include the following:

(1) A list of national, State, and regional organizations that provide services regarding such adoptions, including exchanges and other information on communicating with the organizations. The list shall represent the full national diversity of adoption organizations.

(2) Information beneficial to individuals who adopt such children, including lists of support groups for adoptive parents and other postadoptive services.

(c) Other programs

With respect to the adoption of children with special needs, the Secretary shall make grants—

(1) to provide assistance to support groups for adoptive parents, adopted children, and siblings of adopted children; and

(2) to carry out studies to identify—

(A) the barriers to completion of the adoption process; and

(B) those components that lead to favorable long-term outcomes for families that adopt children with special needs.

(d) Application for grant

The Secretary may make an award of a grant or contract under this section only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Funding

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

(July 1, 1944, ch. 373, title III, § 330G, as added Pub. L. 106–310, div. A, title XII, § 1211, Oct. 17, 2000, 114 Stat. 1135.)

§ 254c–8. Healthy start for infants

(a) In general

(1) Continuation and expansion of program

The Secretary, acting through the Administrator of the Health Resources and Services Administration, Maternal and Child Health Bureau, shall under authority of this section continue in effect the Healthy Start Initiative and may, during fiscal year 2001 and subsequent years, carry out such program on a national basis.

(2) Definition

For purposes of paragraph (1), the term ''Healthy Start Initiative'' is a reference to the program that, as an initiative to reduce the rate of infant mortality and improve perinatal outcomes, makes grants for project areas with high annual rates of infant mortality and that, prior to the effective date of this section, was a demonstration program carried out under section 241 of this title.

(b) Considerations in making grants

(1) Requirements

In making grants under subsection (a), the Secretary shall require that applicants (in addition to meeting all eligibility criteria established by the Secretary) establish, for project areas under such subsection, community-based consortia of individuals and organizations (including agencies responsible for administering block grant programs under title V of the Social Security Act [42 U.S.C. 701 et seq.], consumers of project services, public health departments, hospitals, health centers under section 254b of this title, and other significant sources of health care services) that are appropriate for participation in projects under subsection (a).

(2) Other considerations

In making grants under subsection (a), the Secretary shall take into consideration the following:

(A) Factors that contribute to infant mortality, such as low birthweight.

(B) The extent to which applicants for such grants facilitate—

(i) a community-based approach to the delivery of services; and

(ii) a comprehensive approach to women's health care to improve perinatal outcomes.

(3) Special projects

Nothing in paragraph (2) shall be construed to prevent the Secretary from awarding grants under subsection (a) for special projects that are intended to address significant disparities in perinatal health indicators in communities along the United States-Mexico border or in Alaska or Hawaii.

(c) Coordination

Recipients of grants under subsection (a) shall coordinate their services and activities with the State agency or agencies that administer block grant programs under title V of the Social Security Act [42 U.S.C. 701 et seq.] in order to promote cooperation, integration, and dissemination of information with Statewide systems and with other community services funded under the Maternal and Child Health Block Grant.

(d) Rule of construction

Except to the extent inconsistent with this section, this section may not be construed as affecting the authority of the Secretary to make modifications in the program carried out under subsection (a).

(e) Funding

(1) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated—

(A) $120,000,000 for fiscal year 2008; and

(B) for each of fiscal years 2009 through 2013, the amount authorized for the preceding fiscal year increased by the percentage increase in the Consumer Price Index for all urban consumers for such year.

(2) Allocation

(A) Program administration

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 5 percent for coordination, dissemination, technical assistance, and data activities that are determined by the Secretary to be appropriate for carrying out the program under this section.

(B) Evaluation

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 1 percent for evaluations of projects carried out under subsection (a). Each such evaluation shall include a determination of whether such projects have been effective in reducing the disparity in health status between the general population and individuals who are members of racial or ethnic minority groups.

(July 1, 1944, ch. 373, title III, § 330H, as added Pub. L. 106–310, div. A, title XV, § 1501, Oct. 17, 2000, 114 Stat. 1146; amended Pub. L. 108–271, § 8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–339, § 2, Oct. 3, 2008, 122 Stat. 3733.)

REFERENCES IN TEXT

The effective date of this section, referred to in subsec. (a)(2), is the date of enactment of Pub. L. 106–310, which was approved Oct. 17, 2000.

The Social Security Act, referred to in subsecs. (b)(1) and (c), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title V of the Act is classified generally to subchapter V (§ 701 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

2008—Subsec. (a)(3). Pub. L. 110–339, § 2(b)(1), struck out par. (3). Text read as follows: ''Effective upon increased funding beyond fiscal year 1999 for such Initiative, additional grants may be made to States to assist communities with technical assistance, replication of successful projects, and State policy formation to reduce infant and maternal mortality and morbidity.''

Subsec. (b). Pub. L. 110–339, § 2(a), substituted ''Considerations in making grants'' for ''Requirements for making grants'' in heading, designated existing provisions as par. (1), inserted par. heading, and added pars. (2) and (3).

Subsec. (e). Pub. L. 110–339, § 2(b)(2), (c), added subsec. (e) and struck out former subsec. (e) which related to additional services for at-risk pregnant women and infants.

Subsec. (f). Pub. L. 110–339, § 2(b)(2), struck out subsec. (f) which related to funding of program and additional services for at-risk pregnant women and infants.

2004—Subsec. (e)(3). Pub. L. 108–271 substituted ''Government Accountability Office'' for ''General Accounting Office'' in heading.

§ 254c–9. Establishment of program of grants

(a) In general

The Secretary of Health and Human Services shall in accordance with sections 254c–9 to 254c–13 of this title make grants to provide for projects for the establishment, operation, and coordination of effective and cost-efficient systems for the delivery of essential services to individuals with lupus and their families.

(b) Recipients of grants

A grant under subsection (a) may be made to an entity only if the entity is a public or nonprofit private entity, which may include a State or local government; a public or nonprofit private hospital, community-based organization, hospice, ambulatory care facility, community health center, migrant health center, or homeless health center; or other appropriate public or nonprofit private entity.

(c) Certain activities

To the extent practicable and appropriate, the Secretary shall ensure that projects under subsection (a) provide services for the diagnosis and disease management of lupus. Activities that the Secretary may authorize for such projects may also include the following:

(1) Delivering or enhancing outpatient, ambulatory, and home-based health and support services, including case management and comprehensive treatment services, for individuals with lupus; and delivering or enhancing support services for their families.

(2) Delivering or enhancing inpatient care management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities of individuals with lupus.

(3) Improving the quality, availability, and organization of health care and support services (including transportation services, attendant care, homemaker services, day or respite care, and providing counseling on financial assistance and insurance) for individuals with lupus and support services for their families.

(d) Integration with other programs

To the extent practicable and appropriate, the Secretary shall integrate the program under sections 254c–9 to 254c–13 of this title with other grant programs carried out by the Secretary, including the program under section 254b of this title.

(Pub. L. 106–505, title V, § 521, Nov. 13, 2000, 114 Stat. 2343.)

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254c–10. Certain requirements

A grant may be made under section 254c–9 of this title only if the applicant involved makes the following agreements:

(1) Not more than 5 percent of the grant will be used for administration, accounting, reporting, and program oversight functions.

(2) The grant will be used to supplement and not supplant funds from other sources related to the treatment of lupus.

(3) The applicant will abide by any limitations deemed appropriate by the Secretary on any charges to individuals receiving services pursuant to the grant. As deemed appropriate by the Secretary, such limitations on charges may vary based on the financial circumstances of the individual receiving services.

(4) The grant will not be expended to make payment for services authorized under section 254c–9(a) of this title to the extent that payment has been made, or can reasonably be expected to be made, with respect to such services—

(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.

(5) The applicant will, at each site at which the applicant provides services under section 254c–9(a) of this title, post a conspicuous notice informing individuals who receive the services of any Federal policies that apply to the applicant with respect to the imposition of charges on such individuals.

(Pub. L. 106–505, title V, § 522, Nov. 13, 2000, 114 Stat. 2344.)

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254c–11. Technical assistance

The Secretary may provide technical assistance to assist entities in complying with the re-

quirements of sections 254c–9 to 254c–13 of this title in order to make such entities eligible to receive grants under section 254c–9 of this title.

(Pub. L. 106–505, title V, § 523, Nov. 13, 2000, 114 Stat. 2344.)

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254c–12. Definitions

For purposes of sections 254c–9 to 254c–13 of this title:

(1) Official poverty line

The term ''official poverty line'' means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(2) Secretary

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

(Pub. L. 106–505, title V, § 524, Nov. 13, 2000, 114 Stat. 2344.)

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254c–13. Authorization of appropriations

For the purpose of carrying out sections 254c–9 to 254c–13 of this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.

(Pub. L. 106–505, title V, § 525, Nov. 13, 2000, 114 Stat. 2345.)

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 254c–14. Telehealth network and telehealth resource centers grant programs

(a) Definitions

In this section:

(1) Director; Office

The terms ''Director'' and ''Office'' mean the Director and Office specified in subsection (c).

(2) Federally qualified health center and rural health clinic

The term ''Federally qualified health center'' and ''rural health clinic'' have the meanings given the terms in section 1395x(aa) of this title.

(3) Frontier community

The term ''frontier community'' shall have the meaning given the term in regulations issued under subsection (r).

(4) Medically underserved area

The term ''medically underserved area'' has the meaning given the term ''medically underserved community'' in section 295p(6) of this title.

(5) Medically underserved population

The term ''medically underserved population'' has the meaning given the term in section 254b(b)(3) of this title.

(6) Telehealth services

The term ''telehealth services'' means services provided through telehealth technologies.

(7) Telehealth technologies

The term ''telehealth technologies'' means technologies relating to the use of electronic information, and telecommunications technologies, to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health.

(b) Programs

The Secretary shall establish, under section 241 of this title, telehealth network and telehealth resource centers grant programs.

(c) Administration

(1) Establishment

There is established in the Health Resources and Services Administration an Office for the Advancement of Telehealth. The Office shall be headed by a Director.

(2) Duties

The telehealth network and telehealth resource centers grant programs established under section 241 of this title shall be administered by the Director, in consultation with the State offices of rural health, State offices concerning primary care, or other appropriate State government entities.

(d) Grants

(1) Telehealth network grants

The Director may, in carrying out the telehealth network grant program referred to in subsection (b), award grants to eligible entities for projects to demonstrate how telehealth technologies can be used through telehealth networks in rural areas, frontier communities, and medically underserved areas, and for medically underserved populations, to—

(A) expand access to, coordinate, and improve the quality of health care services;

(B) improve and expand the training of health care providers; and

(C) expand and improve the quality of health information available to health care providers, and patients and their families, for decisionmaking.

(2) Telehealth resource centers grants

The Director may, in carrying out the telehealth resource centers grant program referred to in subsection (b), award grants to eligible entities for projects to demonstrate how telehealth technologies can be used in the areas and communities, and for the populations, described in paragraph (1), to establish telehealth resource centers.

(e) Grant periods

The Director may award grants under this section for periods of not more than 4 years.

(f) Eligible entities

(1) Telehealth network grants

(A) Grant recipient

To be eligible to receive a grant under subsection (d)(1), an entity shall be a nonprofit entity.

(B) Telehealth networks

(i) In general

To be eligible to receive a grant under subsection (d)(1), an entity shall demonstrate that the entity will provide services through a telehealth network.

(ii) Nature of entities

Each entity participating in the telehealth network may be a nonprofit or for-profit entity.

(iii) Composition of network

The telehealth network shall include at least 2 of the following entities (at least 1 of which shall be a community-based health care provider):

(I) Community or migrant health centers or other Federally qualified health centers.

(II) Health care providers, including pharmacists, in private practice.

(III) Entities operating clinics, including rural health clinics.

(IV) Local health departments.

(V) Nonprofit hospitals, including community access hospitals.

(VI) Other publicly funded health or social service agencies.

(VII) Long-term care providers.

(VIII) Providers of health care services in the home.

(IX) Providers of outpatient mental health services and entities operating outpatient mental health facilities.

(X) Local or regional emergency health care providers.

(XI) Institutions of higher education.

(XII) Entities operating dental clinics.

(2) Telehealth resource centers grants

To be eligible to receive a grant under subsection (d)(2), an entity shall be a nonprofit entity.

(g) Applications

To be eligible to receive a grant under subsection (d), an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(2) a description of the manner in which the project funded under the grant will meet the health care needs of rural or other populations to be served through the project, or improve the access to services of, and the quality of the services received by, those populations;

(3) evidence of local support for the project, and a description of how the areas, communities, or populations to be served will be involved in the development and ongoing operations of the project;

(4) a plan for sustaining the project after Federal support for the project has ended;

(5) information on the source and amount of non-Federal funds that the entity will provide for the project;

(6) information demonstrating the long-term viability of the project, and other evidence of institutional commitment of the entity to the project;

(7) in the case of an application for a project involving a telehealth network, information demonstrating how the project will promote the integration of telehealth technologies into the operations of health care providers, to avoid redundancy, and improve access to and the quality of care; and

(8) other such information as the Secretary determines to be appropriate.

(h) Terms; conditions; maximum amount of assistance

The Secretary shall establish the terms and conditions of each grant program described in subsection (b) and the maximum amount of a grant to be awarded to an individual recipient for each fiscal year under this section. The Secretary shall publish, in a publication of the Health Resources and Services Administration, notice of the application requirements for each grant program described in subsection (b) for each fiscal year.

(i) Preferences

(1) Telehealth networks

In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) Organization

The eligible entity is a rural community-based organization or another community-based organization.

(B) Services

The eligible entity proposes to use Federal funds made available through such a grant to develop plans for, or to establish, telehealth networks that provide mental health, public health, long-term care, home care, preventive, case management services, or prenatal care for high-risk pregnancies.

(C) Coordination

The eligible entity demonstrates how the project to be carried out under the grant will be coordinated with other relevant federally funded projects in the areas, communities, and populations to be served through the grant.

(D) Network

The eligible entity demonstrates that the project involves a telehealth network that includes an entity that—

(i) provides clinical health care services, or educational services for health care providers and for patients or their families; and

(ii) is—

(I) a public library;

(II) an institution of higher education; or

(III) a local government entity.

(E) Connectivity

The eligible entity proposes a project that promotes local connectivity within areas, communities, or populations to be served through the project.

(F) Integration

The eligible entity demonstrates that health care information has been integrated into the project.

(2) Telehealth resource centers

In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) Provision of services

The eligible entity has a record of success in the provision of telehealth services to medically underserved areas or medically underserved populations.

(B) Collaboration and sharing of expertise

The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.

(C) Broad range of telehealth services

The eligible entity has a record of providing a broad range of telehealth services, which may include—

(i) a variety of clinical specialty services;

(ii) patient or family education;

(iii) health care professional education; and

(iv) rural residency support programs.

(j) Distribution of funds

(1) In general

In awarding grants under this section, the Director shall ensure, to the greatest extent possible, that such grants are equitably distributed among the geographical regions of the United States.

(2) Telehealth networks

In awarding grants under subsection (d)(1) for a fiscal year, the Director shall ensure that—

(A) not less than 50 percent of the funds awarded shall be awarded for projects in rural areas; and

(B) the total amount of funds awarded for such projects for that fiscal year shall be not less than the total amount of funds awarded for such projects for fiscal year 2001 under section 254c of this title (as in effect on the day before October 26, 2002).

(k) Use of funds

(1) Telehealth network program

The recipient of a grant under subsection (d)(1) may use funds received through such grant for salaries, equipment, and operating or other costs, including the cost of—

(A) developing and delivering clinical telehealth services that enhance access to community-based health care services in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations;

(B) developing and acquiring, through lease or purchase, computer hardware and software, audio and video equipment, computer network equipment, interactive equipment, data terminal equipment, and other equipment that furthers the objectives of the telehealth network grant program;

(C)(i) developing and providing distance education, in a manner that enhances access to care in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations; or

(ii) mentoring, precepting, or supervising health care providers and students seeking to become health care providers, in a manner that enhances access to care in the areas and communities, or for the populations, described in clause (i);

(D) developing and acquiring instructional programming;

(E)(i) providing for transmission of medical data, and maintenance of equipment; and

(ii) providing for compensation (including travel expenses) of specialists, and referring health care providers, who are providing telehealth services through the telehealth network, if no third party payment is available for the telehealth services delivered through the telehealth network;

(F) developing projects to use telehealth technology to facilitate collaboration between health care providers;

(G) collecting and analyzing usage statistics and data to document the cost-effectiveness of the telehealth services; and

(H) carrying out such other activities as are consistent with achieving the objectives of this section, as determined by the Secretary.

(2) Telehealth resource centers

The recipient of a grant under subsection (d)(2) may use funds received through such grant for salaries, equipment, and operating or other costs for—

(A) providing technical assistance, training, and support, and providing for travel expenses, for health care providers and a range of health care entities that provide or will provide telehealth services;

(B) disseminating information and research findings related to telehealth services;

(C) promoting effective collaboration among telehealth resource centers and the Office;

(D) conducting evaluations to determine the best utilization of telehealth technologies to meet health care needs;

(E) promoting the integration of the technologies used in clinical information systems with other telehealth technologies;

(F) fostering the use of telehealth technologies to provide health care information

and education for health care providers and consumers in a more effective manner; and

(G) implementing special projects or studies under the direction of the Office.

(*l*) Prohibited uses of funds

An entity that receives a grant under this section may not use funds made available through the grant—

(1) to acquire real property;

(2) for expenditures to purchase or lease equipment, to the extent that the expenditures would exceed 40 percent of the total grant funds;

(3) in the case of a project involving a telehealth network, to purchase or install transmission equipment (such as laying cable or telephone lines, or purchasing or installing microwave towers, satellite dishes, amplifiers, or digital switching equipment);

(4) to pay for any equipment or transmission costs not directly related to the purposes for which the grant is awarded;

(5) to purchase or install general purpose voice telephone systems;

(6) for construction; or

(7) for expenditures for indirect costs (as determined by the Secretary), to the extent that the expenditures would exceed 15 percent of the total grant funds.

(m) Collaboration

In providing services under this section, an eligible entity shall collaborate, if feasible, with entities that—

(1)(A) are private or public organizations, that receive Federal or State assistance; or

(B) are public or private entities that operate centers, or carry out programs, that receive Federal or State assistance; and

(2) provide telehealth services or related activities.

(n) Coordination with other agencies

The Secretary shall coordinate activities carried out under grant programs described in subsection (b), to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar programs, to maximize the effect of public dollars in funding meritorious proposals.

(*o*) Outreach activities

The Secretary shall establish and implement procedures to carry out outreach activities to advise potential end users of telehealth services in rural areas, frontier communities, medically underserved areas, and medically underserved populations in each State about the grant programs described in subsection (b).

(p) Telehealth

It is the sense of Congress that, for purposes of this section, States should develop reciprocity agreements so that a provider of services under this section who is a licensed or otherwise authorized health care provider under the law of 1 or more States, and who, through telehealth technology, consults with a licensed or otherwise authorized health care provider in another State, is exempt, with respect to such consultation, from any State law of the other State that prohibits such consultation on the basis that the first health care provider is not a licensed or authorized health care provider under the law of that State.

(q) Report

Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsection (b).

(r) Regulations

The Secretary shall issue regulations specifying, for purposes of this section, a definition of the term ''frontier area''. The definition shall be based on factors that include population density, travel distance in miles to the nearest medical facility, travel time in minutes to the nearest medical facility, and such other factors as the Secretary determines to be appropriate. The Secretary shall develop the definition in consultation with the Director of the Bureau of the Census and the Administrator of the Economic Research Service of the Department of Agriculture.

(s) Authorization of appropriations

There are authorized to be appropriated to carry out this section—

(1) for grants under subsection (d)(1), $40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006; and

(2) for grants under subsection (d)(2), $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(July 1, 1944, ch. 373, title III, § 330I, as added Pub. L. 107–251, title II, § 212, Oct. 26, 2002, 116 Stat. 1632; amended Pub. L. 108–163, § 2(c), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 113–55, title I, § 103(a), Nov. 27, 2013, 127 Stat. 642.)

AMENDMENTS

2013—Subsec. (i)(1)(B). Pub. L. 113–55 substituted ''case management services, or prenatal care for high-risk pregnancies'' for ''or case management services''.

2003—Subsec. (a)(4). Pub. L. 108–163, § 2(c)(1), substituted ''section 295p(6)'' for ''section 295p''.

Subsec. (c)(1). Pub. L. 108–163, § 2(c)(2), substituted ''Health Resources and Services Administration'' for ''Health and Resources and Services Administration''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments 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.

§ 254c–15. Rural emergency medical service training and equipment assistance program

(a) Grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the ''Secretary'') shall award grants to eligible entities to enable such entities to provide for improved emergency medical services in rural areas.

(b) Eligibility

To be eligible to receive a grant under this section, an entity shall—

(1) be—

(A) a State emergency medical services office;

(B) a State emergency medical services association;

(C) a State office of rural health;

(D) a local government entity;

(E) a State or local ambulance provider; or

(F) any other entity determined appropriate by the Secretary; and

(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, that includes—

(A) a description of the activities to be carried out under the grant; and

(B) an assurance that the eligible entity will comply with the matching requirement of subsection (e).

(c) Use of funds

An entity shall use amounts received under a grant made under subsection (a), either directly or through grants to emergency medical service squads that are located in, or that serve residents of, a nonmetropolitan statistical area, an area designated as a rural area by any law or regulation of a State, or a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification, originally published in a notice of availability of funds in the Federal Register on February 27, 1992, 57 Fed. Reg. 6725), to—

(1) recruit emergency medical service personnel;

(2) recruit volunteer emergency medical service personnel;

(3) train emergency medical service personnel in emergency response, injury prevention, safety awareness, and other topics relevant to the delivery of emergency medical services;

(4) fund specific training to meet Federal or State certification requirements;

(5) develop new ways to educate emergency health care providers through the use of technology-enhanced educational methods (such as distance learning);

(6) acquire emergency medical services equipment, including cardiac defibrillators;

(7) acquire personal protective equipment for emergency medical services personnel as required by the Occupational Safety and Health Administration; and

(8) educate the public concerning cardiopulmonary resuscitation, first aid, injury prevention, safety awareness, illness prevention, and other related emergency preparedness topics.

(d) Preference

In awarding grants under this section the Secretary shall give preference to—

(1) applications that reflect a collaborative effort by 2 or more of the entities described in subparagraphs (A) through (F) of subsection (b)(1); and

(2) applications submitted by entities that intend to use amounts provided under the grant to fund activities described in any of paragraphs (1) through (5) of subsection (c).

(e) Matching requirement

The Secretary may not award a grant under this section to an entity unless the entity agrees that the entity will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to 25 percent of the amount received under the grant.

(f) Emergency medical services

In this section, the term ''emergency medical services''—

(1) means resources used by a qualified public or private nonprofit entity, or by any other entity recognized as qualified by the State involved, to deliver medical care outside of a medical facility under emergency conditions that occur—

(A) as a result of the condition of the patient; or

(B) as a result of a natural disaster or similar situation; and

(2) includes services delivered by an emergency medical services provider (either compensated or volunteer) or other provider recognized by the State involved that is licensed or certified by the State as an emergency medical technician or its equivalent (as determined by the State), a registered nurse, a physician assistant, or a physician that provides services similar to services provided by such an emergency medical services provider.

(g) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

(2) Administrative costs

The Secretary may use not more than 10 percent of the amount appropriated under paragraph (1) for a fiscal year for the administrative expenses of carrying out this section.

(July 1, 1944, ch. 373, title III, § 330J, as added Pub. L. 107–251, title II, § 221, Oct. 26, 2002, 116 Stat. 1638.)

§ 254c–16. Mental health services delivered via telehealth

(a) Definitions

In this section:

(1) Eligible entity

The term ''eligible entity'' means a public or nonprofit private telehealth provider network that offers services that include mental health services provided by qualified mental health providers.

(2) Qualified mental health professionals

The term ''qualified mental health professionals'' refers to providers of mental health services reimbursed under the medicare program carried out under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who have additional training in the treatment of mental illness in children and adolescents or who have additional training in the treatment of mental illness in the elderly.

(3) Special populations

The term ''special populations'' refers to the following 2 distinct groups:

(A) Children and adolescents in mental health underserved rural areas or in mental health underserved urban areas.

(B) Elderly individuals located in long-term care facilities in mental health underserved rural or urban areas.

(4) Telehealth

The term ''telehealth'' means the use of electronic information and telecommunications technologies to support long distance clinical health care, patient and professional health-related education, public health, and health administration.

(b) Program authorized

(1) In general

The Secretary, acting through the Director of the Office for the Advancement of Telehealth of the Health Resources and Services Administration, shall award grants to eligible entities to establish demonstration projects for the provision of mental health services to special populations as delivered remotely by qualified mental health professionals using telehealth and for the provision of education regarding mental illness as delivered remotely by qualified mental health professionals using telehealth.

(2) Populations served

The Secretary shall award the grants under paragraph (1) in a manner that distributes the grants so as to serve equitably the populations described in subparagraphs (A) and (B) of subsection (a)(3).

(c) Use of funds

(1) In general

An eligible entity that receives a grant under this section shall use the grant funds—

(A) for the populations described in subsection (a)(3)(A)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services; and

(B) for the populations described in subsection (a)(3)(B)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, in long-term care facilities as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services.

(2) Other uses

An eligible entity that receives a grant under this section may also use the grant funds to—

(A) pay telecommunications costs; and

(B) pay qualified mental health professionals on a reasonable cost basis as determined by the Secretary for services rendered.

(3) Prohibited uses

An eligible entity that receives a grant under this section shall not use the grant funds to—

(A) purchase or install transmission equipment (other than such equipment used by qualified mental health professionals to deliver mental health services using telehealth under the project involved); or

(B) build upon or acquire real property.

(d) Equitable distribution

In awarding grants under this section, the Secretary shall ensure, to the greatest extent possible, that such grants are equitably distributed among geographical regions of the United States.

(e) Application

An entity that desires a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary determines to be reasonable.

(f) Report

Not later than 4 years after October 26, 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report that shall evaluate activities funded with grants under this section.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002 and such sums as may be necessary for fiscal years 2003 through 2006.

(July 1, 1944, ch. 373, title III, § 330K, as added Pub. L. 107–251, title II, § 221, Oct. 26, 2002, 116 Stat. 1640; amended Pub. L. 108–163, § 2(d), Dec. 6, 2003, 117 Stat. 2021.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XVIII of the Act is classified generally to subchapter XVIII (§ 1395 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

2003—Subsec. (b)(2). Pub. L. 108–163, § 2(d)(1), substituted ''subsection (a)(3)'' for ''subsection (a)(4)''.

Subsec. (c)(1)(A). Pub. L. 108–163, § 2(d)(2)(A), substituted ''subsection (a)(3)(A)'' for ''subsection (a)(4)(A)''.

Subsec. (c)(1)(B). Pub. L. 108–163, § 2(d)(2)(B), substituted ''subsection (a)(3)(B)'' for ''subsection (a)(4)(B)''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments 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.

§ 254c–17. Repealed. Pub. L. 108–163, § 2(e)(2), Dec. 6, 2003, 117 Stat. 2021

Section, Pub. L. 107–251, title I, § 102, Oct. 26, 2002, 116 Stat. 1627, provided for grants to State professional licensing boards to develop and implement State policies to promote telemedicine.

EFFECTIVE DATE OF REPEAL

Repeal 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 an Effective Date of 2003 Amendments note under section 233 of this title.

§ 254c–18. Telemedicine; incentive grants regarding coordination among States

(a) In general

The Secretary may make grants to State professional licensing boards to carry out programs under which such licensing boards of various States cooperate to develop and implement State policies that will reduce statutory and regulatory barriers to telemedicine.

(b) Authorization of appropriations

For the purpose of carrying out subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(July 1, 1944, ch. 373, title III, § 330L, as added Pub. L. 108–163, § 2(e)(1), Dec. 6, 2003, 117 Stat. 2021.)

EFFECTIVE DATE

Section 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 an Effective Date of 2003 Amendments note under section 233 of this title.

§ 254c–19. Pediatric mental health care access grants

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and Indian tribes and tribal organizations (for purposes of this section, as such terms are defined in section 5304 of title 25) to promote behavioral health integration in pediatric primary care by—

(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

(b) Program requirements

(1) In general

A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

(H) assist with referrals to specialty care and community or behavioral health resources; and

(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

(2) Pediatric mental health teams

In this subsection, the term ''pediatric mental health team'' means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker, or mental health counselor. Such a team may be regionally based.

(c) Application

A State, political subdivision of a State, Indian tribe, or tribal organization seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

(d) Evaluation

A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

(e) Access to broadband

In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

(f) Matching requirement

The Secretary may not award a grant under this section unless the State, political subdivision of a State, Indian tribe, or tribal organiza-

tion involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian tribe, or tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated, $9,000,000 for the period of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 330M, as added Pub. L. 114–255, div. B, title X, § 10002, Dec. 13, 2016, 130 Stat. 1262.)

SUBPART II—NATIONAL HEALTH SERVICE CORPS PROGRAM

CODIFICATION

Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2268, added heading ''Subpart II—National Health Service Corps Program''.

§ 254d. National Health Service Corps

(a) Establishment; composition; purpose; definitions

(1) For the purpose of eliminating health manpower shortages in health professional shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—

(A) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate,

(B) such civilian employees of the United States as the Secretary may appoint, and

(C) such other individuals who are not employees of the United States.

(2) The Corps shall be utilized by the Secretary to provide primary health services in health professional shortage areas.

(3) For purposes of this subpart and subpart III:

(A) The term ''Corps'' means the National Health Service Corps.

(B) The term ''Corps member'' means each of the officers, employees, and individuals of which the Corps consists pursuant to paragraph (1).

(C) The term ''health professional shortage area'' has the meaning given such term in section 254e(a) of this title.

(D) The term ''primary health services'' means health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals.

(E)(i) The term ''behavioral and mental health professionals'' means health service psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, psychiatric nurse specialists, and psychiatrists.

(ii) The term ''graduate program of behavioral and mental health'' means a program that trains behavioral and mental health professionals.

(b) Recruitment and fellowship programs

(1) The Secretary may conduct at schools of medicine, osteopathic medicine, dentistry, and, as appropriate, nursing and other schools of the health professions, including schools at which graduate programs of behavioral and mental health are offered, and at entities which train allied health personnel, recruiting programs for the Corps, the Scholarship Program, and the Loan Repayment Program. Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.

(2) In the case of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants who have an interest and a commitment to providing primary health care, the Secretary may establish fellowship programs to enable such health professionals to gain exposure to and expertise in the delivery of primary health services in health professional shortage areas. To the maximum extent practicable, the Secretary shall ensure that any such programs are established in conjunction with accredited residency programs, and other training programs, regarding such health professions.

(c) Travel and moving expenses; persons entitled; reimbursement; limitation

(1) The Secretary may reimburse an applicant for a position in the Corps (including an individual considering entering into a written agreement pursuant to section 254n of this title) for the actual and reasonable expenses incurred in traveling to and from the applicant's place of residence to an eligible site to which the applicant may be assigned under section 254f of this title for the purpose of evaluating such site with regard to being assigned at such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(2) The Secretary may also reimburse the applicant for the actual and reasonable expenses incurred for the travel of 1 family member to accompany the applicant to such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(3) In the case of an individual who has entered into a contract for obligated service under the Scholarship Program or under the Loan Repayment Program, the Secretary may reimburse such individual for all or part of the actual and reasonable expenses incurred in transporting the individual, the individual's family, and the family's possessions to the site of the individual's assignment under section 254f of this title. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(d) Monthly pay adjustments of members directly engaged in delivery of health services in health professional shortage area; "monthly pay" defined; monthly pay adjustment of member with service obligation incurred under Scholarship Program or Loan Repayment Program; personnel system applicable

(1) The Secretary may, under regulations promulgated by the Secretary, adjust the monthly

pay of each member of the Corps (other than a member described in subsection (a)(1)(C)) who is directly engaged in the delivery of health services in a health professional shortage area as follows:

(A) During the first 36 months in which such a member is so engaged in the delivery of health services, his monthly pay may be increased by an amount which when added to the member's monthly pay and allowances will provide a monthly income competitive with the average monthly income from a practice of an individual who is a member of the profession of the Corps member, who has equivalent training, and who has been in practice for a period equivalent to the period during which the Corps member has been in practice.

(B) During the period beginning upon the expiration of the 36 months referred to in subparagraph (A) and ending with the month in which the member's monthly pay and allowances are equal to or exceed the monthly income he received for the last of such 36 months, the member may receive in addition to his monthly pay and allowances an amount which when added to such monthly pay and allowances equals the monthly income he received for such last month.

(C) For each month in which a member is directly engaged in the delivery of health services in a health professional shortage area in accordance with an agreement with the Secretary entered into under section 294n(f)(1)(C)[1] of this title, under which the Secretary is obligated to make payments in accordance with section 294n(f)(2)[1] of this title, the amount of any monthly increase under subparagraph (A) or (B) with respect to such member shall be decreased by an amount equal to one-twelfth of the amount which the Secretary is obligated to pay upon the completion of the year of practice in which such month occurs.

For purposes of subparagraphs (A) and (B), the term ''monthly pay'' includes special pay received under chapter 5 of title 37.

(2) In the case of a member of the Corps who is directly engaged in the delivery of health services in a health professional shortage area in accordance with a service obligation incurred under the Scholarship Program or the Loan Repayment Program, the adjustment in pay authorized by paragraph (1) may be made for such a member only upon satisfactory completion of such service obligation, and the first 36 months of such member's being so engaged in the delivery of health services shall, for purposes of paragraph (1)(A), be deemed to begin upon such satisfactory completion.

(3) A member of the Corps described in subparagraph (C) of subsection (a)(1) shall when assigned to an entity under section 254f of this title be subject to the personnel system of such entity, except that such member shall receive during the period of assignment the income that the member would receive if the member was a member of the Corps described in subparagraph (B) of such subsection.

[1] See References in Text note below.

(e) Employment ceiling of Department not affected by Corps members

Corps members assigned under section 254f of this title to provide health services in health professional shortage areas shall not be counted against any employment ceiling affecting the Department.

(f) Assignment of personnel provisions inapplicable to members whose service obligation incurred under Scholarship Program or Loan Repayment Program

Sections 215 and 217 of this title shall not apply to members of the National Health Service Corps during their period of obligated service under the Scholarship Program or the Loan Repayment Program, except when such members are Commissioned Corps officers who entered into a contract with[2] Secretary under section 254*l* or 254*l*–1 of this title after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 215 or 217 of this title with respect to any such officer to[3] would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services.

(g) Conversion from Corps member to commissioned officer; retirement credits

(1) The Secretary shall, by rule, prescribe conversion provisions applicable to any individual who, within a year after completion of service as a member of the Corps described in subsection (a)(1)(C), becomes a commissioned officer in the Regular or Reserve Corps of the Service.

(2) The rules prescribed under paragraph (1) shall provide that in applying the appropriate provisions of this chapter which relate to retirement, any individual who becomes such an officer shall be entitled to have credit for any period of service as a member of the Corps described in subsection (a)(1)(C).

(h) Effective administration of program

The Secretary shall ensure that adequate staff is provided to the Service with respect to effectively administering the program for the Corps.

(i) Demonstration projects; waivers

(1) In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time.

(2) A waiver described in paragraph (1) may be provided by the Secretary only if—

(A) the entity for which the service is to be performed—

(i) has been approved under section 254f–1 of this title for assignment of a Corps member; and

(ii) has requested in writing assignment of a health professional who would serve half time;

[2] So in original. The word ''the'' probably should appear.

[3] So in original.

(B) the Secretary has determined that assignment of a health professional who would serve half time would be appropriate for the area where the entity is located;

(C) a Corps member who is required to perform obligated service has agreed in writing to be assigned for half-time service to an entity described in subparagraph (A);

(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

(E) the Corps member agrees in writing to fulfill all of the service obligations under section 254m of this title through half-time clinical practice and either—

(i) double the period of obligated service that would otherwise be required; or

(ii) in the case of contracts entered into under section 254*l*–1 of this title, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and

(F) the Corps member agrees in writing that if the Corps member begins providing half-time service but fails to begin or complete the period of obligated service, the method stated in 254*o*(c) of this title for determining the damages for breach of the individual's written contract will be used after converting periods of obligated service or of service performed into their full-time equivalents.

(3) In evaluating waivers issued under paragraph (1), the Secretary shall examine the effect of multidisciplinary teams.

(j) Definitions

For the purposes of this subpart and subpart III:

(1) The term ''Department'' means the Department of Health and Human Services.

(2) The term ''Loan Repayment Program'' means the National Health Service Corps Loan Repayment Program established under section 254*l*–1 of this title.

(3) The term ''Scholarship Program'' means the National Health Service Corps Scholarship Program established under section 254*l* of this title.

(4) The term ''State'' includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(5) The terms ''full time'' and ''full-time'' mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

(6) The terms ''half time'' and ''half-time'' mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.

(July 1, 1944, ch. 373, title III, § 331, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2268; amended Pub. L. 97–35, title XXVII, § 2701, Aug. 13, 1981, 95 Stat. 902; Pub. L. 100–177, title II, § 202(b), title III, § 301, Dec. 1, 1987, 101 Stat. 996, 1003; Pub. L. 100–607, title VI, § 629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title I, § 101, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3013, 3035; Pub. L. 107–251, title III, § 301, Oct. 26, 2002, 116 Stat. 1642; Pub. L. 109–417, title II, § 206(c)(2), Dec. 19, 2006, 120 Stat. 2853; Pub. L. 111–148, title X, § 10501(n)(1), (2), Mar. 23, 2010, 124 Stat. 1002, 1003.)

REFERENCES IN TEXT

Section 294n of this title, referred to in subsec. (d)(1)(C), was in the original a reference to section 741 of act July 1, 1944. Section 741 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, § 102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 776 of act July 1, 1944, relating to acquired immune deficiency syndrome, which was classified to section 294n of this title, and subsequently renumbered section 2692 and transferred to section 300ff–111 of this title.

AMENDMENTS

2010—Subsec. (i)(1). Pub. L. 111–148, § 10501(n)(1)(A), substituted ''issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time'' for ''carry out demonstration projects in which individuals who have entered into a contract for obligated service under the Loan Repayment Program receive waivers under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical service that is not full-time''.

Subsec. (i)(2)(A)(ii), (B). Pub. L. 111–148, § 10501(n)(1)(B)(i), substituted ''half time'' for ''less than full time''.

Subsec. (i)(2)(C). Pub. L. 111–148, § 10501(n)(1)(B)(ii), substituted ''half-time service'' for ''less than full-time service''.

Subsec. (i)(2)(D), (E). Pub. L. 111–148, § 10501(n)(1)(B)(iii), amended subpars. (D) and (E) generally. Prior to amendment, subpars. (D) and (E) read as follows:

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

''(E) the Corps member agrees in writing that the period of obligated service pursuant to section 254*l*–1 of this title will be extended so that the aggregate amount of less than full-time service performed will equal the amount of service that would be performed through full-time service under section 254m of this title; and''.

Subsec. (i)(2)(F). Pub. L. 111–148, § 10501(n)(1)(B)(ii), substituted ''half-time service'' for ''less than full-time service''.

Subsec. (i)(3). Pub. L. 111–148, § 10501(n)(1)(C), substituted ''In evaluating waivers issued under paragraph (1)'' for ''In evaluating a demonstration project described in paragraph (1)''.

Subsec. (j)(5), (6). Pub. L. 111–148, § 10501(n)(2), added pars. (5) and (6).

2006—Subsec. (f). Pub. L. 109–417 inserted before period at end '', except when such members are Commissioned Corps officers who entered into a contract with Secretary under section 254*l* or 254*l*–1 of this title after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 215 or 217 of this title with respect to any such officer to would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services''.

2002—Subsec. (a)(3)(E). Pub. L. 107–251, § 301(a)(1), added subpar. (E).

Subsec. (b)(1). Pub. L. 107–251, § 301(a)(2)(A), substituted ''health professions, including schools at which

graduate programs of behavioral and mental health are offered,'' for ''health professions''.

Subsec. (b)(2). Pub. L. 107–251, § 301(a)(2)(B), inserted ''behavioral and mental health professionals,'' after ''dentists,''.

Subsec. (c). Pub. L. 107–251, § 301(a)(3), added subsec. (c) and struck out former subsec. (c) which read as follows: ''The Secretary may reimburse applicants for positions in the Corps (including individuals considering entering into a written agreement pursuant to section 254n of this title) for actual and reasonable expenses incurred in traveling to and from their places of residence to a health professional shortage area (designated under section 254e of this title) in which they may be assigned for the purpose of evaluating such area with regard to being assigned in such area. The Secretary shall not reimburse an applicant for more than one such trip.''

Subsecs. (i), (j). Pub. L. 107–251, § 301(b), added subsec. (i) and redesignated former subsec. (i) as (j).

1990—Subsec. (a). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in pars. (1), (2), and (3)(C).

Pub. L. 101–597, § 101(a), designated existing provisions as par. (1), substituted ''For the purpose of eliminating health manpower shortages in health manpower shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—'' for ''There is established, within the Service, the National Health Service Corps (hereinafter in this subpart referred to as the 'Corps') which (1) shall consist of—'', substituted ''States.'' for ''States,'' at end of subpar. (C), struck out closing provisions which read ''(such officers, employees, and individuals hereinafter in this subpart referred to as 'Corps members'), and (2) shall be utilized by the Secretary to improve the delivery of health services in health manpower shortage areas as defined in section 254e(a) of this title.'', and added pars. (2) and (3).

Subsec. (b). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2).

Pub. L. 101–597, § 101(b), designated existing provision as par. (1), inserted at end ''Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.'', and added par. (2).

Subsec. (c). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (d)(1). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in introductory provisions and in subpar. (C).

Subsec. (d)(1)(A). Pub. L. 101–597, § 101(c), struck out ''(not to exceed $1,000)'' after ''by an amount''.

Subsecs. (d)(2), (e). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (h). Pub. L. 101–597, § 101(d), added subsec. (h) and struck out former subsec. (h) which read as follows: ''In assigning members of the Corps to health manpower shortage areas, to the extent practicable, the Secretary shall—

''(1) give priority to meeting the needs of the Indian Health Service and the needs of health programs or facilities operated by tribes or tribal organizations under the Indian Self-Determination Act (25 U.S.C. 450f et seq.); and

''(2) provide special consideration to the homeless populations who do not have access to primary health care services.''

Subsec. (i). Pub. L. 101–597, § 101(e), substituted ''of this subpart and subpart III'' for ''of this subpart''.

1988—Subsec. (b). Pub. L. 100–607 substituted ''osteopathic medicine'' for ''osteopathy''.

1987—Subsec. (b). Pub. L. 100–177, § 202(b)(1), inserted reference to Loan Repayment Program.

Subsec. (c). Pub. L. 100–177, § 202(b)(2), made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

Subsecs. (d)(2), (f). Pub. L. 100–177, § 202(b)(3), (4), inserted reference to Loan Repayment Program.

Subsec. (h). Pub. L. 100–177, § 301(2), added subsec. (h). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 100–177, §§ 202(b)(5), 301(1), redesignated subsec. (h) as (i), added par. (2), and redesignated former pars. (2) and (3) as (3) and (4), respectively.

1981—Subsec. (a)(1). Pub. L. 97–35, § 2701(a), revised provisions and, as so revised, set out existing provisions in cls. (A) and (B), and added cl. (C).

Subsec. (b). Pub. L. 97–35, § 2701(b), substituted ''may'' for ''shall''.

Subsec. (c). Pub. L. 97–35, § 2701(c), inserted provisions respecting a written agreement under section 254n of this title.

Subsec. (d). Pub. L. 97–35, § 2701(d), in par. (1) inserted reference to member described in subsec. (a)(1)(C) of this section, in subpars. (1)(A) and (B) substituted ''may'' for ''shall'', and added par. (3).

Subsec. (g). Pub. L. 97–35, § 2701(e), substituted provisions relating to conversion from Corps member to commissioned officer and retirement credits, for provisions relating to school participation in development of administrative guidelines.

Subsec. (h). Pub. L. 97–35, § 2701(f), in par. (1) substituted ''Health and Human Services'' for ''Health, Education, and Welfare'', in par. (2) substituted ''254*l*'' for ''294t'', and in par. (3) inserted reference to Commonwealth with respect to the Northern Mariana Islands.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–597, title V, § 501, Nov. 16, 1990, 104 Stat. 3036, provided that: ''This Act and the amendments made by this Act [enacting sections 254f–1, 254*o*–1, and 254r of this title, amending this section, sections 242a, 254e to 254i, 254k, 254*l* to 254q–1, 254s, 294h, 294n, 294aa, 295g–1, 296m, 1320c–5, 1395*l*, 1395u, 1395x, 3505d, and 9840 of this title, and section 2123 of Title 10, Armed Forces, and enacting provisions set out as notes under sections 201, 254*l*–1, and 254*o* of this title] shall take effect October 1, 1990, or upon the date of the enactment of this Act [Nov. 16, 1990], whichever occurs later.''

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

SPECIAL REPORT ON PRESENT AND FUTURE DIRECTION OF NATIONAL HEALTH SERVICE CORPS; SUBMISSION TO CONGRESS NOT LATER THAN FEBRUARY 1, 1979

Pub. L. 95–626, title I, § 116(c), Nov. 10, 1978, 92 Stat. 3569, directed Secretary, not later than Feb. 1, 1979, in consultation with National Advisory Council of National Health Service Corps and National Advisory Council on Health Professions Education, to submit to Congress a report on the direction of the National Health Service Corps, particularly its role as a health manpower program and as a health services delivery program, the use of members of the Corps in health manpower shortage areas to meet urban and rural health needs, the types of health professions needed to meet urban and rural health needs, and the projected size, composition, and use of the Corps through 1985.

EFFECTIVE DATE; OTHER PROVISIONS: HEALTH MANPOWER SHORTAGE AREA; APPROVAL OF APPLICATIONS FOR ASSIGNMENT OF CORPS PERSONNEL; ASSIGNMENT PERIOD, COMMENCEMENT; CREDIT FOR MONTHS OF PRIOR HEALTH CARE AND SERVICES FOR ADDITIONAL PAY BENEFIT; NATIONAL ADVISORY COUNCIL ON THE NATIONAL HEALTH SERVICE CORPS, CONTINUATION OF COUNCIL AND APPOINTMENT OF MEMBERS

Pub. L. 94–484, title IV, § 407(c), Oct. 12, 1976, 90 Stat. 2278, provided that:

''(1) The amendment made by subsections (a) and (b) [enacting this subpart and repealing section 254b of this title] shall apply only with respect to fiscal years beginning after September 30, 1977, except that the Secretary of Health, Education, and Welfare [now Health and Human Services] shall carry out the activities described in section 332 of the Public Health Service Act (as added by such amendment) [42 U.S.C. 254e] after the date of enactment of this Act [Oct. 12, 1976].

''(2)(A) Any area for which a designation under section 329(b) of the Public Health Service Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b(b)] was in effect on such date and in which National Health Service Corps personnel were, on such date, providing, under an assignment made under such section (as so in effect), health care and services for persons residing in such area shall, effective October 1, 1977, be considered under subpart II of part C of title III of such Act (as added by subsection (b) of this section) [42 U.S.C. 254d et seq.] to (i) be designated a health manpower shortage area (as defined by section 332 of such Act (as so added)) [42 U.S.C. 254e], and (ii) have had an application approved under section 333 of such Act (as so added)) [42 U.S.C. 254f] for the assignment of Corps personnel unless, as determined under subparagraph (B) of this paragraph, the assignment period applicable to such area (within the meaning of section 334 (as so added)) [former 42 U.S.C. 254g] has expired.

''(B) The assignment period (within the meaning of such section 334) [former 42 U.S.C. 254g] applicable to an area described in subparagraph (A) of this paragraph shall be considered to have begun on the date Corps personnel were first assigned to such area under section 329 of such Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b].

''(C) In the case of any physician or dentist member of the Corps who was providing health care and services on September 30, 1977, under an assignment made under section 329(b) of such Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b(b)], the number of the months during which such member provided such care and services before October 1, 1977, shall be counted in determining the application of the additional pay provisions of section 331(d) of such Act (as added by subsection (b) of this section) [42 U.S.C. 254d(d)] to such number.

''(3) The amendment made by subsection (b) which established an Advisory Council previously established under section 329 of the Public Health Service Act [former 42 U.S.C. 254b] shall not be construed as requiring the establishment of a new Advisory Council under such section 337 [42 U.S.C. 254j], and the amendment made by such subsection with respect to the composition of such Advisory Council shall apply with respect to appointments made to the Advisory Council after October 1, 1977, and the Secretary of Health, Education, and Welfare [now Health and Human Services] shall make appointments to the Advisory Council after such date in a manner which will bring about, at the earliest feasible time, the Advisory Council composition prescribed by the amendment.''

§ 254e. Health professional shortage areas

(a) Designation by Secretary; removal from areas designated; "medical facility" defined

(1) For purposes of this subpart the term ''health professional shortage area'' means (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage and which is not reasonably accessible to an adequately served area, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of this title shall be automatically designated as having such a shortage. The Secretary shall not remove an area from the areas determined to be health professional shortage areas under subparagraph (A) of the preceding sentence until the Secretary has afforded interested persons and groups in such area an opportunity to provide data and information in support of the designation as a health professional shortage area or a population group described in subparagraph (B) of such sentence or a facility described in subparagraph (C) of such sentence, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Secretary.

(2) For purposes of this subsection, the term ''medical facility'' means a facility for the delivery of health services and includes—

(A) a hospital, State mental hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, community mental health center, migrant health center, facility operated by a city or county health department, and community health center;

(B) such a facility of a State correctional institution or of the Indian Health Service, and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.];

(C) such a facility used in connection with the delivery of health services under section 248 of this title (relating to hospitals), 249 of this title (relating to care and treatment of persons under quarantine and others), 250 of this title (relating to care and treatment of Federal prisoners), 251 of this title (relating to examination and treatment of certain Federal employees), 252 of this title (relating to examination of aliens), 253 of this title (relating to services to certain Federal employees), 247e of this title (relating to services for persons with Hansen's disease), or 254b(h) of this title (relating to the provision of health services to homeless individuals); and

(D) a Federal medical facility.

(3) Homeless individuals (as defined in section 254b(h)(5) of this title), seasonal agricultural workers (as defined in section 254b(g)(3) of this title) and migratory agricultural workers (as so defined)), and residents of public housing (as defined in section 1437a(b)(1) of this title) may be population groups under paragraph (1).

(b) Criteria for designation of health professional shortage areas; promulgation of regulations

The Secretary shall establish by regulation criteria for the designation of areas, population groups, medical facilities, and other public facilities, in the States, as health professional shortage areas. In establishing such criteria, the Secretary shall take into consideration the following:

(1) The ratio of available health manpower to the number of individuals in an area or pop-

ulation group, or served by a medical facility or other public facility under consideration for designation.

(2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility under consideration for designation.

(3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools.

(c) Considerations in determination of designation

In determining whether to make a designation, the Secretary shall take into consideration the following:

(1) The recommendations of the Governor of each State in which the area, population group, medical facility, or other public facility under consideration for designation is in whole or part located.

(2) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII, XIX, or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], cannot obtain such services because of suspension of physicians from the programs under such titles.

(d) Designation; publication of descriptive lists

(1) In accordance with the criteria established under subsection (b) and the considerations listed in subsection (c), the Secretary shall designate health professional shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations.

(2) For purposes of paragraph (1), a complete descriptive list shall be published in the Federal Register not later than July 1 of 1991 and each subsequent year.

(e) Notice of proposed designation of areas and facilities; time for comment

(1) Prior to the designation of a public facility, including a Federal medical facility, as a health professional shortage area, the Secretary shall give written notice of such proposed designation to the chief administrative officer of such facility and request comments within 30 days with respect to such designation.

(2) Prior to the designation of a health professional shortage area under this section, the Secretary shall, to the extent practicable, give written notice of the proposed designation of such area to appropriate public or private nonprofit entities which are located or have a demonstrated interest in such area and request comments from such entities with respect to the proposed designation of such area.

(f) Notice of designation

The Secretary shall give written notice of the designation of a health professional shortage area, not later than 60 days from the date of such designation, to—

(1) the Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or part located; and

(2) appropriate public or nonprofit private entities which are located or which have a demonstrated interest in the area so designated.

(g) Recommendations to Secretary

Any person may recommend to the Secretary the designation of an area, population group, medical facility, or other public facility as a health professional shortage area.

(h) Public information programs in designated areas

The Secretary may conduct such information programs in areas, among population groups, and in medical facilities and other public facilities designated under this section as health professional shortage areas as may be necessary to inform public and nonprofit private entities which are located or have a demonstrated interest in such areas of the assistance available under this subchapter by virtue of the designation of such areas.

(i) Dissemination

The Administrator of the Health Resources and Services Administration shall disseminate information concerning the designation criteria described in subsection (b) to—

(1) the Governor of each State;

(2) the representative of any area, population group, or facility selected by any such Governor to receive such information;

(3) the representative of any area, population group, or facility that requests such information; and

(4) the representative of any area, population group, or facility determined by the Administrator to be likely to meet the criteria described in subsection (b).

(j) Regulations and report

(1) The Secretary shall submit the report described in paragraph (2) if the Secretary, acting through the Administrator of the Health Resources and Services Administration, issues—

(A) a regulation that revises the definition of a health professional shortage area for purposes of this section; or

(B) a regulation that revises the standards concerning priority of such an area under section 254f–1 of this title.

(2) On issuing a regulation described in paragraph (1), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that describes the regulation.

(3) Each regulation described in paragraph (1) shall take effect 180 days after the committees described in paragraph (2) receive a report referred to in such paragraph describing the regulation.

(July 1, 1944, ch. 373, title III, § 332, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2270; amended Pub. L. 95–142, § 7(d), Oct. 25, 1977, 91 Stat. 1193; Pub. L. 96–32, § 7(d), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title IX, § 986(b)(4), title XXVII, § 2702(a), (b), (c), Aug. 13, 1981, 95 Stat. 603, 903, 904; Pub. L. 100–77, title VI, § 602, July 22, 1987, 101 Stat. 515; Pub. L. 100–177, title III, § 302, Dec. 1, 1987, 101 Stat. 1003; Pub. L. 100–607, title VIII, § 802(b)(2), Nov. 4, 1988, 102 Stat. 3169; Pub. L. 100–628, title VI, § 602(b)(2), Nov. 7, 1988, 102 Stat. 3242; Pub. L. 101–597, title I, § 102, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3014, 3035; Pub. L. 107–251, title III, § 302(a), (d)(2), title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1643, 1645, 1664; Pub. L. 108–163, § 2(f)(1), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 110–355, § 3(b), Oct. 8, 2008, 122 Stat. 3993.)

References in Text

The Indian Self-Determination Act, referred to in subsec. (a)(2)(B), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§ 5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Social Security Act, referred to in subsec. (c)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 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.

Prior Provisions

A prior section 332 of act July 1, 1944, was renumbered section 340, and was classified to section 256 of this title prior to repeal by Pub. L. 95–626.

Amendments

2008—Subsec. (a)(1). Pub. L. 110–355 struck out ''Not earlier than 6 years after such date of designation, and every 6 years thereafter, each such center or clinic shall demonstrate that the center or clinic meets the applicable requirements of the Federal regulations regarding the definition of a health professional shortage area for purposes of this section.'' before ''The Secretary shall not''.

2003—Subsec. (a)(1). Pub. L. 108–163, § 2(f)(1)(A), substituted ''such date of designation'' for ''such date of enactment'' and ''regarding'' for '', issued after the date of enactment of this Act, that revise''.

Subsec. (a)(3). Pub. L. 108–163, § 2(f)(1)(B), substituted ''254b(h)(5)'' for ''254b(h)(4)''.

Subsec. (b)(2). Pub. L. 108–163, § 2(f)(1)(C), struck out comma before period at end.

Subsec. (j). Pub. L. 108–163, § 2(f)(1)(D), added subsec. (j).

2002—Subsec. (a)(1). Pub. L. 107–251, § 302(a)(1)(A), inserted after first sentence ''All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of this title shall be automatically designated as having such a shortage. Not earlier than 6 years after such date of enactment, and every 6 years thereafter, each such center or clinic shall demonstrate that the center or clinic meets the applicable requirements of the Federal regulations, issued after the date of enactment of this Act, that revise the definition of a health professional shortage area for purposes of this section.''

Subsec. (a)(2)(C). Pub. L. 107–251, § 601(a), substituted ''254b(h)'' for ''256''.

Subsec. (a)(3). Pub. L. 107–251, § 302(a)(1)(B), substituted ''254b(h)(4) of this title), seasonal agricultural workers (as defined in section 254b(g)(3) of this title) and migratory agricultural workers (as so defined)), and residents of public housing (as defined in section 1437a(b)(1) of this title) may be population groups'' for ''256(r) of this title) may be a population group''.

Subsec. (b)(2). Pub. L. 107–251, § 302(a)(2), struck out after ''designation,'' the following: ''with special consideration to indicators of—

''(A) infant mortality,

''(B) access to health services,

''(C) health status, and

''(D) ability to pay for health services''.

Subsec. (c)(2)(B). Pub. L. 107–251, § 302(a)(3), substituted ''XVIII, XIX, or XXI of the Social Security Act'' for ''XVIII or XIX of the Social Security Act''.

Subsec. (i). Pub. L. 107–251, § 302(d)(2), added subsec. (i).

1990—Subsec. (a)(1). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (a)(2)(A). Pub. L. 101–597, § 102(b)(1), inserted ''facility operated by a city or county health department,'' before ''and community health center''.

Subsec. (a)(2)(B). Pub. L. 101–597, § 102(b)(2), inserted before semicolon '', and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act''.

Subsec. (a)(2)(C). Pub. L. 101–597, § 102(b)(3), substituted ''section'' for ''sections'' before ''248'', struck out ''or'' before ''253'' and ''or section'' before ''247e'', and inserted before semicolon '', or 256 of this title (relating to the provision of health services to homeless individuals)''.

Subsec. (b). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, § 102(c)(1), struck out '', promulgated not later than May 1, 1977,'' after ''establish by regulation''.

Subsec. (c). Pub. L. 101–597, § 102(c)(2), redesignated pars. (2) and (3) as (1) and (2), respectively, and struck out former par. (1) which read as follows:

''(A) The recommendations of each health systems agency (designated under section 300*l*–4 of this title) for a health service area which includes all or any part of the area, population group, medical facility, or other public facility under consideration for designation.

''(B) The recommendations of the State health planning and development agency (designated under section 300m of this title) if such area, population group, medical facility, or other public facility is within a health service area for which no health systems agency has been designated.''

Subsec. (d). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (1).

Pub. L. 101–597, § 102(a), (c)(3), designated existing provision as par. (1), struck out '', not later than November 1, 1977,'' after ''Secretary shall designate'', and added par. (2).

Subsec. (e). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (f). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, § 102(c)(4), redesignated par. (3) as (2) and struck out former par. (2) which read as follows:

''(A) each health systems agency (designated under section 300*l*–4 of this title) for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated; or

''(B) the State health planning and development agency of the State (designated under section 300m of this title) if there is a part of such area, population group, medical facility, or other public facility within a health service area for which no health systems agency has been designated; and''.

Subsecs. (g), (h). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

1988—Subsec. (a)(3). Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, substituting ''section 256(r)'' for ''section 256(q)(2)''.

1987—Subsec. (a)(1). Pub. L. 100–177, § 302(1), inserted sentence at end relating to removal of an area from areas determined to be health manpower shortage areas.

Subsec. (a)(3). Pub. L. 100–77 added par. (3).

Subsec. (b)(2)(D). Pub. L. 100–177, § 302(2), added subpar. (D).

1981—Subsec. (a)(1)(A). Pub. L. 97–35, § 2702(a), inserted provisions respecting reasonable accessibility to adequately served area.

Subsec. (a)(2)(C). Pub. L. 97–35, § 986(b)(4), substituted ''persons under quarantine'' for ''seamen''.

Subsec. (e). Pub. L. 97–35, § 2702(c), designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 97–35, § 2702(b), substituted ''may'' for ''shall''.

1979—Subsec. (a)(2)(C). Pub. L. 96–32 substituted ''section 247e of this title'' for ''part D of subchapter II of this chapter''.

1977—Subsec. (c)(3). Pub. L. 95–142 added par. (3).

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments 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 1988 AMENDMENTS

Pub. L. 100–628, title VI, § 631, Nov. 7, 1988, 102 Stat. 3244, provided that: ''The amendments made by subsection (a) of section 601 [amending section 256 of this title] shall take effect in accordance with subsection (b) of such section [formerly set out as a note under section 256 of this title]. The amendments otherwise made by this title [amending this section and sections 256, 290bb–2, 290cc–21, 290cc–28, 290cc–29, 290cc–35, 290cc–36, 290dd, 290ee, and 290ee–1 of this title and amending provisions set out as a note under section 290aa–3 of this title] shall take effect October 1, 1988, or upon the date of the enactment of this Act [Nov. 7, 1988], whichever occurs later.''

Pub. L. 100–607, title VIII, § 831, Nov. 4, 1988, 102 Stat. 3171, provided that: ''The amendments made by subsection (a) of section 801 [amending section 256 of this title] shall take effect in accordance with subsection (b) of such section [formerly set out as a note under section 256 of this title]. The amendments otherwise made by this title [amending this section and sections 256, 290bb–2, 290cc–21, 290cc–28, 290cc–29, 290cc–35, 290cc–36, 290dd, 290ee, and 290ee–1 of this title and amending provisions set out as a note under section 290aa–3 of this title] shall take effect October 1, 1988, or upon the date of the enactment of this Act [Nov. 4, 1988], whichever occurs later.''

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by section 986(b)(4) of Pub. L. 97–35 effective Oct. 1, 1981, see section 986(c) of Pub. L. 97–35, set out as a note under section 249 of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–142, § 7(e)(1), Oct. 25, 1977, 91 Stat. 1194, provided that: ''The amendment made by subsection (d) [amending this section] shall apply with respect to determinations and designations made on and after the date of the enactment of this Act [Oct. 25, 1977].''

REGULATIONS

Pub. L. 107–251, title III, § 302(b), Oct. 26, 2002, 116 Stat. 1644, which required the Secretary to submit a report to Congress, if the Secretary issued regulations revising the definition of a health professional shortage area under this section and standards concerning priority of such an area under section 254f–1 of this title, was repealed by Pub. L. 108–163, § 2(f)(2), Dec. 6, 2003, 117 Stat. 2022.

IMPROVEMENT OF SITE DESIGNATION PROCESS

Pub. L. 107–251, title III, § 302(d)(1), Oct. 26, 2002, 116 Stat. 1644, provided that: ''The Administrator of the Health Resources and Services Administration, in consultation with the Association of State and Territorial Dental Directors, dental societies, and other interested parties, shall revise the criteria on which the designations of dental health professional shortage areas are based so that such criteria provide a more accurate reflection of oral health care need, particularly in rural areas.''

GAO STUDY

Pub. L. 107–251, title III, § 302(e), Oct. 26, 2002, 116 Stat. 1645, provided that: ''Not later than February 1, 2005, the Comptroller General of the United States shall submit to the Congress a report on the appropriateness of the criteria, including but not limited to infant mortality rates, access to health services taking into account the distance to primary health services, the rate of poverty and ability to pay for health services, and low birth rates, established by the Secretary of Health and Human Services for the designation of health professional shortage areas and whether the deeming of federally qualified health centers and rural health clinics as such areas is appropriate and necessary.''

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center, considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

EVALUATION OF CRITERIA USED TO DESIGNATE HEALTH MANPOWER SHORTAGE AREAS; REPORT TO CONGRESS

Pub. L. 97–35, title XXVII, § 2702(c), Aug. 13, 1981, 95 Stat. 903, directed the Secretary of Health and Human Services, effective Oct. 1, 1981, to evaluate the criteria used under section 254e(b) of this title to determine if the use of the criteria resulted in areas which did not have a shortage of health professions personnel being designated as health manpower shortage areas, and to consider different criteria (including the actual use of health professions personnel in an area by the residents, taking into account their health status and indicators of unmet demand and likelihood that such demand would not be met in two years) which might be used to designate health manpower shortage areas. The Secretary was to report the results of his activities to Congress not later than Nov. 30, 1982.

§ 254f. Corps personnel

(a) Conditions necessary for assignment of Corps personnel to area; contents of application for assignment; assignment to particular facility; approval of applications

(1) The Secretary may assign members of the Corps to provide, under regulations promulgated by the Secretary, health services in or to a health professional shortage area during the assignment period only if—

(A) a public or private entity, which is located or has a demonstrated interest in such area makes application to the Secretary for such assignment;

(B) such application has been approved by the Secretary;

(C) the entity agrees to comply with the requirements of section 254g of this title; and

(D) the Secretary has (i) conducted an evaluation of the need and demand for health manpower for the area, the intended use of Corps members to be assigned to the area, community support for the assignment of Corps members to the area, the area's efforts to secure health manpower for the area, and the fiscal management capability of the entity to which Corps members would be assigned and (ii) on the basis of such evaluation has determined that—

(I) there is a need and demand for health manpower for the area;

(II) there has been appropriate and efficient use of any Corps members assigned to the entity for the area;

(III) there is general community support for the assignment of Corps members to the entity;

(IV) the area has made unsuccessful efforts to secure health manpower for the area;

(V) there is a reasonable prospect of sound fiscal management, including efficient collection of fee-for-service, third-party, and other appropriate funds, by the entity with respect to Corps members assigned to such entity; and

(VI) the entity demonstrates willingness to support or facilitate mentorship, professional development, and training opportunities for Corps members.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the applicant that the area or population group to be served by the applicant has a shortage of personal health services and that the Corps member will be located so that the member will provide services to the greatest number of persons residing in such area or included in such population group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under section 254e(b) of this title and on additional criteria which the Secretary shall prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services.

(2) Corps members may be assigned to a Federal health care facility, but only upon the request of the head of the department or agency of which such facility is a part.

(3) In approving applications for assignment of members of the Corps the Secretary shall not discriminate against applications from entities which are not receiving Federal financial assistance under this chapter. In approving such applications, the Secretary shall give preference to applications in which a nonprofit entity or public entity shall provide a site to which Corps members may be assigned.

(b) Corps member income assurances; grants respecting sufficiency of financial resources

(1) The Secretary may not approve an application for the assignment of a member of the Corps described in subparagraph (C) of section 254d(a)(1) of this title to an entity unless the application of the entity contains assurances satisfactory to the Secretary that the entity (A) has sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 254d(a)(1) of this title, or (B) would have such financial resources if a grant was made to the entity under paragraph (2).

(2)(A) If in approving an application of an entity for the assignment of a member of the Corps described in subparagraph (C) of section 254d(a)(1) of this title the Secretary determines that the entity does not have sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 254d(a)(1) of this title, the Secretary may make a grant to the entity to assure that the member of the Corps assigned to it will receive during the period of assignment to the entity such an income.

(B) The amount of any grant under subparagraph (A) shall be determined by the Secretary. Payments under such a grant may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary. No grant may be made unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c) Assignment of members without regard to ability of area to pay for services

The Secretary shall assign Corps members to entities in health professional shortage areas without regard to the ability of the individuals in such areas, population groups, medical facilities, or other public facilities to pay for such services.

(d) Entities entitled to aid; forms of assistance; coordination of efforts; agreements for assignment of Corps members; qualified entity

(1) The Secretary may provide technical assistance to a public or private entity which is located in a health professional shortage area and which desires to make an application under this section for assignment of a Corps member to such area. Assistance provided under this paragraph may include assistance to an entity in (A) analyzing the potential use of health professions personnel in defined health services delivery areas by the residents of such areas, (B) determining the need for such personnel in such areas, (C) determining the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice, (D) determining the types of inpatient and other health services that should be provided by such personnel in such areas, and (E) developing long-term plans for addressing health professional shortages and improving access to health care. The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care Associations and Offices, and other entities concerned with site development and community needs assessment.

(2) The Secretary may provide, to public and private entities which are located in a health professional shortage area to which area a Corps member has been assigned, technical assistance to assist in the retention of such member in such area after the completion of such member's assignment to the area.

(3) The Secretary may provide, to health professional shortage areas to which no Corps member has been assigned, (A) technical assistance to assist in the recruitment of health manpower for such areas, and (B) current information on public and private programs which provide assistance in the securing of health manpower.

(4)(A) The Secretary shall undertake to demonstrate the improvements that can be made in the assignment of members of the Corps to health professional shortage areas and in the delivery of health care by Corps members in such areas through coordination with States, political subdivisions of States, agencies of States and political subdivisions, and other public and private entities which have expertise in the planning, development, and operation of centers for the delivery of primary health care. In carrying out this subparagraph, the Secretary shall enter into agreements with qualified entities which provide that if—

(i) the entity places in effect a program for the planning, development, and operation of centers for the delivery of primary health care in health professional shortage areas which reasonably addresses the need for such care in such areas, and

(ii) under the program the entity will perform the functions described in subparagraph (B),

the Secretary will assign under this section members of the Corps in accordance with the program.

(B) For purposes of subparagraph (A), the term ''qualified entity'' means a State, political subdivision of a State, an agency of a State or political subdivision, or other public or private entity operating solely within one State, which the Secretary determines is able—

(i) to analyze the potential use of health professions personnel in defined health services delivery areas by the residents of such areas;

(ii) to determine the need for such personnel in such areas and to recruit, select, and retain health professions personnel (including members of the National Health Service Corps) to meet such need;

(iii) to determine the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice;

(iv) to determine the types of inpatient and other health services that should be provided by such personnel in such areas;

(v) to assist such personnel in the development of their clinical practice and fee schedules and in the management of their practice;

(vi) to assist in the planning and development of facilities for the delivery of primary health care; and

(vii) to assist in establishing the governing bodies of centers for the delivery of such care and to assist such bodies in defining and carrying out their responsibilities.

(e) Practice within State by Corps member

Notwithstanding any other law, any member of the Corps licensed to practice medicine, osteopathic medicine, dentistry, or any other health profession in any State shall, while serving in the Corps, be allowed to practice such profession in any State.

(July 1, 1944, ch. 373, title III, § 333, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2272; amended Pub. L. 97–35, title XXVII, § 2703, Aug. 13, 1981, 95 Stat. 904; Pub. L. 100–177, title III, §§ 303, 304, Dec. 1, 1987, 101 Stat. 1004; Pub. L. 100–607, title VI, § 629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title I, § 103, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3015, 3035; Pub. L. 107–251, title III, § 303, Oct. 26, 2002, 116 Stat. 1645; Pub. L. 108–163, § 2(g), Dec. 6, 2003, 117 Stat. 2022; Pub. L. 110–355, § 3(c), Oct. 8, 2008, 122 Stat. 3993.)

AMENDMENTS

2008—Subsec. (a)(1)(D)(ii)(VI). Pub. L. 110–355 added subcl. (VI).

2003—Subsec. (a)(1)(C). Pub. L. 108–163 realigned margin.

2002—Subsec. (a)(1). Pub. L. 107–251, § 303(1)(A)(i), struck out ''(specified in the agreement described in section 254g of this title)'' after ''assignment period'' in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 107–251, § 303(1)(A)(ii), struck out ''nonprofit'' before ''private entity''.

Subsec. (a)(1)(C). Pub. L. 107–251, § 303(1)(A)(iii), added subpar. (C) and struck out former subpar. (C) which read as follows: ''an agreement has been entered into between the entity which has applied and the Secretary, in accordance with section 254g of this title; and''.

Subsec. (a)(3). Pub. L. 107–251, § 303(1)(B), inserted at end ''In approving such applications, the Secretary shall give preference to applications in which a nonprofit entity or public entity shall provide a site to which Corps members may be assigned.''

Subsec. (d)(1). Pub. L. 107–251, § 303(2), struck out ''nonprofit'' before ''private entity'' in first sentence, added cl. (E), and inserted at end ''The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care Associations and Offices, and other entities concerned with site development and community needs assessment.''

Subsec. (d)(2). Pub. L. 107–251, § 303(2)(A), struck out ''nonprofit'' before ''private entities''.

Subsec. (d)(4). Pub. L. 107–251, § 303(2)(A), struck out ''nonprofit'' before ''private entities'' in introductory provisions of subpar. (A) and before ''private entity'' in introductory provisions of subpar. (B).

1990—Subsec. (a)(1). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in introductory and closing provisions.

Subsec. (a)(1)(D)(ii)(II). Pub. L. 101–597, § 103(a), substituted ''has been'' and ''any Corps'' for ''will be'' and ''Corps'', respectively.

Subsec. (b). Pub. L. 101–597, § 103(b), redesignated subsec. (d) as (b) and struck out former subsec. (b) which related to approval of application for assignment of Corps personnel subject to review and comment on application by health service agencies in designated area.

Subsec. (c). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, § 103(b), redesignated subsec. (e) as (c) and struck out former subsec. (c) which related to applications, consideration and approval by Secretary, priorities, cooperation with Corps members, and com-

ments by health professionals and societies in designated areas.

Subsec. (d). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in pars. (1) to (4)(A)(i).

Pub. L. 101–597, § 103(b)(2), redesignated subsec. (g) as (d). Former subsec. (d) redesignated (b).

Subsec. (e). Pub. L. 101–597, § 103(b)(2), redesignated subsec. (i) as (e). Former subsec. (e) redesignated (c).

Subsec. (f). Pub. L. 101–597, § 103(b)(1), struck out subsec. (f) which provided for selection of Corps members for assignment upon basis of characteristics.

Subsec. (g). Pub. L. 101–597, § 103(b)(2), redesignated subsec. (g) as (d).

Subsec. (h). Pub. L. 101–597, § 103(b)(1), struck out subsec. (h) which related to study and contracts for study of methods of assignments of Corps members.

Subsec. (i). Pub. L. 101–597, § 103(b)(2), redesignated subsec. (i) as (e).

Subsecs. (j), (k). Pub. L. 101–597, § 103(b)(1), struck out subsecs. (j) and (k) which provided for placement of physicians in medically underserved areas and assignment of family physicians, respectively.

1988—Subsec. (i). Pub. L. 100–607 substituted ''osteopathic medicine'' for ''osteopathy''.

1987—Subsec. (j). Pub. L. 100–177, § 303, added subsec. (j).

Subsec. (k). Pub. L. 100–177, § 304, added subsec. (k).

1981—Subsec. (a). Pub. L. 97–35, § 2703(a), (b), amended par. (1)(D) generally and, among changes, made numerous changes in nomenclature, inserted at end of par. (1) provisions respecting application, and added par. (3).

Subsec. (c). Pub. L. 97–35, § 2703(c), struck out par. (2) which related to special considerations, and redesignated pars. (3) and (4) as (2) and (3), respectively.

Subsecs. (d) to (f). Pub. L. 97–35, § 2703(d), added subsec. (d) and redesignated former subsecs. (d), (e), and (f) as (e), (f), and (g), respectively.

Subsec. (g). Pub. L. 97–35, § 2703(d), (e), redesignated former subsec. (f) as (g) and substituted ''may'' for ''shall'' in pars. (1) to (3), inserted provisions respecting health professions personnel in par. (1), added par. (4), and struck out requirement respecting demonstrated interest in pars. (1) and (2). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 97–35, § 2703(d), (f), redesignated former subsec. (g) as (h) and directed that ''may'' be substituted for ''shall'' which was executed by substituting ''may'' for ''shall'' in two places preceding par. (1). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 97–35, § 2703(d), (g), redesignated former subsec. (h) as (i) and inserted reference to other health profession.

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 1981 AMENDMENT

Pub. L. 97–35, title XXVII, § 2703(d), Aug. 13, 1981, 95 Stat. 905, provided that the amendment made by that section is effective Oct. 1, 1981.

§ 254f–1. Priorities in assignment of Corps personnel

(a) In general

In approving applications made under section 254f of this title for the assignment of Corps members, the Secretary shall—

(1) give priority to any such application that—

(A) is made regarding the provision of primary health services to a health professional shortage area with the greatest such shortage; and

(B) is made by an entity that—

(i) serves a health professional shortage area described in subparagraph (A);

(ii) coordinates the delivery of primary health services with related health and social services;

(iii) has a documented record of sound fiscal management; and

(iv) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity;

(2) with respect to the geographic area in which the health professional shortage area is located, take into consideration the willingness of individuals in the geographic area, and of the appropriate governmental agencies or health entities in the area, to assist and cooperate with the Corps in providing effective primary health services; and

(3) take into consideration comments of medical, osteopathic, dental, or other health professional societies whose members deliver services to the health professional shortage area, or if no such societies exist, comments of physicians, dentists, or other health professionals delivering services to the area.

(b) Establishment of criteria for determining priorities

(1) In general

The Secretary shall establish criteria specifying the manner in which the Secretary makes a determination under subsection (a)(1)(A) of the health professional shortage areas with the greatest such shortages.

(2) Publication of criteria

The criteria required in paragraph (1) shall be published in the Federal Register not later than July 1, 1991. Any revisions made in the criteria by the Secretary shall be effective upon publication in the Federal Register.

(c) Notifications regarding priorities

(1) Proposed list

The Secretary shall prepare and publish a proposed list of health professional shortage areas and entities that would receive priority under subsection (a)(1) in the assignment of Corps members. The list shall contain the information described in paragraph (2), and the relative scores and relative priorities of the entities submitting applications under section 254f of this title, in a proposed format. All such entities shall have 30 days after the date of publication of the list to provide additional data and information in support of inclusion on the list or in support of a higher priority determination and the Secretary shall reasonably consider such data and information in preparing the final list under paragraph (2).

(2) Preparation of list for applicable period

For the purpose of carrying out paragraph (3), the Secretary shall prepare and, as appropriate, update a list of health professional shortage areas and entities that are receiving priority under subsection (a)(1) in the assignment of Corps members. Such list—

(A) shall include a specification, for each such health professional shortage area, of

the entities for which the Secretary has provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments; and

(B) shall, of the entities for which an authorization described in subparagraph (A) has been provided, specify—

(i) the entities provided such an authorization for the assignment of Corps members who are participating in the Scholarship Program;

(ii) the entities provided such an authorization for the assignment of Corps members who are participating in the Loan Repayment Program; and

(iii) the entities provided such an authorization for the assignment of Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs.

The Secretary may set forth such specifications by medical specialty.

(3) Notification of affected parties

(A) Entities

Not later than 30 days after the Secretary has added to a list under paragraph (2) an entity specified as described in subparagraph (A) of such paragraph, the Secretary shall notify such entity that the entity has been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

(B) Individuals

In the case of an individual obligated to provide service under the Scholarship Program, not later than 3 months before the date described in section 254m(b)(5) of this title, the Secretary shall provide to such individual the names of each of the entities specified as described in paragraph (2)(B)(i) that is appropriate for the individual's medical specialty and discipline.

(4) Revisions

If the Secretary proposes to make a revision in the list under paragraph (2), and the revision would adversely alter the status of an entity with respect to the list, the Secretary shall notify the entity of the revision. Any entity adversely affected by such a revision shall be notified in writing by the Secretary of the reasons for the revision and shall have 30 days from such notification to file a written appeal of the determination involved which shall be reasonably considered by the Secretary before the revision to the list becomes final. The revision to the list shall be effective with respect to assignment of Corps members beginning on the date that the revision becomes final.

(d) Limitation on number of entities offered as assignment choices in Scholarship Program

(1) Determination of available Corps members

By April 1 of each calendar year, the Secretary shall determine the number of participants in the Scholarship Program who will be available for assignments under section 254f of this title during the program year beginning on July 1 of that calendar year.

(2) Determination of number of entities

At all times during a program year, the number of entities specified under subsection (c)(2)(B)(i) shall be—

(A) not less than the number of participants determined with respect to that program year under paragraph (1); and

(B) not greater than twice the number of participants determined with respect to that program year under paragraph (1).

(July 1, 1944, ch. 373, title III, § 333A, as added and amended Pub. L. 101–597, title I, § 104, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3015, 3035; Pub. L. 107–251, title III, § 304, Oct. 26, 2002, 116 Stat. 1646; Pub. L. 108–163, § 2(h), Dec. 6, 2003, 117 Stat. 2022.)

AMENDMENTS

2003—Subsec. (c)(4). Pub. L. 108–163 substituted ''30 days from such notification'' for ''30 days''.

2002—Subsec. (a)(1)(A). Pub. L. 107–251, § 304(1), struck out '', as determined in accordance with subsection (b) of this section'' after ''such shortage''.

Subsec. (b). Pub. L. 107–251, § 304(2), (7), redesignated subsec. (c) as (b) and struck out heading and text of former subsec. (b). Text read as follows: ''In making a determination under subsection (a)(1)(A) of this section of the health professional shortage areas with the greatest such shortages, the Secretary may consider only the following factors:

''(1) The ratio of available health manpower to the number of individuals in the area or population group involved, or served by the medical facility or other public facility involved.

''(2) Indicators of need as follows:

''(A) The rate of low birthweight births.

''(B) The rate of infant mortality.

''(C) The rate of poverty.

''(D) Access to primary health services, taking into account the distance to such services.''

Subsec. (c). Pub. L. 107–251, § 304(7), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Subsec. (c)(1). Pub. L. 107–251, § 304(3), struck out second sentence, which read as follows: ''Such criteria shall specify the manner in which the factors described in subsection (b) of this section are implemented regarding such a determination.''

Subsec. (d). Pub. L. 107–251, § 304(7), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1). Pub. L. 107–251, § 304(4)(B), added par. (1). Former par. (1) redesignated (2).

Subsec. (d)(2). Pub. L. 107–251, § 304(4)(C), in introductory provisions, substituted ''paragraph (3)'' for ''paragraph (2)'' and ''prepare and, as appropriate, update a list of health professional shortage areas and entities'' for ''prepare a list of health professional shortage areas'' and struck out ''for the period applicable under subsection (f) of this section'' after ''Corps members''.

Pub. L. 107–251, § 304(4)(A), redesignated par. (1) as (2). Former par. (2) redesignated (3).

Subsec. (d)(3). Pub. L. 107–251, § 304(4)(D), added par. (3) and struck out heading and text of former par. (3). Text read as follows:

''(A) Not later than 30 days after the preparation of each list under paragraph (1), the Secretary shall notify entities specified for purposes of subparagraph (A) of such paragraph of the fact that the entities have been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

''(B) In the case of individuals with respect to whom a period of obligated service under the Scholarship Pro-

gram will begin during the period under subsection (f) of this section for which a list under paragraph (1) is prepared, the Secretary shall, not later than 30 days after the preparation of each such list, provide to such individuals the names of each of the entities specified for purposes of paragraph (1)(B)(i) that is appropriate to the medical specialty of the individuals.''

Pub. L. 107–251, § 304(4)(A), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (d)(4). Pub. L. 107–251, § 304(4)(E), added par. (4) and struck out heading and text of former par. (4). Text read as follows: ''If the Secretary makes a revision in a list under paragraph (1) during the period under subsection (f) of this section to which the list is applicable, and the revision alters the status of an entity with respect to the list, the Secretary shall notify the entity of the effect on the entity of the revision. Such notification shall be provided not later than 30 days after the date on which the revision is made.''

Pub. L. 107–251, § 304(4)(A), redesignated par. (3) as (4).

Subsec. (e). Pub. L. 107–251, § 304(7), redesignated subsec. (e) as (d).

Pub. L. 107–251, § 304(5), added subsec. (e) and struck out heading and text of former subsec. (e). Text related to limitation on the number of entities offered as assignment choices in the Scholarship Program based on the number of participants available for assignments.

Subsec. (f). Pub. L. 107–251, § 304(6), struck out heading and text of subsec. (f), which related to applicable period regarding priorities in assignment of Corps members.

1990—Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in subsecs. (a) to (c)(1), (d)(1), and (e)(3).

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.

§ 254g. Charges for services by entities using Corps members

(a) Availability of services regardless of ability to pay or payment source

An entity to which a Corps member is assigned shall not deny requested health care services, and shall not discriminate in the provision of services to an individual—

(1) because the individual is unable to pay for the services; or

(2) because payment for the services would be made under—

(A) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(B) the medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.); or

(C) the State children's health insurance program under title XXI of such Act (42 U.S.C. 1397aa et seq.).

(b) Charges for services

The following rules shall apply to charges for health care services provided by an entity to which a Corps member is assigned:

(1) In general

(A) Schedule of fees or payments

Except as provided in paragraph (2), the entity shall prepare a schedule of fees or payments for the entity's services, consistent with locally prevailing rates or charges and designed to cover the entity's reasonable cost of operation.

(B) Schedule of discounts

Except as provided in paragraph (2), the entity shall prepare a corresponding schedule of discounts (including, in appropriate cases, waivers) to be applied to the payment of such fees or payments. In preparing the schedule, the entity shall adjust the discounts on the basis of a patient's ability to pay.

(C) Use of schedules

The entity shall make every reasonable effort to secure from patients fees and payments for services in accordance with such schedules, and fees or payments shall be sufficiently discounted in accordance with the schedule described in subparagraph (B).

(2) Services to beneficiaries of Federal and federally assisted programs

In the case of health care services furnished to an individual who is a beneficiary of a program listed in subsection (a)(2), the entity—

(A) shall accept an assignment pursuant to section 1842(b)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395u(b)(3)(B)(ii)) with respect to an individual who is a beneficiary under the medicare program; and

(B) shall enter into an appropriate agreement with—

(i) the State agency administering the program under title XIX of such Act [42 U.S.C. 1396 et seq.] with respect to an individual who is a beneficiary under the medicaid program; and

(ii) the State agency administering the program under title XXI of such Act [42 U.S.C. 1397aa et seq.] with respect to an individual who is a beneficiary under the State children's health insurance program.

(3) Collection of payments

The entity shall take reasonable and appropriate steps to collect all payments due for health care services provided by the entity, including payments from any third party (including a Federal, State, or local government agency and any other third party) that is responsible for part or all of the charge for such services.

(July 1, 1944, ch. 373, title III, § 334, as added Pub. L. 107–251, title III, § 305, Oct. 26, 2002, 116 Stat. 1647; amended Pub. L. 108–163, § 2(i), Dec. 6, 2003, 117 Stat. 2022.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(2) and (b)(2)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 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.

PRIOR PROVISIONS

A prior section 254g, act July 1, 1944, ch. 373, title III, § 334, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2274; amended Pub. L. 97–35, title XXVII, § 2704, Aug. 13, 1981, 95 Stat. 906; Pub. L. 98–194, § 3, Dec. 1, 1983, 97 Stat. 1345; Pub. L. 100–177, title II, § 202(c), Dec. 1, 1987, 101 Stat. 996; Pub. L. 101–597, title I, § 105, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035,

related to shared responsibility for costs of Corps personnel providing health services in or to a health professional shortage area during the assignment period, prior to repeal by Pub. L. 107–251, title III, § 305, Oct. 26, 2002, 116 Stat. 1647.

AMENDMENTS

2003—Subsec. (b)(1)(B). Pub. L. 108–163 inserted ''the payment of'' after ''applied to''.

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.

§ 254h. Provision of health services by Corps members

(a) Means of delivery of services; cooperation with other health care providers

In providing health services in a health professional shortage area, Corps members shall utilize the techniques, facilities, and organizational forms most appropriate for the area, population group, medical facility, or other public facility, and shall, to the maximum extent feasible, provide such services (1) to all individuals in, or served by, such health professional shortage area regardless of their ability to pay for the services, and (2) in a manner which is cooperative with other health care providers serving such health professional shortage area.

(b) Utilization of existing health facilities; lease, acquisition, and use of equipment and supplies; permanent and temporary professional services

(1) Notwithstanding any other provision of law, the Secretary may (A) to the maximum extent feasible make such arrangements as he determines necessary to enable Corps members to utilize the health facilities in or serving the health professional shortage area in providing health services; (B) make such arrangements as he determines are necessary for the use of equipment and supplies of the Service and for the lease or acquisition of other equipment and supplies; and (C) secure the permanent or temporary services of physicians, dentists, nurses, administrators, and other health personnel. If there are no health facilities in or serving such area, the Secretary may arrange to have Corps members provide health services in the nearest health facilities of the Service or may lease or otherwise provide facilities in or serving such area for the provision of health services.

(2) If the individuals in or served by a health professional shortage area are being served (as determined under regulations of the Secretary) by a hospital or other health care delivery facility of the Service, the Secretary may, in addition to such other arrangements as he may make under paragraph (1), arrange for the utilization of such hospital or facility by Corps members in providing health services, but only to the extent that such utilization will not impair the delivery of health services and treatment through such hospital or facility to individuals who are entitled to health services and treatment through such hospital or facility.

(c) Loan; purposes; limitations

The Secretary may make one loan to any entity with an approved application under section 254f of this title to assist such entity in meeting the costs of (1) establishing medical, dental, or other health profession practices, including the development of medical practice management systems; (2) acquiring equipment for use in providing health services; and (3) renovating buildings to establish health facilities. No loan may be made under this subsection unless an application therefor is submitted to, and approved by, the Secretary. The amount of any such loan shall be determined by the Secretary, except that no such loan may exceed $50,000.

(d) Property and equipment disposal; fair market value; sale at less than full market value

Upon the expiration of the assignment of all Corps members to a health professional shortage area, the Secretary may (notwithstanding any other provision of law) sell, to any appropriate local entity, equipment and other property of the United States utilized by such members in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property; except that the Secretary may make such sales for a lesser value to an appropriate local entity, if he determines that the entity is financially unable to pay the full market value.

(e) Admitting privileges denied to Corps member by hospital; notice and hearing; denial of Federal funds for violation; "hospital" defined

(1)(A) It shall be unlawful for any hospital to deny an authorized Corps member admitting privileges when such Corps member otherwise meets the professional qualifications established by the hospital for granting such privileges and agrees to abide by the published bylaws of the hospital and the published bylaws, rules, and regulations of its medical staff.

(B) Any hospital which is found by the Secretary, after notice and an opportunity for a hearing on the record, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under this chapter or under titles XVIII, XIX, or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.].

(2) For purposes of this subsection, the term ''hospital'' includes a State or local public hospital, a private profit hospital, a private nonprofit hospital, a general or special hospital, and any other type of hospital (excluding a hospital owned or operated by an agency of the Federal Government), and any related facilities.

(July 1, 1944, ch. 373, title III, § 335, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2275; amended Pub. L. 97–35, title XXVII, § 2705, Aug. 13, 1981, 95 Stat. 907; Pub. L. 101–597, title I, § 106, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035; Pub. L. 107–251, title III, § 306, Oct. 26, 2002, 116 Stat. 1648.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (e)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 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.

AMENDMENTS

2002—Subsec. (e)(1)(B). Pub. L. 107–251 substituted ''titles XVIII, XIX, or XXI of the Social Security Act'' for ''titles XVIII or XIX of the Social Security Act''.

1990—Subsecs. (a), (b)(1)(A), (2), (d). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (e)(1)(A). Pub. L. 101–597, § 106, substituted ''authorized Corps member admitting privileges'' for ''authorized physician or dentist member of the Corps admitting privileges''.

1981—Subsec. (a)(2). Pub. L. 97–35, § 2705(a), substituted provisions respecting cooperation with other health care providers, for provisions respecting direct health services programs.

Subsec. (c)(4). Pub. L. 97–35, § 2705(b), struck out cl. (4) relating to appropriate continuing education programs.

§ 254h–1. Facilitation of effective provision of Corps services

(a) Consideration of individual characteristics of members in making assignments

In making an assignment of a Corps member to an entity that has had an application approved under section 254f of this title, the Secretary shall, subject to making the assignment in accordance with section 254f–1 of this title, seek to assign to the entity a Corps member who has (and whose spouse, if any, has) characteristics that increase the probability that the member will remain in the health professional shortage area involved after the completion of the period of service in the Corps.

(b) Counseling on service in Corps

(1) In general

The Secretary shall, subject to paragraph (3), offer appropriate counseling on service in the Corps to individuals during the period of membership in the Corps, particularly during the initial period of each assignment.

(2) Career advisor regarding obligated service

(A) In the case of individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, counseling under paragraph (1) shall include appropriate counseling on matters particular to such obligated service. The Secretary shall ensure that career advisors for providing such counseling are available to such individuals throughout the period of participation in the Scholarship or Loan Repayment Program.

(B) With respect to the Scholarship Program, counseling under paragraph (1) shall include counseling individuals during the period in which the individuals are pursuing an educational degree in the health profession involved, including counseling to prepare the individual for service in the Corps.

(3) Extent of counseling services

With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, this subsection shall be carried out regarding such individuals throughout the period of obligated service (and, additionally, throughout the period specified in paragraph (2)(B), in the case of the Scholarship Program). With respect to Corps members generally, this subsection shall be carried out to the extent practicable.

(c) Grants regarding preparation of students for practice

With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, the Secretary may make grants to, and enter into contracts with, public and nonprofit private entities (including health professions schools) for the conduct of programs designed to prepare such individuals for the effective provision of primary health services in the health professional shortage areas to which the individuals are assigned.

(d) Professional development and training

(1) In general

The Secretary shall assist Corps members in establishing and maintaining professional relationships and development opportunities, including by—

(A) establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned;

(B) establishing professional development, training, and mentorship linkages between the Corps member involved and the larger health professions community, including through distance learning, direct mentorship, and development and implementation of training modules designed to meet the educational needs of offsite Corps members;

(C) establishing professional networks among Corps members; or

(D) engaging in other professional development, mentorship, and training activities for Corps members, at the discretion of the Secretary.

(2) Assistance in establishing professional relationships

In providing such assistance under paragraph (1), the Secretary shall focus on establishing relationships with hospitals, with academic medical centers and health professions schools, with area health education centers under section 294a of this title, with health education and training centers under section 294b[1] of this title, and with border health education and training centers under such section 294b[1] of this title. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(3) Supplement not supplant

Such efforts under this subsection shall supplement, not supplant, non-government efforts by professional health provider societies to establish and maintain professional relationships and development opportunities.

[1] See References in Text note below.

(e) Temporary relief from Corps duties

(1) In general

The Secretary shall, subject to paragraph (4), provide assistance to Corps members in establishing arrangements through which Corps members may, as appropriate, be provided temporary relief from duties in the Corps in order to pursue continuing education in the health professions, to participate in exchange programs with teaching centers, to attend professional conferences, or to pursue other interests, including vacations.

(2) Assumption of duties of member

(A) Temporary relief under paragraph (1) may be provided only if the duties of the Corps member involved are assumed by another health professional. With respect to such temporary relief, the duties may be assumed by Corps members or by health professionals who are not Corps members, if the Secretary approves the professionals for such purpose. Any health professional so approved by the Secretary shall, during the period of providing such temporary relief, be deemed to be a Corps member for purposes of section 233 of this title (including for purposes of the remedy described in such section), section 254f(f) of this title, and section 254h(e) of this title.

(B) In carrying out paragraph (1), the Secretary shall provide for the formation and continued existence of a group of health professionals to provide temporary relief under such paragraph.

(3) Recruitment from general health professions community

In carrying out paragraph (1), the Secretary shall—

(A) encourage health professionals who are not Corps members to enter into arrangements under which the health professionals temporarily assume the duties of Corps members for purposes of paragraph (1); and

(B) with respect to the entities to which Corps members have been assigned under section 254f of this title, encourage the entities to facilitate the development of arrangements described in subparagraph (A).

(4) Limitation

In carrying out paragraph (1), the Secretary may not, except as provided in paragraph (5), obligate any amounts (other than for incidental expenses) for the purpose of—

(A) compensating a health professional who is not a Corps member for assuming the duties of a Corps member; or

(B) paying the costs of a vacation, or other interests that a Corps member may pursue during the period of temporary relief under such paragraph.

(5) Sole providers of health services

In the case of any Corps member who is the sole provider of health services in the geographic area involved, the Secretary may, from amounts appropriated under section 254k of this title, obligate on behalf of the member such sums as the Secretary determines to be necessary for purposes of providing temporary relief under paragraph (1).

(f) Determinations regarding effective service

In carrying out subsection (a) and sections 254*l*(d) and 254*l*–1(d) of this title, the Secretary shall carry out activities to determine—

(1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health professional shortage areas after the completion of the period of service in the Corps;

(2) the characteristics of health manpower shortage areas, and of entities seeking assignments of Corps members, that are more likely to retain Corps members after the members have completed the period of service in the Corps; and

(3) the appropriate conditions for the assignment and utilization in health manpower shortage areas of certified nurse practitioners, certified nurse midwives, and physician assistants.

(July 1, 1944, ch. 373, title III, § 336, as added Pub. L. 97–35, title XXVII, § 2706(b), Aug. 13, 1981, 95 Stat. 907; amended Pub. L. 100–177, title II, § 202(d), Dec. 1, 1987, 101 Stat. 997; Pub. L. 101–597, title I, § 107, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035; Pub. L. 107–251, title III, § 307(a), Oct. 26, 2002, 116 Stat. 1649; Pub. L. 110–355, § 3(d), Oct. 8, 2008, 122 Stat. 3993.)

REFERENCES IN TEXT

Section 294b of this title, referred to in subsec. (d)(2), was repealed and a new section 294b enacted by Pub. L. 111–148, title V, § 5403(b), Mar. 23, 2010, 124 Stat. 648, and, as so enacted, no longer relates to health education and training centers.

PRIOR PROVISIONS

A prior section 336 of act July 1, 1944, was renumbered section 336A by Pub. L. 97–35, § 2706(a), and is classified to section 254i of this title.

AMENDMENTS

2008—Subsec. (d). Pub. L. 110–355 amended subsec. (d) generally. Prior to amendment, text read as follows: ''The Secretary shall assist Corps members in establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned, including such relationships with hospitals, with health professions schools, with area health education centers under section 295g–1 of this title, with health education and training centers under such section, and with border health education and training centers under such section. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.''

2002—Subsecs. (c), (f)(1). Pub. L. 107–251 substituted ''health professional shortage areas'' for ''health manpower shortage areas''.

1990—Pub. L. 101–597, § 107, amended section generally. Prior to amendment, section read as follows:

''(a) The Secretary may make grants to and enter into contracts with public and private nonprofit entities for the conduct of programs which are designed to prepare individuals subject to a service obligation under the National Health Service Corps Scholarship Program or Loan Repayment Program to effectively provide health services in the health manpower shortage area to which they are assigned.

''(b) No grant may be made or contract entered into under subsection (a) of this section unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.''

Subsec. (a). Pub. L. 101–597, § 401(b)[(a)], substituted ''health professional shortage area'' for ''health manpower shortage area''.

1987—Subsec. (a). Pub. L. 100–177 substituted ''Scholarship Program or Loan Repayment Program'' for ''scholarship program''.

§ 254i. Annual report to Congress; contents

The Secretary shall submit an annual report to Congress, and shall include in such report with respect to the previous calendar year—

(1) the number, identity, and priority of all health professional shortage areas designated in such year and the number of health professional shortage areas which the Secretary estimates will be designated in the subsequent year;

(2) the number of applications filed under section 254f of this title in such year for assignment of Corps members and the action taken on each such application;

(3) the number and types of Corps members assigned in such year to health professional shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps;

(4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;

(5) the number of patients seen and the number of patient visits recorded during such year with respect to each health professional shortage area to which a Corps member was assigned during such year;

(6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health professional shortage areas after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election;

(7) the results of evaluations and determinations made under section 254f(a)(1)(D) of this title during such year; and

(8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with section 254g of this title, and the amount which was paid to the Secretary in such year under such agreements.

(July 1, 1944, ch. 373, title III, § 336A, formerly § 336, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2277, renumbered § 336A, Pub. L. 97–35, title XXVII, § 2706(a), Aug. 13, 1981, 95 Stat. 907; amended Pub. L. 97–375, title II, § 206(a), Dec. 21, 1982, 96 Stat. 1823; Pub. L. 101–597, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, § 307(b), Oct. 26, 2002, 116 Stat. 1649.)

AMENDMENTS

2002—Par. (8). Pub. L. 107–251 struck out ''agreements under'' after ''in accordance with''.

1990—Pars. (1), (3), (5), (6). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1982—Pub. L. 97–375 struck out ''on May 1 of each year'' after ''report to Congress''.

§ 254j. National Advisory Council on National Health Service Corps

(a) Establishment; appointment of members

There is established a council to be known as the National Advisory Council on the National Health Service Corps (hereinafter in this section referred to as the ''Council''). The Council shall be composed of not more than 15 members appointed by the Secretary. The Council shall consult with, advise, and make recommendations to, the Secretary with respect to his responsibilities in carrying out this subpart (other than section 254r[1] of this title), and shall review and comment upon regulations promulgated by the Secretary under this subpart.

(b) Term of members; compensation; expenses

(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause.

(2) Members of the Council (other than members who are officers or employees of the United States), while attending meetings or conferences thereof or otherwise serving on the business of the Council, shall be entitled to receive for each day (including traveltime) in which they are so serving compensation at a rate fixed by the Secretary (but not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule); and while so serving away from their homes or regular places of business all members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government Service employed intermittently.

(c) Termination

Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council.

(July 1, 1944, ch. 373, title III, § 337, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2277; amended Pub. L. 96–32, § 7(g), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title XXVII, § 2707, Aug. 13, 1981, 95 Stat. 907; Pub. L. 97–414, § 8(f), Jan. 4, 1983, 96 Stat. 2061; Pub. L. 103–183, title VII, § 706(b), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 111–148, title X, § 10501(n)(3), Mar. 23, 2010, 124 Stat. 1003.)

REFERENCES IN TEXT

Section 254r of this title, referred to in subsec. (a), was in the original a reference to section 338G of act July 1, 1944, which was renumbered section 338I by Pub. L. 100–177, title II, § 201(1), Dec. 1, 1987, 101 Stat. 992, and repealed by Pub. L. 100–713, title I, § 104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (c), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2010—Subsec. (b)(1). Pub. L. 111–148 struck out at end ''Members may not be reappointed to the Council.''

[1] See References in Text note below.

1993—Subsec. (b)(2). Pub. L. 103–183 inserted ''compensation at a rate fixed by the Secretary (but not to exceed'' before ''the daily equivalent'' and substituted ''Schedule);'' for ''Schedule;''.

1983—Subsec. (a). Pub. L. 97–414 inserted ''(other than section 254r of this title)'' after ''carrying out this subpart''.

1981—Subsec. (a). Pub. L. 97–35, § 2707(a), amended subsec. (a) generally, striking out pars. (1) to (5) respecting required status and background of members appointed by the Secretary.

Subsec. (b)(1). Pub. L. 97–35, § 2707(b), inserted ''not'' before ''be reappointed''.

1979—Subsec. (b)(2). Pub. L. 96–32 substituted ''section 5703 of title 5'' for ''section 5703(b) of title 5''.

TERMINATION OF ADVISORY COMMITTEES

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.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 254k. Authorization of appropriations

(a) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through 2012.

(b) An appropriation under an authorization under subsection (a) for any fiscal year may be made at any time before that fiscal year and may be included in an Act making an appropriation under an authorization under subsection (a) for another fiscal year; but no funds may be made available from any appropriation under such authorization for obligation under sections 254d through 254h, section 254i, and section 254j of this title before the fiscal year for which such appropriation is authorized.

(July 1, 1944, ch. 373, title III, § 338, as added Pub. L. 94–484, title IV, § 407(b)(3), Oct. 12, 1976, 90 Stat. 2278; amended Pub. L. 95–626, title I, § 122, Nov. 10, 1978, 92 Stat. 3570; Pub. L. 96–76, title II, § 202(c), Sept. 29, 1979, 93 Stat. 582; Pub. L. 97–35, title XXVII, § 2708, Aug. 13, 1981, 95 Stat. 908; Pub. L. 100–177, title III, § 305, Dec. 1, 1987, 101 Stat. 1004; Pub. L. 101–597, title I, § 108, Nov. 16, 1990, 104 Stat. 3021; Pub. L. 107–251, title III, § 308, Oct. 26, 2002, 116 Stat. 1649; Pub. L. 110–355, § 3(a)(1), Oct. 8, 2008, 122 Stat. 3993.)

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–355 substituted ''2008 through 2012'' for ''2002 through 2006''.

2002—Subsec. (a). Pub. L. 107–251 struck out par. (1) designation before ''For the purpose'', substituted ''2002 through 2006'' for ''1991 through 2000'', and struck out par. (2) which read as follows: ''In the case of individuals who serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program, the Secretary each fiscal year shall, to the extent practicable, make assignments under section 254f of this title of such individuals who are certified nurse midwives, certified nurse practitioners, or physician assistants.''

1990—Subsec. (a). Pub. L. 101–597 added subsec. (a) and struck out former subsec. (a) which read as follows: ''To carry out this subpart, there are authorized to be appropriated $65,000,000 for fiscal year 1988, $65,000,000 for fiscal year 1989, and $65,000,000 for fiscal year 1990.''

1987—Subsec. (a). Pub. L. 100–177 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: ''To carry out the purposes of this subpart, there are authorized to be appropriated $47,000,000 for the fiscal year ending September 30, 1978; $64,000,000 for the fiscal year ending September 30, 1979; $82,000,000 for the fiscal year ending September 30, 1980; $110,000,000 for the fiscal year ending September 30, 1982; $120,000,000 for the fiscal year ending September 30, 1983; and $130,000,000 for the fiscal year ending September 30, 1984.''

1981—Subsec. (a). Pub. L. 97–35, § 2708(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

Subsec. (b). Pub. L. 97–35, § 2708(b), substituted reference to sections 254d to 254h, 254i, and 254j of this title for reference to this subpart.

1979—Subsec. (a). Pub. L. 96–76 substituted ''$82,000,000'' for ''$70,000,000''.

1978—Subsec. (a). Pub. L. 95–626 substituted ''$64,000,000'' for ''$57,000,000'' as amount authorized to be appropriated for fiscal year ending Sept. 30, 1979.

SUBPART III—SCHOLARSHIP PROGRAM AND LOAN REPAYMENT PROGRAM

CODIFICATION

Pub. L. 100–177, title II, § 202(f), Dec. 1, 1987, 101 Stat. 999, inserted subpart III heading and redesignated former subpart III as IV.

§ 254*l*. National Health Service Corps Scholarship Program

(a) Establishment

The Secretary shall establish the National Health Service Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) Eligibility; application; written contract

To be eligible to participate in the Scholarship Program, an individual must—

(1) be accepted for enrollment, or be enrolled, as a full-time student (A) in an accredited (as determined by the Secretary) educational institution in a State and (B) in a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession, or an appropriate degree from a graduate program of behavioral and mental health;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps;

(3) submit an application to participate in the Scholarship Program; and

(4) sign and submit to the Secretary, at the time of submittal of such application, a written contract (described in subsection (f)) to ac-

cept payment of a scholarship and to serve (in accordance with this subpart) for the applicable period of obligated service in a health professional shortage area.

(c) Review and evaluation of information and forms by prospective applicant

(1) In disseminating application forms and contract forms to individuals desiring to participate in the Scholarship Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 254*o* of this title in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 254n of this title and such other information as may be necessary for the individual to understand the individual's prospective participation in the Scholarship Program and service in the Corps, including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program.

(2) The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Scholarship Program. The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Scholarship Program on a date sufficiently early to insure that such individuals have adequate time to carefully review and evaluate such forms and information.

(3)(A) The Secretary shall distribute to health professions schools materials providing information on the Scholarship Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Scholarship Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Scholarship Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Scholarship Program are assigned under section 254f of this title, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Scholarship Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d) Factors considered in providing contracts; priorities

(1) Subject to section 254f–1 of this title, in providing contracts under the Scholarship Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services;

(B) the Secretary, in considering applications from individuals accepted for enrollment or enrolled in dental school, shall consider applications from all individuals accepted for enrollment or enrolled in any accredited dental school in a State; and

(C) may[1] consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Scholarship Program, the Secretary shall give priority—

(A) first, to any application for such a contract submitted by an individual who has previously received a scholarship under this section or under section 294z[1] of this title;

(B) second, to any application for such a contract submitted by an individual who has characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) third, subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) Commencement of participation in Scholarship Program; notice

(1) An individual becomes a participant in the Scholarship Program only upon the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

(2) The Secretary shall provide written notice to an individual promptly upon the Secretary's approving, under paragraph (1), of the individual's participation in the Scholarship Program.

(f) Written contract; contents

The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (2), the Secretary agrees (i) to provide the individual with a scholarship (described in subsection (g)) in each such school year or years for a period of years (not to exceed four school years) determined by the individual, during which period

[1] So in original.

the individual is pursuing a course of study described in subsection (b)(1)(B), and (ii) to accept (subject to the availability of appropriated funds for carrying out sections 254d through 254h and section 254j of this title) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (2), the individual agrees—

(i) to accept provision of such a scholarship to the individual;

(ii) to maintain enrollment in a course of study described in subsection (b)(1)(B) until the individual completes the course of study;

(iii) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study);

(iv) if pursuing a degree from a school of medicine or osteopathic medicine, to complete a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(v) to serve for a time period (hereinafter in the subpart referred to as the ''period of obligated service'') equal to—

(I) one year for each school year for which the individual was provided a scholarship under the Scholarship Program, or

(II) two years,

whichever is greater, as a provider of primary health services in a health professional shortage area (designated under section 254e of this title) to which he is assigned by the Secretary as a member of the Corps, or as otherwise provided in this subpart;

(2) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual which is conditioned thereon, is contingent upon funds being appropriated for scholarships under this subpart and to carry out the purposes of sections 254d through 254h and sections 254j and 254k of this title;

(3) a statement of the damages to which the United States is entitled, under section 254*o* of this title, for the individual's breach of the contract; and

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

(g) Scholarship provisions; contract with educational institution; increase in monthly stipend

(1) A scholarship provided to a student for a school year under a written contract under the Scholarship Program shall consist of—

(A) payment to, or (in accordance with paragraph (2)) on behalf of, the student of the amount (except as provided in section 292k[2] of this title) of—

(i) the tuition of the student in such school year; and

(ii) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the student in such school year; and

(B) payment to the student of a stipend of $400 per month (adjusted in accordance with paragraph (3)) for each of the 12 consecutive months beginning with the first month of such school year.

(2) The Secretary may contract with an educational institution, in which a participant in the Scholarship Program is enrolled, for the payment to the educational institution of the amounts of tuition and other reasonable educational expenses described in paragraph (1)(A). Payment to such an educational institution may be made without regard to section 3324(a) and (b) of title 31.

(3) The amount of the monthly stipend, specified in paragraph (1)(B) and as previously adjusted (if at all) in accordance with this paragraph, shall be increased by the Secretary for each school year ending in a fiscal year beginning after September 30, 1978, by an amount (rounded to the next highest multiple of $1) equal to the amount of such stipend multiplied by the overall percentage (under section 5303 of title 5) of the adjustment (if such adjustment is an increase) in the rates of pay under the General Schedule made effective in the fiscal year in which such school year ends.

(h) Employment ceiling of Department unaffected

Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic training, shall not be counted against any employment ceiling affecting the Department.

(July 1, 1944, ch. 373, title III, §338A, formerly title VII, §751, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281; amended Pub. L. 95–215, §5, Dec. 19, 1977, 91 Stat. 1506; Pub. L. 95–623, §12(c), Nov. 9, 1978, 92 Stat. 3457; Pub. L. 95–626, title I, §113(b), Nov. 10, 1978, 92 Stat. 3563; Pub. L. 96–32, §7(i), July 10, 1979, 93 Stat. 84; renumbered §338A and amended Pub. L. 97–35, title XXVII, §2709(a), (b), Aug. 13, 1981, 95 Stat. 908; Pub. L. 99–129, title II, §210(b), Oct. 22, 1985, 99 Stat. 537; Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–509, title V, §529 [title I, §101(b)(4)(K)], Nov. 5, 1990, 104 Stat. 1427, 1440; Pub. L. 101–597, title II, §201, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3021, 3035; Pub. L. 107–251, title III, §309, Oct. 26, 2002, 116 Stat. 1649; Pub. L. 108–163, §2(j), Dec. 6, 2003, 117 Stat. 2022.)

REFERENCES IN TEXT

Section 294z of this title, referred to in subsec. (d)(2)(A), was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

Section 292k of this title, referred to in subsec. (g)(1)(A), was in the original a reference to section 711 of act July 1, 1944. Section 711 of that Act was renumbered as section 710 by Pub. L. 97–35, title XXVII, §2720(b), Aug. 13, 1981, 95 Stat. 915, and subsequently

[2] See References in Text note below.

omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, § 102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 710 of act July 1, 1944, relating to insurance accounts, a new section 711, relating to powers and responsibilities of the Secretary, and a new section 712, relating to participation by Federal credit unions, which are classified to sections 292i, 292j, and 292k, respectively, of this title.

The General Schedule, referred to in subsec. (g)(3), is set out under section 5332 of Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (g)(2), ''section 3324(a) and (b) of title 31'' substituted for ''section 3648 of the Revised Statutes (31 U.S.C. 529)'' on authority of Pub. L. 97–258, § 4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

Section was formerly classified to section 294t of this title prior to its renumbering by Pub. L. 97–35.

AMENDMENTS

2003—Subsec. (d)(1)(B). Pub. L. 108–163 realigned margin.

2002—Subsec. (a)(1). Pub. L. 107–251, § 309(1), inserted ''behavioral and mental health professionals,'' after ''dentists,''.

Subsec. (b)(1)(B). Pub. L. 107–251, § 309(2), inserted '', or an appropriate degree from a graduate program of behavioral and mental health'' after ''other health profession''.

Subsec. (c)(1). Pub. L. 107–251, § 309(3), made technical amendment to references in original act which appear in subpar. (A) as reference to section 254*o* of this title and in subpar. (B) as reference to section 254n of this title.

Subsec. (d)(1)(B), (C). Pub. L. 107–251, § 309(4), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (f)(1)(B)(iv), (v). Pub. L. 107–251, § 309(5)(A), added cl. (iv) and redesignated former cl. (iv) as (v).

Subsec. (f)(3). Pub. L. 107–251, § 309(5)(B), made technical amendment to reference in original act which appears in text as reference to section 254*o* of this title.

Subsec. (i). Pub. L. 107–251, § 309(6), struck out subsec. (i), which required an annual report to Congress on the Scholarship Program.

1990—Subsec. (a). Pub. L. 101–597, § 201(a)(1), substituted ''Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—'' and pars. (1) and (2) for ''Corps Scholarship Program (hereinafter in this subpart referred to as the 'Scholarship Program') to assure an adequate supply of trained physicians, dentists, and nurses for the National Health Service Corps (hereinafter in this subpart referred to as the 'Corps') and, if needed by the Corps, podiatrists, optometrists, pharmacists, clinical psychologists, graduates of schools of veterinary medicine, graduates of schools of public health, graduates of programs in health administration, graduates of programs for the training of physician assistants, expanded function dental auxiliaries, and nurse practitioners (as defined in section 296m of this title), and other health professionals.''

Subsec. (b)(4). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (c). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (3)(B), (C).

Pub. L. 101–597, § 201(b), inserted par. (1) designation, redesignated former pars. (1) and (2) as subpars. (A) and (B), inserted before period at end of subpar. (B) '', including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program'', inserted par. (2) designation, and added par. (3).

Subsec. (d). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2)(B).

Pub. L. 101–597, § 201(c), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: ''In determining which applications under the Scholarship Program to approve (and which contracts to accept), the Secretary shall give priority—

''(1) first, to applications made (and contracts submitted) by individuals who have previously received scholarships under the Scholarship Program or under section 294z of this title; and

''(2) second, to applications made (and contracts submitted)—

''(A) for the school year beginning in calendar year 1978, by individuals who are entering their first, second, or third year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year;

''(B) for the school year beginning in calendar year 1979, by individuals who are entering their first or second year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year; and

''(C) for each school year thereafter, by individuals who are entering their first year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year.''

Subsec. (f)(1)(B)(iv). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in closing provisions.

Pub. L. 101–597, § 201(a)(2), substituted ''as a provider of primary health services'' after ''whichever is greater,''.

Subsec. (g)(3). Pub. L. 101–509 substituted ''(under section 5303 of title 5)'' for ''(as set forth in the report transmitted to the Congress under section 5305 of title 5)''.

Subsec. (i). Pub. L. 101–597, § 201(d)(1), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: ''The Secretary shall report to Congress on March 1 of each year—''.

Subsec. (i)(4), (5). Pub. L. 101–597, § 201(d)(2), added pars. (4) and (5) and struck out former par. (4) which read as follows: ''the amount of tuition paid in the aggregate and at each educational institution for the school year beginning in such year and for prior school years.''

Subsec. (i)(6). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, § 201(d)(2)(C), added par. (6).

1988—Subsec. (b)(1). Pub. L. 100–607 substituted ''osteopathic medicine'' for ''osteopathy''.

1985—Subsec. (g)(1). Pub. L. 99–129 struck out ''or under section 294z of this title (relating to scholarships for first-year students of exceptional financial need),'' after ''Scholarship Program''.

1981—Subsec. (a). Pub. L. 97–35, § 2709(b)(1), inserted reference to clinical psychologists.

Subsec. (c). Pub. L. 97–35, § 2709(b)(2), (3), substituted ''254*o*'' for ''294w'' in par. (1), and inserted provisions relating to information concerning meeting the service obligation in par. (2).

Subsec. (f). Pub. L. 97–35, § 2709(b)(4)–(6), in par. (1) substituted reference to sections 254d to 254h and 254j of this title, for reference to subpart II of part D of subchapter II of this chapter, in par. (2) substituted reference to sections 254d to 254h, 254j and 254k of this title, for reference to subpart II of part D of subchapter II of this chapter, and in par. (3) substituted ''254*o*'' for ''294w''.

Subsec. (j). Pub. L. 97–35, § 2709(b)(7), struck out subsec. (j) which related to consultation and participation of schools.

1979—Subsec. (g)(3). Pub. L. 96–32 substituted ''section 5305 of title 5'' for ''section 5303 of title 5''.

1978—Subsec. (f). Pub. L. 95–626 substituted ''subpart II of part D'' for ''subpart II of part C'' in pars. (1)(A) and (2).

Subsec. (i). Pub. L. 95–623 substituted March 1 for December 1 as the date for Secretary's annual report to Congress.

1977—Subsec. (d)(2). Pub. L. 95–215 substituted provisions relating to the school years beginning in calendar years 1978 and 1979 for provisions relating to the school year ending in the fiscal year beginning Oct. 1, 1977.

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 1990 AMENDMENT

Amendment by Pub. L. 101–509 effective on such date as the President shall determine, but not earlier than 90 days, and not later than 180 days, after Nov. 5, 1990, see section 529 [title III, §305] of Pub. L. 101–509, set out as a note under section 5301 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–129, title II, §228, Oct. 22, 1985, 99 Stat. 548, provided that:

''(a) Except as provided in subsection (b), this Act and the amendments and repeals made by this Act [enacting sections 294q–1 to 294q–3 of this title, amending this section and sections 292a, 292b, 292h, 292j, 293c, 294a, 294b, 294d, 294e, 294g, 294j, 294m to 294p, 294z, 295f to 295f–2, 295g, 295g–1, 295g–3, 295g–4, 295g–6 to 295g–8, 295g–8b, 295h, 295h–1a to 295h–1c, 296k, 296*l*, 296m, 297a, 298b–5, and 300aa–14 of this title, repealing sections 292c, 295 to 295e–5, 295g–2, 295g–5, 295g–8a, and 295g–9 of this title, enacting provisions set out as notes under sections 201, 292h, 293c, 294d, 294n, and 300aa–14 of this title and section 3811 of Title 50, War and National Defense, and amending provisions set out as a note under section 298b–5 of this title] shall take effect on the date of enactment of this Act [Oct. 22, 1985].

''(b)(1) The amendments made by section 101(a) of this Act [amending section 294a of this title] shall take effect as of October 1, 1985.

''(2) The amendments made by section 208(e) of this Act [amending section 294e of this title] shall take effect nine months after the date of enactment of this Act [Oct. 22, 1985].

''(3) The amendment made by section 208(h) of this Act [amending section 294a of this title] shall take effect as of October 1, 1983.

''(4) The provisions of section 746 of the Public Health Service Act (as added by the amendment made by section 209(h)(2) of this Act) [former 42 U.S.C. 294q–2] shall take effect as of June 30, 1984.

''(5) The amendments made by section 209(j) of this Act [amending sections 294m and 297a of this title] shall take effect as of June 30, 1984.

''(6) The amendments made by section 213(a) of this Act [amending section 295g–1 of this title] shall take effect as of October 1, 1985.''

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–215, §5, Dec. 19, 1977, 91 Stat. 1506, provided that the amendment made by that section is effective Oct. 1, 1977.

EFFECTIVE DATE

Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, provided that the enactment of sections 254*l* to 254r of this title and repeal of section 234 of this title by Pub. L. 94–484 is effective Oct. 1, 1977.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

Pub. L. 94–484, title IV, §408(b)(2), Oct. 12, 1976, 90 Stat. 2288, as amended, eff. Oct. 12, 1976, by Pub. L. 95–83, title III, §307(p), Aug. 1, 1977, 91 Stat. 394, provided that:

''(A) Except as provided in subparagraphs (B) and (C), the amendment made by paragraph (1) of this subsection [enacting this section and sections 254*l*–1 to 254r of this title and repealing section 234 of this title] shall apply with respect to scholarships awarded under the National Health Service Corps Scholarship Program from appropriations for such Program for fiscal years beginning after September 30, 1977.

''(B) The provisions of section 225(f)(1) of the Public Health Service Act (as in effect on September 30, 1977) [former 42 U.S.C. 234(f)(1)] prescribing the financial obligation of a participant in the Public Health and National Health Service Corps Scholarship Program who fails to complete an active duty service obligation incurred under that Program shall apply to any individual who received a scholarship under such Program from appropriations for such Program for any fiscal year ending before October 1, 1977.

''(C) If an individual received a scholarship under the Public Health and National Health Service Corps Scholarship Program for any school year beginning before the date of the enactment of this Act [Oct. 12, 1976], periods of internship or residency served by such individual in a facility of the National Health Service Corps or other facility of the Public Health Service shall be creditable in satisfying such individual's service obligation incurred under that Program for such scholarship or for any scholarship received under the National Health Service Corps Scholarship Program for any subsequent school year. If an individual received a scholarship under the Public Health and National Health Service Corps Program for the first time from appropriations for such Program for the fiscal year ending September 30, 1977, periods of internship or residency served by such individual in such a facility shall be creditable in satisfying such individual's service obligation incurred under that Program for such scholarship.''

SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS

Pub. L. 107–251, title III, §302(c), Oct. 26, 2002, 116 Stat. 1644, provided that: ''The Secretary of Health and Human Services, in consultation with organizations representing individuals in the dental field and organizations representing publicly funded health care providers, shall develop and implement a plan for increasing the participation of dentists and dental hygienists in the National Health Service Corps Scholarship Program under section 338A of the Public Health Service Act (42 U.S.C. 254*l*) and the Loan Repayment Program under section 338B of such Act (42 U.S.C. 254*l*–1).''

§ 254*l*–1. National Health Service Corps Loan Repayment Program

(a) Establishment

The Secretary shall establish a program to be known as the National Health Service Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) Eligibility

To be eligible to participate in the Loan Repayment Program, an individual must—

(1)(A) have a degree in medicine, osteopathic medicine, dentistry, or another health profession, or an appropriate degree from a graduate program of behavioral and mental health, or be certified as a nurse midwife, nurse practitioner, or physician assistant;

(B) be enrolled in an approved graduate training program in medicine, osteopathic

medicine, dentistry, behavioral and mental health, or other health profession; or

(C) be enrolled as a full-time student—

(i) in an accredited (as determined by the Secretary) educational institution in a State; and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps; and

(3) submit to the Secretary an application for a contract described in subsection (f) (relating to the payment by the Secretary of the educational loans of the individual in consideration of the individual serving for a period of obligated service).

(c) Information to be included with application and contract forms; understandability; availability

(1) Summary and information

In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 254*o* of this title in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 254n of this title and such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program and service in the Corps.

(2) Understandability

The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) Availability

The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

(4) Recruitment and retention

(A) The Secretary shall distribute to health professions schools materials providing information on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Loan Repayment Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Loan Repayment Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Loan Repayment Program are assigned under section 254f of this title, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Loan Repayment Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d) Factors considered in providing contracts; priorities

(1) Subject to section 254f–1 of this title, in providing contracts under the Loan Repayment Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Loan Repayment Program, the Secretary shall give priority—

(A) to any application for such a contract submitted by an individual whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps;

(B) to any application for such a contract submitted by an individual who has (and whose spouse, if any, has) characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) Approval required for participation

An individual becomes a participant in the Loan Repayment Program only upon the Secretary and the individual entering into a written contract described in subsection (f).

(f) Contents of contracts

The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out sections 254d through 254h of this title and section 254j of this title) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(C), to maintain enrollment in a course of study or training described in such subsection until the individual completes the course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(C), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

(iv) to serve for a time period (hereinafter in this subpart referred to as the ''period of obligated service'') equal to 2 years or such longer period as the individual may agree to, as a provider of primary health services in a health professional shortage area (designated under section 254e of this title) to which such individual is assigned by the Secretary as a member of the Corps or released under section 254n of this title;

(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv), including extensions resulting in an aggregate period of obligated service in excess of 4 years;

(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subpart and to carry out the purposes of sections 254d through 254h of this title and sections 254j and 254k of this title;

(4) a statement of the damages to which the United States is entitled, under section 254*o* of this title for the individual's breach of the contract; and

(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

(g) Payments

(1) In general

A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for—

(A) tuition expenses;

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

(C) reasonable living expenses as determined by the Secretary.

(2) Payments for years served

(A) In general

For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to $50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation, on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

(i) affects the ability of the Secretary to maximize the number of contracts that can be provided under the Loan Repayment Program from the amounts appropriated for such contracts;

(ii) provides an incentive to serve in health professional shortage areas with the greatest such shortages; and

(iii) provides an incentive with respect to the health professional involved remaining in a health professional shortage area, and continuing to provide primary health services, after the completion of the period of obligated service under the Loan Repayment Program.

(B) Repayment schedule

Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) Tax liability

For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

(4) Payment schedule

The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) Employment ceiling

Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

(July 1, 1944, ch. 373, title III, § 338B, as added Pub. L. 100–177, title II, § 201(3), Dec. 1, 1987, 101 Stat. 992; amended Pub. L. 100–607, title VI, § 629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title II, § 202(a)–(g)(1), (h), title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3023–3026, 3035; Pub. L. 105–392, title I, § 109, Nov. 13, 1998, 112 Stat. 3562; Pub. L. 107–251, title III, § 310, Oct. 26, 2002, 116 Stat. 1650; Pub. L. 108–163, § 2(k), Dec. 6, 2003, 117 Stat. 2022; Pub. L. 111–148, title X, § 10501(n)(4), Mar. 23, 2010, 124 Stat. 1003.)

PRIOR PROVISIONS

A prior section 338B of act July 1, 1944, was renumbered section 338C by section 201(2) of Pub. L. 100–177 and is classified to section 254m of this title.

AMENDMENTS

2010—Subsec. (g)(2)(A). Pub. L. 111–148 substituted ''$50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation,'' for ''$35,000'' in introductory provisions.

2003—Subsec. (e). Pub. L. 108–163 made technical amendment.

2002—Subsec. (a)(1). Pub. L. 107–251, § 310(1)(A), inserted ''behavioral and mental health professionals,'' after ''dentists,''.

Subsec. (a)(2). Pub. L. 107–251, § 310(1)(B), struck out ''(including mental health professionals)'' before period at end.

Subsec. (b)(1)(A). Pub. L. 107–251, § 310(2), added subpar. (A) and struck out former subpar. (A) which read as follows: ''must have a degree in medicine, osteopathic medicine, dentistry, or other health profession, or be certified as a nurse midwife, nurse practioner, or physician assistant;''.

Subsec. (e)(1). Pub. L. 107–251, § 310(3), struck out par. (1) designation and heading.

Subsec. (i). Pub. L. 107–251, § 310(4), struck out subsec. (i), which required an annual report to Congress about the Loan Repayment Program.

1998—Subsec. (b)(1)(B). Pub. L. 105–392 substituted ''behavioral and mental health, or other health profession'' for ''or other health profession''.

1990—Subsec. (a). Pub. L. 101–597, § 202(a)(1), substituted ''Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—'' and pars. (1) and (2) for ''Corps Loan Repayment Program (hereinafter in this subpart referred to as the 'Loan Repayment Program') in order to assure—

''(1) an adequate supply of trained physicians, dentists, and nurses for the Corps; and

''(2) if needed by the Corps, an adequate supply of podiatrists, optometrists, pharmacists, clinical psychologists, graduates of schools of veterinary medicine, graduates of schools of public health, graduates of programs in health administration, graduates of programs for the training of physician assistants, expanded function dental auxiliaries, and nurse practitioners (as defined in section 296m of this title), and other health professionals.''

Subsec. (b)(1). Pub. L. 101–597, § 202(b)(1)(A), amended par. (1) generally. Prior to amendment, par. (1) read as follows:

''(A) be enrolled—

''(i) as a full-time student—

''(I) in an accredited (as determined by the Secretary) educational institution in a State; and

''(II) in the final year of a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession; or

''(ii) in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession; or

''(B) have—

''(i) a degree in medicine, osteopathic medicine, dentistry, or other health profession;

''(ii) completed an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession in a State, except that the Secretary may waive the completion requirement of this clause for good cause; and

''(iii) a license to practice medicine, osteopathic medicine, dentistry, or other health profession in a State;''.

Subsec. (b)(2) to (4). Pub. L. 101–597, § 202(b)(2)(A), inserted ''and'' at end of par. (2), added par. (3), and struck out former pars. (3) and (4) which read as follows:

''(3) submit an application to participate in the Loan Repayment Program; and

''(4) sign and submit to the Secretary, at the time of the submission of such application, a written contract (described in subsection (f) of this section) to accept repayment of educational loans and to serve (in accordance with this subpart) for the applicable period of obligated service in a health manpower shortage area.''

Subsec. (c)(4). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in subpars. (B) and (C).

Pub. L. 101–597, § 202(c), added par. (4).

Subsec. (d). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2)(B).

Pub. L. 101–597, § 202(d), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: ''In determining which applications under the Loan Repayment Program to approve (and which contracts to accept), the Secretary shall give priority to applications made by—

''(1) individuals whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps; and

''(2) individuals who are committed to service in medically underserved areas.''

Subsec. (e). Pub. L. 101–597, § 202(b)(2)(B), substituted ''only upon the Secretary and the individual entering into a written contract described in subsection (f).'' for ''only on the Secretary's approval of the individual's application submitted under subsection (b)(3) of this section and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4) of this section.'' in par. (1) and struck out par. (2) which read as follows: ''The Secretary shall provide written notice to an individual promptly on—

''(A) the Secretary's approving, under paragraph (1), of the individual's participation in the Loan Repayment Program; or

''(B) the Secretary's disapproving an individual's participation in such Program.''

Subsec. (f)(1)(B)(ii), (iii). Pub. L. 101–597, § 202(b)(1)(B), substituted ''subsection (b)(1)(C)'' for ''subsection (b)(1)(A)''.

Subsec. (f)(1)(B)(iv). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, § 202(a)(2), inserted ''as a provider of primary health services'' before ''in a health''.

Subsec. (f)(2). Pub. L. 101–597, § 202(e), inserted before semicolon at end ", including extensions resulting in an aggregate period of obligated service in excess of 4 years".

Subsec. (g)(1). Pub. L. 101–597, § 202(f)(1), inserted "regarding the undergraduate or graduate education of the individual (or both), which loans were made" after "loans received by the individual".

Subsec. (g)(2)(A). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in cls. (ii) and (iii).

Pub. L. 101–597, § 202(f)(2)(A), substituted "For each year" for "Except as provided in subparagraph (B) and paragraph (3), for each year" and "$35,000" for "$20,000", inserted at end "In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—", and added immediately thereafter cls. (i) to (iii).

Subsec. (g)(2)(B), (C). Pub. L. 101–597, § 202(f)(2)(B), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "For each year of obligated service that an individual contracts under subsection (f) of this section to serve in the Indian Health Service, or to serve in a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (25 U.S.C. 450f et seq.), the Secretary may pay up to $25,000 on behalf of the individual for loans described in paragraph (1)."

Subsec. (g)(3). Pub. L. 101–597, § 202(g)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "In addition to payments made under paragraph (2), in any case in which payments on behalf of an individual under the Loan Repayment Program result in an increase in Federal, State, or local income tax liability for such individual, the Secretary may, on the request of such individual, make payments to such individual in a reasonable amount, as determined by the Secretary, to reimburse such individual for all or part of the increased tax liability of the individual."

Subsec. (i). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (8).

Pub. L. 101–597, § 202(h), amended subsec. (i) generally. Prior to amendment, subsec. (i) read as follows: "The Secretary shall, not later than March 1 of each year, submit to the Congress a report specifying—

"(1) the number, and type of health profession training, of individuals receiving loan payments under the Loan Repayment Program;

"(2) the educational institution at which such individuals are receiving their training;

"(3) the number of applications filed under this section in the school year beginning in such year and in prior school years; and

"(4) the amount of loan payments made in the year reported on."

1988—Subsec. (b)(1). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy" wherever appearing.

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 1990 AMENDMENT

Pub. L. 101–597, title II, § 202(g)(2), Nov. 16, 1990, 104 Stat. 3026, provided that: "The amendment made by paragraph (1) [amending this section] shall apply only with respect to contracts under section 338B of the Public Health Service Act [42 U.S.C. 254*l*–1] (relating to service in the National Health Service Corps) that are entered into on or after the effective date of this Act [Nov. 16, 1990]."

REGULATIONS

Pub. L. 100–177, title II, § 205, Dec. 1, 1987, 101 Stat. 1003, provided that: "Not later than 180 days after the effective date of the amendments made by this title [Dec. 21, 1987], the Secretary of Health and Human Services shall issue regulations for the loan repayment programs established by the amendments [enacting this section and sections 254q and 254q–1 of this title, amending sections 242a, 254d, 254g, 254h–1, and 254*o* of this title, and repealing former section 254q of this title]."

CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS

Pub. L. 114–255, div. B, title IX, § 9023, Dec. 13, 2016, 130 Stat. 1253, provided that: "The Administrator of the Health Resources and Services Administration shall clarify the eligibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 254*l*–1(b)(1)(B)) of child and adolescent psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 254*l* et seq.)."

§ 254m. Obligated service under contract

(a) Service in full-time clinical practice

Except as provided in section 254n of this title, each individual who has entered into a written contract with the Secretary under section 254*l* or 254*l*–1 of this title shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service. Notwithstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 256h of this title, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation.

(b) Notice to individual; information for informed decision; eligibility; notice to Secretary; qualification and appointment as commissioned officer; appointment as civilian member; designation of non-United States employee as member; deferment of obligated service

(1) If an individual is required under subsection (a) to provide service as specified in section 254*l*(f)(1)(B)(v) or 254*l*–1(f)(1)(B)(iv) of this title (hereinafter in this subsection referred to as "obligated service"), the Secretary shall, not later than ninety days before the date described in paragraph (5), determine if the individual shall provide such service—

(A) as a member of the Corps who is a commissioned officer in the Regular or Reserve Corps of the Service or who is a civilian employee of the United States, or

(B) as a member of the Corps who is not such an officer or employee,

and shall notify such individual of such determination.

(2) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is a commissioned officer in the Service or a civilian employee of the United States, the Secretary shall, not later than sixty days before the date described in paragraph (5), provide such individual with suffi-

cient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis. To be eligible to provide obligated service as a commissioned officer in the Service, an individual shall notify the Secretary, not later than thirty days before the date described in paragraph (5), of the individual's desire to provide such service as such an officer. If an individual qualifies for an appointment as such an officer, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint the individual as a commissioned officer of the Regular or Reserve Corps of the Service and shall designate the individual as a member of the Corps.

(3) If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a commissioned officer in the Service, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint such individual as a civilian employee of the United States and designate the individual as a member of the Corps.

(4) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is not an employee of the United States, the Secretary shall, as soon as possible after the date described in paragraph (5), designate such individual as a member of the Corps to provide such service.

(5)(A) In the case of the Scholarship Program, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for the degree for which the individual receives the scholarship, except that—

(i) for an individual receiving such a degree after September 30, 2000, from a school of medicine or osteopathic medicine, such date shall be the date the individual completes a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(ii) at the request of an individual, the Secretary may, consistent with the needs of the Corps, defer such date until the end of a period of time required for the individual to complete advanced training (including an internship or residency).

(B) No period of internship, residency, or other advanced clinical training shall be counted toward satisfying a period of obligated service under this subpart.

(C) In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (4)—

(i) shall be the date determined under subparagraph (A) in the case of an individual who is enrolled in the final year of a course of study;

(ii) shall, in the case of an individual who is enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession, be the date the individual completes such training program; and

(iii) shall, in the case of an individual who has a degree in medicine, osteopathic medicine, dentistry, or other health profession and who has completed graduate training, be the date the individual enters into an agreement with the Secretary under section 254*l*–1 of this title.

(c) Obligated service period; commencement

An individual shall be considered to have begun serving a period of obligated service—

(1) on the date such individual is appointed as an officer in a Regular or Reserve Corps of the Service or is designated as a member of the Corps under subsection (b)(3) or (b)(4), or

(2) in the case of an individual who has entered into an agreement with the Secretary under section 254n of this title, on the date specified in such agreement,

whichever is earlier.

(d) Assignment of personnel

The Secretary shall assign individuals performing obligated service in accordance with a written contract under the Scholarship Program to health professional shortage areas in accordance with sections 254d through 254h and sections 254j and 254k of this title. If the Secretary determines that there is no need in a health professional shortage area (designated under section 254e of this title) for a member of the profession in which an individual is obligated to provide service under a written contract and if such individual is an officer in the Service or a civilian employee of the United States, the Secretary may detail such individual to serve his period of obligated service as a full-time member of such profession in such unit of the Department as the Secretary may determine.

(July 1, 1944, ch. 373, title III, § 338C, formerly title VII, § 752, as added Pub. L. 94–484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2284; amended Pub. L. 95–626, title I, § 113(b), Nov. 10, 1978, 92 Stat. 3563; Pub. L. 96–76, title II, § 202(a), (b), Sept. 29, 1979, 93 Stat. 582; renumbered § 338B and amended Pub. L. 97–35, title XXVII, § 2709(a), (c), Aug. 13, 1981, 95 Stat. 908, 909; Pub. L. 97–414, § 8(g)(1), Jan. 4, 1983, 96 Stat. 2061; renumbered § 338C and amended Pub. L. 100–177, title II, § 201(2), title III, § 306, Dec. 1, 1987, 101 Stat. 992, 1004; Pub. L. 100–607, title VI, § 629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, § 311, Oct. 26, 2002, 116 Stat. 1650; Pub. L. 111–148, title V, § 5508(b), title X, § 10501(n)(5), Mar. 23, 2010, 124 Stat. 670, 1003.)

CODIFICATION

Section was formerly classified to section 294u of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338C of act July 1, 1944, was renumbered section 338D by section 201(2) of Pub. L. 100–177 and is classified to section 254n of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, § 10501(n)(5), in second sentence, substituted ''The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service'' for ''For the purpose of calculating time spent in full-time clinical practice under this subsection, up to 50 percent of time spent teaching by a member of the Corps may be counted toward his or her service obligation'' and inserted at end ''Not-

withstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 256h of this title, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation.''

Pub. L. 111–148, §5508(b), amended subsec. (a) generally. Prior to amendment, text read as follows: ''Except as provided in section 254n of this title, each individual who has entered into a written contract with the Secretary under section 254*l* or 254*l*–1 of this title shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract.''

2002—Subsec. (b)(1). Pub. L. 107–251, §311(1)(A), substituted ''section 254*l*(f)(1)(B)(v)'' for ''254*l*(f)(1)(B)(iv)'' in introductory provisions.

Subsec. (b)(5)(A). Pub. L. 107–251, §311(1)(B)(i), added subpar. (A) and struck out former subpar. (A) which read as follows: ''In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, or pharmacy, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for such degree, except that—

''(i) at the request of such an individual with whom the Secretary has entered into a contract under section 254*l* of this title prior to October 1, 1985, the Secretary shall defer such date until the end of the period of time (not to exceed the number of years specified in subparagraph (B) or such greater period as the Secretary, consistent with the needs of the Corps, may authorize) required for the individual to complete an internship, residency, or other advanced clinical training; and

''(ii) at the request of such an individual with whom the Secretary has entered into a contract under section 254*l* of this title on or after October 1, 1985, the Secretary may defer such date in accordance with clause (i).''

Subsec. (b)(5)(B). Pub. L. 107–251, §311(1)(B)(i), (iii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows:

''(B)(i) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, or dentistry, the number of years referred to in subparagraph (A)(i) shall be 3 years.

''(ii) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of veterinary medicine, optometry, podiatry, or pharmacy, the number of years referred to in subparagraph (A)(i) shall be 1 year.''

Subsec. (b)(5)(C). Pub. L. 107–251, §311(1)(B)(iii), redesignated subpar. (E) as (C). Former subpar. (C) redesignated (B).

Subsec. (b)(5)(C)(i). Pub. L. 107–251, §311(1)(B)(iv), substituted ''subparagraph (A)'' for ''subparagraph (A), (B), or (D)''.

Subsec. (b)(5)(D). Pub. L. 107–251, §311(1)(B)(ii), struck out subpar. (D) which read as follows: ''In the case of the Scholarship Program, with respect to an individual receiving a degree from an institution other than a school referred to in subparagraph (A), the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the academic training of the individual leading to such degree.''

Subsec. (b)(5)(E). Pub. L. 107–251, §311(1)(B)(iii), redesignated subpar. (E) as (C).

Subsec. (e). Pub. L. 107–251, §311(2), struck out subsec. (e) which related to service under National Research Service Award program as credit against obligated service time.

1990—Subsec. (d). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1988—Subsec. (b)(5). Pub. L. 100–607 substituted ''osteopathic medicine'' for ''osteopathy'' wherever appearing.

1987—Subsec. (a). Pub. L. 100–177, §306(1), inserted ''or 254*l*–1'', and made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

Subsec. (b)(1). Pub. L. 100–177, §306(2), inserted reference to section 254*l*–1(f)(1)(B)(iv).

Subsec. (b)(5). Pub. L. 100–177, §306(3), substituted par. (5) consisting of subpars. (A) to (E) for former par. (5) consisting of subpars. (A) and (B).

Subsec. (c)(2). Pub. L. 100–177, §306(4), made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

1983—Subsec. (e). Pub. L. 97–414 inserted ''or under section 234 of this title as in effect on September 30, 1977'' after ''Scholarship Program''.

1981—Subsec. (a). Pub. L. 97–35, §2709(c)(1), substituted ''254n'' for ''294v'' and ''254*l*'' for ''294t''.

Subsec. (b). Pub. L. 97–35, §2709(c)(2), substituted provisions relating to notice, information, etc., for individuals required to give obligated service, for provisions relating to notice, information, etc., for individuals required to provide service under the Scholarship Program.

Subsec. (c). Pub. L. 97–35, §2709(c)(3), (4), in par. (1) inserted reference to designation under subsec. (b)(3) or (4) of this section, and in par. (2) substituted ''254n'' for ''294v''.

Subsec. (d). Pub. L. 97–35, §2709(c)(5), inserted provision relating to individuals who are officers in the Service or civilian employees of the United States, and substituted reference to sections 254d to 254h, 254j, and 254k of this title, for reference to subpart II of part D of subchapter II of this chapter.

Subsec. (e). Pub. L. 97–35, §2709(c)(6), substituted provisions respecting mandatory determination of service requirement, for provisions respecting discretionary determination of service requirement.

1979—Subsec. (b)(5)(A). Pub. L. 96–76, §202(a), (b)(1), (2), inserted provisions authorizing a greater period than three years for individuals receiving degrees from schools of medicine, osteopathy, and dentistry, and provisions respecting individuals receiving degrees from schools of veterinary medicine, optometry, podiatry, and pharmacy, and substituted ''No period'' for ''No such period''.

Subsec. (b)(5)(B). Pub. L. 96–76, §202(b)(3), substituted ''referred to in subparagraph (A)'' for ''of medicine, osteopathy, or dentistry''.

1978—Subsec. (d). Pub. L. 95–626 substituted ''subpart II of part D'' for ''subpart II of part C''.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXVII, §2709(h), Aug. 13, 1981, 95 Stat. 912, provided that: ''The amendments made by paragraphs (2), (3), and (5)(B) of subsection (c) [amending this section] shall apply with respect to contracts entered into under the National Health Service Corps scholarship program under subpart III of part C of title VII of the Public Health Service Act [42 U.S.C. 294r et seq.] after the date of the enactment of this Act [Aug. 13, 1981]. An individual who before such date has entered into such a contract and who has not begun the period of obligated service required under such contract shall be given the opportunity to revise such contract to permit the individual to serve such period as a member of the National Health Service Corps who is not an employee of the United States.''

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254*l* of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254*l* of this title.

SPECIAL RETENTION PAY FOR REGULAR OR RESERVE OFFICERS FOR PERIOD OFFICER IS OBLIGATED UNDER THIS SECTION

Pub. L. 100–446, title II, Sept. 27, 1988, 102 Stat. 1816, provided that: ''the Secretary of Health and Human Services may authorize special retention pay under paragraph (4) of 37 U.S.C. 302(a) to any regular or reserve officer for the period during which the officer is obligated under section 338B [now 338C] of the Public Health Service Act [42 U.S.C. 254m] and assigned and providing direct health services or serving the officer's obligation as a specialist''.

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 100–202, § 101(g) [title II], Dec. 22, 1987, 101 Stat. 1329–213, 1329–246.

Pub. L. 99–500, § 101(h) [title II], Oct. 18, 1986, 100 Stat. 1783–242, 1783–277, and Pub. L. 99–591, § 101(h) [title II], Oct. 30, 1986, 100 Stat. 3341–242, 3341–277.

§ 254n. Private practice

(a) Application for release of obligations; conditions

The Secretary shall, to the extent permitted by, and consistent with, the requirements of applicable State law, release an individual from all or part of his service obligation under section 254m(a) of this title or under section 234[1] of this title (as in effect on September 30, 1977) if the individual applies for such a release under this section and enters into a written agreement with the Secretary under which the individual agrees to engage for a period equal to the remaining period of his service obligation in the full-time private clinical practice (including service as a salaried employee in an entity directly providing health services) of his health profession—

(1) in the case of an individual who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of his application for such a release, in the health professional shortage area in which such individual is serving on such date or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of the application of the individual for such a release, in the health professional shortage area selected by the Secretary; or

(2) in the case of any other individual, in a health professional shortage area (designated under section 254e of this title) selected by the Secretary.

[1] See References in Text note below.

(b) Written agreement; actions to ensure compliance

(1) The written agreement described in subsection (a) shall—

(A) provide that, during the period of private practice by an individual pursuant to the agreement, the individual shall comply with the requirements of section 254g of this title that apply to entities; and

(B) contain such additional provisions as the Secretary may require to carry out the objectives of this section.

(2) The Secretary shall take such action as may be appropriate to ensure that the conditions of the written agreement prescribed by this subsection are adhered to.

(c) Breach of service contract

If an individual breaches the contract entered into under section 254*l* or 254*l*–1 of this title by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under subsection (a) or to complete such service obligation, the Secretary may permit such individual to perform such service obligation as a member of the Corps.

(d) Travel expenses

The Secretary may pay an individual who has entered into an agreement with the Secretary under subsection (a) an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his private clinical practice.

(e) Sale of equipment and supplies

Upon the expiration of the written agreement under subsection (a), the Secretary may (notwithstanding any other provision of law) sell to the individual who has entered into an agreement with the Secretary under subsection (a), equipment and other property of the United States utilized by such individual in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property, except that the Secretary may make such sales for a lesser value to the individual if he determines that the individual is financially unable to pay the full market value.

(f) Malpractice insurance

The Secretary may, out of appropriations authorized under section 254k of this title, pay to individuals participating in private practice under this section the cost of such individual's malpractice insurance and the lesser of—

(1)(A) $10,000 in the first year of obligated service;

(B) $7,500 in the second year of obligated service;

(C) $5,000 in the third year of obligated service; and

(D) $2,500 in the fourth year of obligated service; or

(2) an amount determined by subtracting such individual's net income before taxes from the income the individual would have received as a member of the Corps for each such year of obligated service.

(g) Technical assistance

The Secretary shall, upon request, provide to each individual released from service obligation under this section technical assistance to assist such individual in fulfilling his or her agreement under this section.

(July 1, 1944, ch. 373, title III, § 338D, formerly title VII, § 753, as added Pub. L. 94–484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2285; amended Pub. L. 96–538, title IV, § 403, Dec. 17, 1980, 94 Stat. 3192; renumbered § 338C and amended Pub. L. 97–35, title XXVII, § 2709(a), (d), Aug. 13, 1981, 95 Stat. 908, 910; renumbered § 338D and amended Pub. L. 100–177, title II, § 201(2), title III, § 307, Dec. 1, 1987, 101 Stat. 992, 1005; Pub. L. 101–597, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, § 312, Oct. 26, 2002, 116 Stat. 1650.)

REFERENCES IN TEXT

Section 234 of this title, referred to in subsec. (a), was repealed by Pub. L. 94–484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

CODIFICATION

Section was formerly classified to section 294v of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338D of act July 1, 1944, was renumbered section 338E by section 201(2) of Pub. L. 100–177 and is classified to section 254*o* of this title.

AMENDMENTS

2002—Subsec. (b). Pub. L. 107–251 added subsec. (b) and struck out former subsec. (b) which related to written agreements, regulations, and actions to ensure compliance.

1990—Subsec. (a)(1), (2). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1987—Subsec. (a). Pub. L. 100–177, § 307(1)–(3), made technical amendment to reference to section 254m of this title to reflect renumbering of corresponding section of original act, in introductory provisions, in par. (1) inserted ''who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and'' after ''individual'' the first time it appeared as the probable intent of Congress, and inserted ''or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health manpower shortage area on the date of the application of the individual for such a release, in the health manpower shortage area selected by the Secretary'', and in par. (2) inserted ''selected by the Secretary''.

Subsec. (b). Pub. L. 100–177, § 307(4), inserted at end ''The Secretary shall take such action as may be appropriate to ensure that the conditions of the written agreement prescribed by this subsection are adhered to.''

Subsec. (c). Pub. L. 100–177, § 307(5), inserted reference to section 254*l*–1.

Subsec. (e). Pub. L. 100–177, § 307(b), designated par. (2) as entire subsection and struck out par. (1) which read as follows: ''The Secretary may make such arrangements as he determines are necessary for the individual for the use of equipment and supplies and for the lease or acquisition of other equipment and supplies.''

1981—Subsec. (a). Pub. L. 97–35, § 2709(d)(1), inserted provision respecting requirements of applicable State law, substituted references to sections 254m(a) and 234 of this title, for reference to section 294u(a) of this title, and in cl. (2) struck out priority requirement under section 254f(c) of this title.

Subsec. (b)(1)(B). Pub. L. 97–35, § 2709(d)(2), inserted ''(i)'' before ''shall not'' and added cl. (ii).

Subsecs. (c) to (g). Pub. L. 97–35, § 2709(d)(3), added subsecs. (c) to (g).

1980—Subsec. (a). Pub. L. 96–538 substituted in par. (2) ''which has'' for ''which (A) has'' and struck out subpar. (B) which referred to a health manpower shortage area which has a sufficient financial base to substain private practice and provide the individual with income of not less than the income of members of the Corps, and struck out provision following par. (2) which provided that in the case of an individual described in par. (1), the Secretary release the individual from his service obligation under this subsection only if the Secretary determines that the area in which the individual is serving met the requirements of cl. (B) of par. (2).

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254*l* of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254*l* of this title.

§ 254*o*. Breach of scholarship contract or loan repayment contract

(a) Failure to maintain academic standing; dismissal from institution; voluntary termination; liability; failure to accept payment

(1) An individual who has entered into a written contract with the Secretary under section 254*l* of this title and who—

(A) fails to maintain an acceptable level of academic standing in the educational institution in which he is enrolled (such level determined by the educational institution under regulations of the Secretary);

(B) is dismissed from such educational institution for disciplinary reasons; or

(C) voluntarily terminates the training in such an educational institution for which he is provided a scholarship under such contract, before the completion of such training,

in lieu of any service obligation arising under such contract, shall be liable to the United States for the amount which has been paid to him, or on his behalf, under the contract.

(2) An individual who has entered into a written contract with the Secretary under section 254*l*–1 of this title and who—

(A) in the case of an individual who is enrolled in the final year of a course of study, fails to maintain an acceptable level of academic standing in the educational institution in which such individual is enrolled (such level determined by the educational institution under regulations of the Secretary) or voluntarily terminates such enrollment or is dismissed from such educational institution before completion of such course of study; or

(B) in the case of an individual who is enrolled in a graduate training program, fails to complete such training program and does not receive a waiver from the Secretary under section 254*l*–1(b)(1)(B)(ii) of this title,

in lieu of any service obligation arising under such contract shall be liable to the United States for the amount that has been paid on behalf of the individual under the contract.

(b) Failure to commence or complete service obligations; formula to determine liability; payment to United States; recovery of delinquent damages; disclosure to credit reporting agencies

(1)(A) Except as provided in paragraph (2), if an individual breaches his written contract by failing (for any reason not specified in subsection (a) or section 254p(d) of this title) to begin such individual's service obligation under section 254*l* of this title in accordance with section 254m or 254n of this title, to complete such service obligation, or to complete a required residency as specified in section 254*l*(f)(1)(B)(iv) of this title, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula

$$A=3\phi\left(\frac{t-s}{t}\right)$$

in which ''A'' is the amount the United States is entitled to recover, ''ϕ'' is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States; ''t'' is the total number of months in the individual's period of obligated service; and ''s'' is the number of months of such period served by him in accordance with section 254m of this title or a written agreement under section 254n of this title.

(B)(i) Any amount of damages that the United States is entitled to recover under this subsection or under subsection (c) shall, within the 1-year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary), be paid to the United States. Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1395ccc of this title.

(ii) If damages described in clause (i) are delinquent for 3 months, the Secretary shall, for the purpose of recovering such damages—

(I) utilize collection agencies contracted with by the Administrator of the General Services Administration; or

(II) enter into contracts for the recovery of such damages with collection agencies selected by the Secretary.

(iii) Each contract for recovering damages pursuant to this subsection shall provide that the contractor will, not less than once each 6 months, submit to the Secretary a status report on the success of the contractor in collecting such damages. Section 3718 of title 31 shall apply to any such contract to the extent not inconsistent with this subsection.

(iv) To the extent not otherwise prohibited by law, the Secretary shall disclose to all appropriate credit reporting agencies information relating to damages of more than $100 that are entitled to be recovered by the United States under this subsection and that are delinquent by more than 60 days or such longer period as is determined by the Secretary.

(2) If an individual is released under section 254n[1] of this title from a service obligation under section 234[1] of this title (as in effect on September 30, 1977) and if the individual does not meet the service obligation incurred under section 254n[1] of this title, subsection (f) of such section 234[1] of this title shall apply to such individual in lieu of paragraph (1) of this subsection.

(3) The Secretary may terminate a contract with an individual under section 254*l* of this title if, not later than 30 days before the end of the school year to which the contract pertains, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid to, or on behalf of, the individual under section 254*l*(g) of this title.

(c) Failure to commence or complete service obligations for other reasons; determination of liability; payment to United States; waiver of recovery for extreme hardship or good cause shown

(1) If (for any reason not specified in subsection (a) or section 254p(d) of this title) an individual breaches the written contract of the individual under section 254*l*–1 of this title by failing either to begin such individual's service obligation in accordance with section 254m or 254n of this title or to complete such service obligation, the United States shall be entitled to recover from the individual an amount equal to the sum of—

(A) the total of the amounts paid by the United States under section 254*l*–1(g) of this title on behalf of the individual for any period of obligated service not served;

(B) an amount equal to the product of the number of months of obligated service that were not completed by the individual, multiplied by $7,500; and

(C) the interest on the amounts described in subparagraphs (A) and (B), at the maximum legal prevailing rate, as determined by the Treasurer of the United States, from the date of the breach;

except that the amount the United States is entitled to recover under this paragraph shall not be less than $31,000.

(2) The Secretary may terminate a contract with an individual under section 254*l*–1 of this title if, not later than 45 days before the end of the fiscal year in which the contract was entered into, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid on behalf of the individual under section 254*l*–1(g) of this title.

(3) Damages that the United States is entitled to recover shall be paid in accordance with subsection (b)(1)(B).

(d) Cancellation of obligation upon death of individual; waiver or suspension of obligation for impossibility, hardship, or unconscionability; release of debt by discharge in bankruptcy, time limitations

(1) Any obligation of an individual under the Scholarship Program (or a contract thereunder)

[1] See References in Text note below.

or the Loan Repayment Program (or a contract thereunder) for service or payment of damages shall be canceled upon the death of the individual.

(2) The Secretary shall by regulation provide for the partial or total waiver or suspension of any obligation of service or payment by an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) whenever compliance by the individual is impossible or would involve extreme hardship to the individual and if enforcement of such obligation with respect to any individual would be unconscionable.

(3)(A) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for payment of damages may be released by a discharge in bankruptcy under title 11 only if such discharge is granted after the expiration of the 7-year period beginning on the first date that payment of such damages is required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

(B)(i) Subparagraph (A) shall apply to any financial obligation of an individual under the provision of law specified in clause (ii) to the same extent and in the same manner as such subparagraph applies to any obligation of an individual under the Scholarship or Loan Repayment Program (or contract thereunder) for payment of damages.

(ii) The provision of law referred to in clause (i) is subsection (f) of section 234[1] of this title, as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94–484.

(e) Inapplicability of Federal and State statute of limitations on actions for collection

Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an action relating to an offset or garnishment, or other action, may be initiated or taken by the Secretary, the Attorney General, or the head of another Federal agency, as the case may be, for the repayment of the amount due from an individual under this section.

(f) Effective date

The amendment made by section 313(a)(4) of the Health Care Safety Net Amendments of 2002 (Public Law 107–251) shall apply to any obligation for which a discharge in bankruptcy has not been granted before the date that is 31 days after October 26, 2002.

(July 1, 1944, ch. 373, title III, §338E, formerly title VII, §754, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2286; amended Pub. L. 95–83, title III, §307(g), Aug. 1, 1977, 91 Stat. 391; renumbered §338D and amended Pub. L. 97–35, title XXVII, §2709(a), (e)(1)–(4)(A), Aug. 13, 1981, 95 Stat. 908, 911; Pub. L. 97–414, §8(g)(2), Jan. 4, 1983, 96 Stat. 2061; renumbered §338E and amended Pub. L. 100–177, title II, §§201(2), 202(e), title III, §308(a), Dec. 1, 1987, 101 Stat. 992, 997, 1006; Pub. L. 100–203, title IV, §4052(b), Dec. 22, 1987, 101 Stat. 1330–97; Pub. L. 100–360, title IV, §411(f)(10)(B), July 1, 1988, 102 Stat. 780; Pub. L. 101–597, title II, §203(a), Nov. 16, 1990, 104 Stat. 3027; Pub. L. 107–251, title III, §313(a), Oct. 26, 2002, 116 Stat. 1651; Pub. L. 108–163, §2(*l*)(1), Dec. 6, 2003, 117 Stat. 2022.)

REFERENCES IN TEXT

Section 234 of this title, referred to in subsecs. (b)(2) and (d)(3)(B)(ii), was repealed by Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

Section 254n of this title, referred to in subsec. (b)(2), in the original referred to section 753, meaning section 753 of the Public Health Service Act, which was classified to section 294v of this title. Section 753 was redesignated section 338C of the Public Health Service Act by Pub. L. 97–35, title XXVII, §2709(a), Aug. 13, 1981, 95 Stat. 908, and was transferred to section 254n of this title. Section 338C of the Public Health Service Act was renumbered section 338D by Pub. L. 100–177, title II, §201(2), Dec. 1, 1987, 101 Stat. 992.

Section 313(a)(4) of the Health Care Safety Net Amendments of 2002, referred to in subsec. (f), is section 313(a)(4) of Pub. L. 107–251, which amended subsec. (d)(3)(A) of this section. See 2002 Amendment note below.

CODIFICATION

Section was formerly classified to section 294w of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338E of act July 1, 1944, was renumbered section 338F by Pub. L. 100–177 and classified to section 254p of this title, and subsequently renumbered 338G by Pub. L. 101–597.

AMENDMENTS

2003—Subsec. (c)(1). Pub. L. 108–163, §2(*l*)(1)(A), realigned margins.

Subsec. (f). Pub. L. 108–163, §2(*l*)(1)(B), added subsec. (f).

2002—Subsec. (a)(1). Pub. L. 107–251, §313(a)(1), substituted semicolon for comma at end of subpar. (A) and ''; or'' for comma at end of subpar. (B), struck out ''or'' at end of subpar. (C), and struck out subpar. (D) which read as follows: ''fails to accept payment, or instructs the educational institution in which he is enrolled not to accept payment, in whole or in part, of a scholarship under such contract,''.

Subsec. (b)(1)(A). Pub. L. 107–251, §313(a)(2)(A)(ii)–(iv), struck out ''either'' before ''to begin'', substituted ''254n of this title,'' for ''254n of this title or'', and inserted ''or to complete a required residency as specified in section 254*l*(f)(1)(B)(iv) of this title,'' before ''the United States'' the first time appearing.

Pub. L. 107–251, §313(a)(2)(A)(i), made technical amendment to reference in original act which appears in text as reference to section 254p of this title.

Subsec. (b)(3). Pub. L. 107–251, §313(a)(2)(B), added par. (3).

Subsec. (c)(1). Pub. L. 107–251, §313(a)(3)(A)(ii), added subpars. (A) to (C) and concluding provisions and struck out former subpars. (A) to (C) which related, respectively, to amounts to be recovered in the case of a contract for a 2-year period of obligated service, in the case of a contract for a period of obligated service of greater than 2 years where the breach occurred before the end of the first 2 years of such period, and in the case of a contract for a period of obligated service of greater than 2 years, where the breach occurred after the first 2 years of such period.

Pub. L. 107–251, §313(a)(3)(A)(i), in introductory provisions, made technical amendment to reference in original act which appears in text as reference to section 254p(d) of this title.

Subsec. (c)(2). Pub. L. 107–251, §313(a)(3)(B), added par. (2) and struck out former par. (2) which read as follows: ''For purposes of paragraph (1), the term 'unserved obli-

gation penalty' means the amount equal to the product of the number of months of obligated service that were not completed by an individual, multiplied by $1,000, except that in any case in which the individual fails to serve 1 year, the unserved obligation penalty shall be equal to the full period of obligated service multiplied by $1,000.''

Subsec. (c)(3), (4). Pub. L. 107–251, § 313(a)(3)(B), (C), redesignated par. (4) as (3) and struck out former par. (3) which read as follows: ''The Secretary may waive, in whole or in part, the rights of the United States to recover amounts under this section in any case of extreme hardship or other good cause shown, as determined by the Secretary.''

Subsec. (d)(3)(A). Pub. L. 107–251, § 313(a)(4), substituted ''7-year period'' for ''five-year period''.

Subsec. (e). Pub. L. 107–251, § 313(a)(5), added subsec. (e).

1990—Subsec. (d)(3). Pub. L. 101–597 designated existing provision as subpar. (A) and added subpar. (B).

1988—Subsec. (b)(1)(B)(i). Pub. L. 100–360 made technical amendment to directory language of Pub. L. 100–203, see 1987 Amendment note below.

1987—Pub. L. 100–177, § 202(e)(6), inserted ''or loan repayment contract'' in section catchline.

Subsec. (a). Pub. L. 100–177, § 202(e)(1), designated existing provisions as par. (1), and former pars. (1) to (4) as subpars. (A) to (D), respectively, and added par. (2).

Subsec. (b)(1). Pub. L. 100–177, § 202(e)(2), designated existing provisions as subpar. (A), made technical amendments to references to sections 254m, 254n, and 254p of this title wherever appearing to reflect renumbering of corresponding sections of original act, inserted ''under section 254*l* of this title'' after first reference to ''service obligation'' as the probable intent of Congress, struck out at end ''Any amount of damages which the United States is entitled to recover under this subsection shall, within the one year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary for good cause shown), be paid to the United States.'', and added subpar. (B).

Subsec. (b)(1)(B)(i). Pub. L. 100–203, as amended by Pub. L. 100–360, inserted at end ''Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1395ccc of this title.''

Subsec. (c). Pub. L. 100–177, § 202(e)(4), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 100–177, §§ 202(e)(3), (5), 308(a), redesignated subsec. (c) as (d), in pars. (1), (2), and (3), inserted ''or the Loan Repayment Program (or a contract thereunder'', and in par. (3) inserted '', and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable''.

1983—Subsec. (b)(1). Pub. L. 97–414 substituted ''section 254p(d)'' for ''section 254q(b)''.

1981—Subsec. (a). Pub. L. 97–35, § 2709(e)(1), (2), redesignated subsec. (b) as (a) and, as so redesignated, in introductory text substituted ''254*l*'' for ''294t'' and added par. (4). Former subsec. (a), which related to liability of individual upon failure to accept payment, was struck out.

Subsec. (b). Pub. L. 97–35, § 2709(e)(1), (3), redesignated subsec. (c) as (b) and, as so redesignated, designated existing provisions as par. (1) and made numerous changes to reflect renumbering of subpart sections, and added par. (2). Former subsec. (b) redesignated (a).

Subsecs. (c), (d). Pub. L. 97–35, § 2709(e)(1), (4)(A), redesignated subsec. (d) as (c) and, as so redesignated, in par. (2) inserted reference to partial or total waiver. Former subsec. (c) redesignated (b).

1977—Subsec. (c). Pub. L. 95–83 substituted '' 'ϕ' is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans'' for '' 'ϕ' is the sum of the amount paid under this subpart to or on behalf of the individual and the interest on such amount which would be payable if at the time it was paid it was a loan''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments 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 2002 AMENDMENT

Pub. L. 107–251, title III, § 313(b), Oct. 26, 2002, 116 Stat. 1652, which provided that the amendment to this section made by section 313(a)(4) of Pub. L. 107–251 was applicable to any obligation for which a discharge in bankruptcy had not been granted before the date that was 31 days after Oct. 26, 2002, was repealed by Pub. L. 108–163, §§ 2(*l*)(2), 3, Dec. 6, 2003, 117 Stat. 2023, effective immediately after enactment of Pub. L. 107–251.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–597, title II, § 203(b), Nov. 16, 1990, 104 Stat. 3027, provided that: ''With respect to any financial obligation of an individual under subsection (f) of section 225 of the Public Health Service Act [former 42 U.S.C. 234], as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94–484, the amendment made by subsection (a) of this section [amending this section] applies to any backruptcy [sic] proceeding in which discharge of such an obligation has not been granted before the date that is 31 days after the date of the enactment of this Act [Nov. 16, 1990].''

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254*l* of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254*l* of this title.

SPECIAL REPAYMENT PROVISIONS

Pub. L. 100–177, title II, § 204, Dec. 1, 1987, 101 Stat. 1000, provided that an individual who breached a written contract entered into under section 254*l* of this title by failing either to begin such individual's service obligation in accordance with section 254m of this title or to complete such service obligation; or otherwise breached such a contract; and, as of Nov. 1, 1987, was liable to United States under subsec. (b) of this section was to be relieved of liability to United States under such section if the individual provided notice to Secretary and service in accordance with a written contract with the Secretary that obligated the individual to provide service in accordance with section and authorized Secretary to exclude an individual from relief from liability under this section for reasons related to the individual's professional competence or conduct.

EXISTING PROCEEDINGS

Pub. L. 100–177, title III, § 308(b), Dec. 1, 1987, 101 Stat. 1006, provided that: ''The amendment made by subsection (a) [amending this section] applies to any bankruptcy proceeding in which discharge of an obligation under section 338E(d)(3) of the Public Health Service Act [42 U.S.C. 254*o*(d)(3)] (as redesignated by sections 201(2) and 202(e)(3) of this Act) has not been granted before the date that is 31 days after the date of enactment of this Act [Dec. 1, 1987].''

§ 254*o*–1. Fund regarding use of amounts recovered for contract breach to replace services lost as result of breach

(a) Establishment of Fund

There is established in the Treasury of the United States a fund to be known as the National Health Service Corps Member Replacement Fund (hereafter in this section referred to as the ''Fund''). The Fund shall consist of such amounts as may be appropriated under subsection (b) to the Fund. Amounts appropriated for the Fund shall remain available until expended.

(b) Authorization of appropriations to Fund

For each fiscal year, there is authorized to be appropriated to the Fund an amount equal to the sum of—

(1) the amount collected during the preceding fiscal year by the Federal Government pursuant to the liability of individuals under section 254*o* of this title for the breach of contracts entered into under section 254*l* or 254*l*–1 of this title;

(2) the amount by which grants under section 254q–1 of this title have, for such preceding fiscal year, been reduced under subsection (g)(2)(B) of such section; and

(3) the aggregate of the amount of interest accruing during the preceding fiscal year on obligations held in the Fund pursuant to subsection (d) and the amount of proceeds from the sale or redemption of such obligations during such fiscal year.

(c) Use of Fund

(1) Payments to certain health facilities

Amounts in the Fund and available pursuant to appropriations Act may, subject to paragraph (2), be expended by the Secretary to make payments to any entity—

(A) to which a Corps member has been assigned under section 254f of this title; and

(B) that has a need for a health professional to provide primary health services as a result of the Corps member having breached the contract entered into under section 254*l* or 254*l*–1 of this title by the individual.

(2) Purpose of payments

An entity receiving payments pursuant to paragraph (1) may expend the payments to recruit and employ a health professional to provide primary health services to patients of the entity, or to enter into a contract with such a professional to provide the services to the patients.

(d) Investment

(1) In general

The Secretary of the Treasury shall invest such amounts of the Fund as such Secretary determines are not required to meet current withdrawals from the Fund. Such investments may be made only in interest-bearing obligations of the United States. For such purpose, such obligations may be acquired on original issue at the issue price, or by purchase of outstanding obligations at the market price.

(2) Sale of obligations

Any obligation acquired by the Fund may be sold by the Secretary of the Treasury at the market price.

(July 1, 1944, ch. 373, title III, § 338F, as added Pub. L. 101–597, title II, § 204, Nov. 16, 1990, 104 Stat. 3027.)

PRIOR PROVISIONS

A prior section 338F of act July 1, 1944, was renumbered section 338G by Pub. L. 101–597 and is classified to section 254p of this title.

Another prior section 338F of act July 1, 1944, was renumbered section 338G by section 201(2) of Pub. L. 100–177 and classified to section 254q of this title, prior to repeal by Pub. L. 100–177, title II, § 203, Dec. 1, 1987, 101 Stat. 999.

§ 254p. Special loans for former Corps members to enter private practice

(a) Persons entitled; conditions

The Secretary may, out of appropriations authorized under section 254k of this title, make one loan to a Corps member who has agreed in writing—

(1) to engage in the private full-time clinical practice of the profession of the member in a health professional shortage area (designated under section 254e of this title) for a period of not less than 2 years which—

(A) in the case of a Corps member who is required to complete a period of obligated service under this subpart, begins not later than 1 year after the date on which such individual completes such period of obligated service; and

(B) in the case of an individual who is not required to complete a period of obligated service under this subpart, begins at such time as the Secretary considers appropriate;

(2) to conduct such practice in accordance with section 254n(b)(1) of this title; and

(3) to such additional conditions as the Secretary may require to carry out this section.

Such a loan shall be used to assist such individual in meeting the costs of beginning the practice of such individual's profession in accordance with such agreement, including the costs of acquiring equipment and renovating facilities for use in providing health services, and of hiring nurses and other personnel to assist in providing health services. Such loan may not be used for the purchase or construction of any building.

(b) Amount of loan; maximum interest rate

(1) The amount of a loan under subsection (a) to an individual shall not exceed $25,000.

(2) The interest rate for any such loan shall not exceed an annual rate of 5 percent.

(c) Application for loan; submission and approval; interest rates and repayment terms

The Secretary may not make a loan under this section unless an application therefor has been submitted to, and approved by, the Secretary. The Secretary shall, by regulation, set interest rates and repayment terms for loans under this section.

(d) Breach of agreement; notice; determination of liability

If the Secretary determines that an individual has breached a written agreement entered into under subsection (a), he shall, as soon as practicable after making such determination, notify the individual of such determination. If within 60 days after the date of giving such notice, such individual is not practicing his profession in accordance with the agreement under such subsection and has not provided assurances satisfactory to the Secretary that he will not knowingly violate such agreement again, the United States shall be entitled to recover from such individual—

(1) in the case of an individual who has received a grant under this section (as in effect prior to October 1, 1984), an amount determined under section 254*o*(b) of this title, except that in applying the formula contained in such section ''ϕ'' shall be the sum of the amount of the grant made under subsection (a) to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at the maximum legal prevailing rate, ''t'' shall be the number of months that such individual agreed to practice his profession under such agreement, and ''s'' shall be the number of months that such individual practices his profession in accordance with such agreement; and

(2) in the case of an individual who has received a loan under this section, the full amount of the principal and interest owed by such individual under this section.

(July 1, 1944, ch. 373, title III, § 338G, formerly title VII, § 755, as added Pub. L. 94–484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2287; renumbered § 338E and amended Pub. L. 97–35, title XXVII, § 2709(a), (f), Aug. 13, 1981, 95 Stat. 908, 911; Pub. L. 97–414, § 8(g)(3), Jan. 4, 1983, 96 Stat. 2061; renumbered § 338F and amended Pub. L. 100–177, title II, § 201(2), title III, § 309, Dec. 1, 1987, 101 Stat. 992, 1006; renumbered § 338G and amended Pub. L. 101–597, title II, § 204, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3027, 3035.)

CODIFICATION

Section was formerly classified to section 294x of this title prior to renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338G of act July 1, 1944, was renumbered section 338H by Pub. L. 101–597 and is classified to section 254q of this title.

Another prior section 338G of act July 1, 1944, was renumbered section 338I by section 201(1) of Pub. L. 100–177 and classified to section 254r of this title, prior to repeal by Pub. L. 100–713, title I, § 104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

Another prior section 338G of act July 1, 1944, was classified to section 254q of this title prior to repeal by Pub. L. 100–177, title II, § 203, Dec. 1, 1987, 101 Stat. 999.

AMENDMENTS

1990—Subsec. (a)(1). Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

1987—Subsec. (a). Pub. L. 100–177, § 309(1), substituted subsec. (a) consisting of pars. (1) to (3) for former subsec. (a) consisting of pars. (1) and (2).

Subsec. (b). Pub. L. 100–177, § 309(1), added subsec. (b) and struck out former subsec. (b) which read as follows: ''The amount of the grant or loan under subsection (a) of this section to an individual shall be—

''(1) $12,500 if the individual agrees to practice his profession in accordance with the agreement for a period of at least one year, but less than two years; or

''(2) $25,000 if the individual agrees to practice his profession in accordance with the agreement for a period of at least two years.''

Subsec. (c). Pub. L. 100–177, § 309(2), struck out ''grant or'' before ''loan'' in first sentence.

Subsec. (d)(1). Pub. L. 100–177, § 309(3), substituted ''under this section (as in effect prior to October 1, 1984)'' for ''under this section'', and made technical amendment to reference to section 254*o*(b) of this title to reflect renumbering of corresponding section of original act.

1983—Subsec. (d)(1). Pub. L. 97–414 substituted ''section 254*o*(b)'' for ''section 254*o*(c)''.

1981—Subsec. (a). Pub. L. 97–35, § 2709(f)(2)–(4), made numerous changes to reflect renumbering of subpart sections, among them inserting references to section 254k of this title and striking out references to section 294v of this title, and added applicability to loans.

Subsec. (b). Pub. L. 97–35, § 2709(f)(5), inserted applicability to loans.

Subsec. (c). Pub. L. 97–35, § 2709(f)(6), inserted provisions relating to loans and interest rates, etc.

Subsec. (d). Pub. L. 97–35, § 2709(f)(7), restructured and revised criteria determining amount of liability of individual within 60 days after the date of notice instead of within 120 days after the date of notice.

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254*l* of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254*l* of this title.

§ 254q. Authorization of appropriations

(a) Authorization of appropriations

For the purpose of carrying out this section,[1] there is authorized to be appropriated, out of any funds in the Treasury not otherwise appropriated, the following:

(1) For fiscal year 2010, $320,461,632.
(2) For fiscal year 2011, $414,095,394.
(3) For fiscal year 2012, $535,087,442.
(4) For fiscal year 2013, $691,431,432.
(5) For fiscal year 2014, $893,456,433.
(6) For fiscal year 2015, $1,154,510,336.
(7) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(A) one plus the average percentage increase in the costs of health professions education during the prior fiscal year; and

(B) one plus the average percentage change in the number of individuals residing in health professions shortage areas designated under section 254f of this title during the prior fiscal year, relative to the number of individuals residing in such areas during the previous fiscal year.

(b) Scholarships for new participants

Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall obligate

[1] So in original. Probably should be ''subpart,''.

not less than 10 percent for the purpose of providing contracts for—

(1) scholarships under this subpart to individuals who have not previously received such scholarships; or

(2) scholarships or loan repayments under the Loan Repayment Program under section 254*l*–1 of this title to individuals from disadvantaged backgrounds.

(c) Scholarships and loan repayments

With respect to certification as a nurse practitioner, nurse midwife, or physician assistant, the Secretary shall, from amounts appropriated under subsection (a) for a fiscal year, obligate not less than a total of 10 percent for contracts for both scholarships under the Scholarship Program under section 254*l* of this title and loan repayments under the Loan Repayment Program under section 254*l*–1 of this title to individuals who are entering the first year of a course of study or program described in section 254*l*(b)(1)(B) of this title that leads to such a certification or individuals who are eligible for the loan repayment program as specified in section 254*l*–1(b) of this title for a loan related to such certification.

(July 1, 1944, ch. 373, title III, § 338H, formerly § 338G, as added Pub. L. 100–177, title II, § 203, Dec. 1, 1987, 101 Stat. 999; renumbered § 338H and amended Pub. L. 101–597, title II, §§ 204, 205, Nov. 16, 1990, 104 Stat. 3027, 3028; Pub. L. 107–251, title III, § 314, Oct. 26, 2002, 116 Stat. 1652; Pub. L. 110–355, § 3(a)(2), Oct. 8, 2008, 122 Stat. 3993; Pub. L. 111–148, title V, § 5207, Mar. 23, 2010, 124 Stat. 612.)

PRIOR PROVISIONS

A prior section 254q, act July 1, 1944, ch. 373, title III, § 338G, formerly title VII, § 756, as added Oct. 12, 1976, Pub. L. 94–484, title IV, § 408(b)(1), 90 Stat. 2288; renumbered § 338F and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, § 2709(a), (g), 95 Stat. 908, 912; renumbered § 338G, Dec. 1, 1987, Pub. L. 100–177, title II, § 201(2), 101 Stat. 992, authorized appropriations for fiscal years 1978 to 1987, prior to repeal by Pub. L. 100–177, § 203.

A prior section 338H of act July 1, 1944, was renumbered section 338I by Pub. L. 101–597 and is classified to section 254q–1 of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148 amended subsec. (a) generally. Prior to amendment, subsec. (a) related to authorization of appropriations for the purposes of carrying out this subpart as follows: for fiscal year 2008, $131,500,000; for fiscal year 2009, $143,335,000; for fiscal year 2010, $156,235,150; for fiscal year 2011, $170,296,310; and for fiscal year 2012, $185,622,980.

2008—Subsec. (a). Pub. L. 110–355 substituted ''appropriated—'' for ''appropriated $146,250,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.'' and added pars. (1) to (5).

2002—Pub. L. 107–251 amended section generally. Prior to amendment, section related to annual report to Congress, authorization of appropriations for fiscal years 1991 through 2000, and reservation of percentage of appropriated amounts for scholarships for new participants and for first-year study in certain fields.

1990—Subsec. (a). Pub. L. 101–597, § 205(a), substituted ''March 1'' for ''January 20'' and ''5 fiscal years'' for ''3 fiscal years'' wherever appearing.

Subsec. (b). Pub. L. 101–597, § 205(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''There are authorized to be appropriated such sums as may be necessary for scholarships and loan repayments under this subpart.''

§ 254q–1. Grants to States for loan repayment programs

(a) In general

(1) Authority for grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability of primary health care services in health professional shortage areas. The National Advisory Council established under section 254j of this title shall advise the Administrator regarding the program under this section.

(2) Loan repayment programs

The programs referred to in paragraph (1) are, subject to subsection (c), programs of entering into contracts under which the State involved agrees to pay all or part of the principal, interest, and related expenses of the educational loans of health professionals in consideration of the professionals agreeing to provide primary health services in health professional shortage areas.

(3) Direct administration by State agency

The Secretary may not make a grant under paragraph (1) unless the State involved agrees that the program operated with the grant will be administered directly by a State agency.

(b) Requirement of matching funds

(1) In general

The Secretary may not make a grant under subsection (a) unless the State agrees that, with respect to the costs of making payments on behalf of individuals under contracts made pursuant to paragraph (2) of such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided in the grant.

(2) Determination of amount of non-Federal contribution

In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government.

(c) Coordination with Federal program

(1) Assignments for health professional shortage areas under Federal program

The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in carrying out the program operated with the grant, the State will assign health professionals participating in the program only to public and nonprofit private entities located in and providing health services in health professional shortage areas.

(2) Remedies for breach of contracts

The Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pur-

suant to paragraph (2) of such subsection will provide remedies for any breach of the contracts by the health professionals involved.

(3) Limitation regarding contract inducements

(A) Except as provided in subparagraph (B), the Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will not be provided on terms that are more favorable to health professionals than the most favorable terms that the Secretary is authorized to provide for contracts under the Loan Repayment Program under section 254*l*–1 of this title, including terms regarding—

(i) the annual amount of payments provided on behalf of the professionals regarding educational loans; and

(ii) the availability of remedies for any breach of the contracts by the health professionals involved.

(B) With respect to the limitation established in subparagraph (A) regarding the annual amount of payments that may be provided to a health professional under a contract provided by a State pursuant to subsection (a)(2), such limitation shall not apply with respect to a contract if—

(i) the excess of such annual payments above the maximum amount authorized in section 254*l*–1(g)(2)(A) of this title for annual payments regarding contracts is paid solely from non-Federal contributions under subsection (b); and

(ii) the contract provides that the health professional involved will satisfy the requirement of obligated service under the contract solely through the provision of primary health services in a health professional shortage area that is receiving priority for purposes of section 254f–1(a)(1) of this title and that is authorized to receive assignments under section 254f of this title of individuals who are participating in the Scholarship Program under section 254*l* of this title.

(d) Restrictions on use of funds

The Secretary may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to conduct activities for which Federal funds are expended—

(A) within the State to provide technical or other nonfinancial assistance under subsection (f) of section 254c[1] of this title;

(B) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(C) under a grant under section 254r of this title; or

(2) for any purpose other than making payments on behalf of health professionals under contracts entered into pursuant to subsection (a)(2).

(e) Reports

The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary such reports regarding the States loan repayment program, as are determined to be appropriate by the Secretary; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(f) Requirement of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(g) Noncompliance

(1) In general

The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) Reduction in grant relative to number of breached contracts

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided by the State under paragraph (2) of such subsection with respect to which there has been an initial breach by the health professionals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) Subject to paragraph (3), in the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of the expenditures of Federal funds made regarding the contracts involved and an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(3) Waiver regarding reduction in grant

The Secretary may waive the requirement established in paragraph (2)(B) with respect to the initial breach of a contract if the Secretary determines that such breach by the health professional involved was attributable solely to the professional having a serious illness.

(h) "State" defined

For purposes of this section, the term ''State'' means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands.

[1] See References in Text note below.

(i) Authorization of appropriations

(1) In general

For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,000,000 for fiscal year 2008, and such sums as may be necessary for each of fiscal years 2009 through 2012.

(2) Availability

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

(j) Public health loan repayment

(1) In general

The Secretary may award grants to States for the purpose of assisting such States in operating loan repayment programs under which such States enter into contracts to repay all or part of the eligible loans borrowed by, or on behalf of, individuals who agree to serve in State, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary.

(2) Loans eligible for repayment

To be eligible for repayment under this subsection, a loan shall be a loan made, insured, or guaranteed by the Federal Government that is borrowed by, or on behalf of, an individual to pay the cost of attendance for a program of education leading to a degree appropriate for serving in a State, local, or tribal health department as determined by the Secretary and the chief executive officer of the State in which the grant is administered, at an institution of higher education (as defined in section 1002 of title 20), including principal, interest, and related expenses on such loan.

(3) Applicability of existing requirements

With respect to awards made under paragraph (1)—

(A) the requirements of subsections (b), (f), and (g) shall apply to such awards; and

(B) the requirements of subsection (c) shall apply to such awards except that with respect to paragraph (1) of such subsection, the State involved may assign an individual only to public and nonprofit private entities that serve health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2007 through 2010.

(July 1, 1944, ch. 373, title III, § 338I, formerly § 338H, as added Pub. L. 100–177, title II, § 203, Dec. 1, 1987, 101 Stat. 999; renumbered § 338I and amended Pub. L. 101–597, title II, § 204, title III, § 301, title IV, § 401(b)[(a)], Nov. 16, 1990, 104 Stat. 3027, 3029, 3035; Pub. L. 105–392, title IV, § 408, Nov. 13, 1998, 112 Stat. 3589; Pub. L. 107–251, title III, § 315, Oct. 26, 2002, 116 Stat. 1653; Pub. L. 109–417, title II, § 203(b), Dec. 19, 2006, 120 Stat. 2849; Pub. L. 110–355, § 3(e), Oct. 8, 2008, 122 Stat. 3994.)

REFERENCES IN TEXT

Section 254c of this title, referred to in subsec. (d)(1)(A), was in the original a reference to section 330, meaning section 330 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of this part by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

PRIOR PROVISIONS

A prior section 338I of act July 1, 1944, was classified to section 254r of this title prior to repeal by Pub. L. 100–713, title I, § 104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

AMENDMENTS

2008—Subsec. (h). Pub. L. 110–355, § 3(e)(1), substituted ''50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands'' for ''several States''.

Subsec. (i)(1). Pub. L. 110–355, § 3(e)(2), substituted ''2008, and such sums as may be necessary for each of fiscal years 2009 through 2012.'' for ''2002 and such sums as may be necessary for each of fiscal years 2003 through 2006.''

2006—Subsec. (j). Pub. L. 109–417 added subsec. (j).

2002—Subsec. (a)(1). Pub. L. 107–251, § 315(1), added par. (1) and struck out heading and text of former par. (1). Text read as follows: ''The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability of primary health services in health professional shortage areas.''

Subsec. (e)(1). Pub. L. 107–251, § 315(2), added par. (1) and struck out former par. (1) which read as follows: ''to submit to the Secretary reports providing the same types of information regarding the program operated pursuant to such subsection as reports submitted pursuant to subsection (i) of section 254*l*–1 of this title provide regarding the Loan Repayment Program under such section; and''.

Subsec. (i)(1). Pub. L. 107–251, § 315(3), added par. (1) and struck out heading and text of former par. (1). Text read as follows: ''For the purpose of making grants under subsection (a) of this section, there is authorized to be appropriated $10,000,000 for each of the fiscal years 1991 through 1995, and such sums as may be necessary for each of the fiscal years 1998 through 2002.''

1998—Subsec. (i)(1). Pub. L. 105–392 inserted '', and such sums as may be necessary for each of the fiscal years 1998 through 2002'' before period at end.

1990—Pub. L. 101–597, § 401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in subsecs. (a)(1), (2) and (c)(1), (3)(B)(ii).

Pub. L. 101–597, § 301, amended section generally, substituting present provisions for provisions which related to: in subsec. (a), grants; in subsec. (b), applications; in subsec. (c), Federal share; and in subsec. (d), authorization of appropriations.

§ 254r. Grants to States for operation of offices of rural health

(a) In general

The Secretary, acting through the Director of the Office of Rural Health Policy (established in section 912 of this title), may make grants to States for the purpose of improving health care in rural areas through the operation of State offices of rural health.

(b) Requirement of matching funds

(1) In general

The Secretary may not make a grant under subsection (a) unless the State involved

agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such subsection, to provide non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than $1 for each $3 of Federal funds provided in the grant;

(B) for any second fiscal year of such payments, not less than $1 for each $1 of Federal funds provided in the grant; and

(C) for any third fiscal year of such payments, not less than $3 for each $1 of Federal funds provided in the grant.

(2) Determination of amount of non-Federal contribution

(A) Subject to subparagraph (B), non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(i) for the first fiscal year of payments under the grant, 100 percent or less of the non-Federal contributions required in paragraph (1) will be provided in the form of in-kind contributions;

(ii) for any second fiscal year of such payments, not more than 50 percent of such non-Federal contributions will be provided in the form of in-kind contributions; and

(iii) for any third fiscal year of such payments, such non-Federal contributions will be provided solely in the form of cash.

(c) Certain required activities

The Secretary may not make a grant under subsection (a) unless the State involved agrees that activities carried out by an office operated pursuant to such subsection will include—

(1) establishing and maintaining within the State a clearinghouse for collecting and disseminating information on—

(A) rural health care issues;

(B) research findings relating to rural health care; and

(C) innovative approaches to the delivery of health care in rural areas;

(2) coordinating the activities carried out in the State that relate to rural health care, including providing coordination for the purpose of avoiding redundancy in such activities; and

(3) identifying Federal and State programs regarding rural health, and providing technical assistance to public and nonprofit private entities regarding participation in such programs.

(d) Requirement regarding annual budget for office

The Secretary may not make a grant under subsection (a) unless the State involved agrees that, for any fiscal year for which the State receives such a grant, the office operated pursuant to subsection (a) will be provided with an annual budget of not less than $50,000.

(e) Certain uses of funds

(1) Restrictions

The Secretary may not make a grant under subsection (a) unless the State involved agrees that—

(A) if research with respect to rural health is conducted pursuant to the grant, not more than 10 percent of the grant will be expended for such research; and

(B) the grant will not be expended—

(i) to provide health care (including providing cash payments regarding such care);

(ii) to conduct activities for which Federal funds are expended—

(I) within the State to provide technical and other nonfinancial assistance under subsection (f) of section 254c[1] of this title;

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

(III) under a grant under section 254q–1 of this title;

(iii) to purchase medical equipment, to purchase ambulances, aircraft, or other vehicles, or to purchase major communications equipment;

(iv) to purchase or improve real property; or

(v) to carry out any activity regarding a certificate of need.

(2) Authorities

Activities for which a State may expend a grant under subsection (a) include—

(A) paying the costs of establishing an office of rural health for purposes of subsection (a);

(B) subject to paragraph (1)(B)(ii)(III), paying the costs of any activity carried out with respect to recruiting and retaining health professionals to serve in rural areas of the State; and

(C) providing grants and contracts to public and nonprofit private entities to carry out activities authorized in this section.

(f) Reports

The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary reports containing such information as the Secretary may require regarding activities carried out under this section by the State; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(g) Requirement of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(h) Noncompliance

The Secretary may not make payments under subsection (a) to a State for any fiscal year sub-

[1] See References in Text note below.

sequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(i) "State" defined

For purposes of this section, the term ''State'' means each of the several States.

(j) Authorization of appropriations

(1) In general

For the purpose of making grants under subsection (a), there are authorized to be appropriated $3,000,000 for fiscal year 1991, $4,000,000 for fiscal year 1992, $3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1998 through 2002.

(2) Availability

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

(k) Termination of program

No grant may be made under this section after the aggregate amounts appropriated under subsection (j)(1) are equal to $36,000,000.

(July 1, 1944, ch. 373, title III, § 338J, as added Pub. L. 101–597, title III, § 302, Nov. 16, 1990, 104 Stat. 3032; amended Pub. L. 105–392, title III, § 301, Nov. 13, 1998, 112 Stat. 3585.)

REFERENCES IN TEXT

Section 254c of this title, referred to in subsec. (e)(1)(B)(ii)(I), was in the original a reference to section 330, meaning section 330 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of this part by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

PRIOR PROVISIONS

A prior section 254r, act July 1, 1944, ch. 373, title III, § 338I, formerly title VII, § 757, as added Aug. 1, 1977, Pub. L. 95–83, title III, § 307(n)(1), 91 Stat. 392; amended Dec. 17, 1980, Pub. L. 96–537, § 3(d), 94 Stat. 3174; renumbered § 338G, Aug. 13, 1981, Pub. L. 97–35, title XXVII, § 2709(a), 95 Stat. 908; Oct. 30, 1984, Pub. L. 98–551, § 3, 98 Stat. 2817; renumbered § 338I, Dec. 1, 1987, Pub. L. 100–177, title II, § 201(1), 101 Stat. 992; Nov. 4, 1988, Pub. L. 100–607, title VI, § 629(a)(3), 102 Stat. 3146, which related to Indian Health Scholarships and was classified to section 294y–1 of this title prior to renumbering by Pub. L. 97–35, was repealed by Pub. L. 100–713, title I, § 104(b)(1), Nov. 23, 1988, 102 Stat. 4787. For provisions continuing scholarships provided on or before Nov. 23, 1988, see section 104(b)(2) of Pub. L. 100–713.

A prior section 338J of act July 1, 1944, was renumbered section 338K by Pub. L. 101–597 and is classified to section 254s of this title.

AMENDMENTS

1998—Subsec. (b)(1). Pub. L. 105–392, § 301(1), struck out ''in cash'' after ''contributions'' in introductory provisions.

Subsec. (j)(1). Pub. L. 105–392, § 301(2), struck out ''and'' after ''1992,'' and inserted before period at end '', and such sums as may be necessary for each of the fiscal years 1998 through 2002''.

Subsec. (k). Pub. L. 105–392, § 301(3), substituted ''$36,000,000'' for ''$10,000,000''.

COMMUNICATIONS FOR RURAL HEALTH PROVIDERS

Pub. L. 102–538, title I, § 154, formerly § 134, Oct. 27, 1992, 106 Stat. 3541, renumbered § 154 by Pub. L. 103–66, title VI, § 6001(a)(2), Aug. 10, 1993, 107 Stat. 379, directed Secretary of Commerce, in conjunction with Secretary of Health and Human Services, to establish an advisory panel to develop recommendations for the improvement of rural health care through the collection of information needed by providers and the improvement in the use of communications to disseminate such information and, not later than 1 year after establishment of Panel to prepare and submit to Congress a report summarizing the recommendations made by the Panel.

Similar provisions were contained in Pub. L. 101–555, § 3, Nov. 15, 1990, 104 Stat. 2760.

§ 254s. Native Hawaiian Health Scholarships

(a) Eligibility

Subject to the availability of funds appropriated under the authority of subsection (d), the Secretary shall provide funds to Papa Ola Lokahi for the purpose of providing scholarship assistance to students who—

(1) meet the requirements of section 254*l*(b) of this title, and

(2) are Native Hawaiians.

(b) Terms and conditions

(1) The scholarship assistance provided under subsection (a) shall be provided under the same terms and subject to the same conditions, regulations, and rules that apply to scholarship assistance provided under section 254*l* of this title.

(2) The Native Hawaiian Health Scholarship program shall not be administered by or through the Indian Health Service.

(c) "Native Hawaiian" defined

For purposes of this section, the term ''Native Hawaiian'' means any individual who is—

(1) a citizen of the United States,

(2) a resident of the State of Hawaii, and

(3) a descendant of the aboriginal people, who prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawaii, as evidenced by—

(A) genealogical records,

(B) Kupuna (elders) or Kama'aina (long-term community residents) verification, or

(C) birth records of the State of Hawaii.

(d) Authorization of appropriations

There are authorized to be appropriated $1,800,000 for each of the fiscal years 1990, 1991, and 1992 for the purpose of funding the scholarship assistance provided under subsection (a).

(July 1, 1944, ch. 373, title III, § 338K, formerly § 338J, as added Pub. L. 100–713, title I, § 106, Nov. 23, 1988, 102 Stat. 4787; renumbered § 338K, Pub. L. 101–597, title III, § 302, Nov. 16, 1990, 104 Stat. 3032; amended Pub. L. 101–644, title IV, § 401, Nov. 29, 1990, 104 Stat. 4668; Pub. L. 107–116, title V, § 514(b), Jan. 10, 2002, 115 Stat. 2220.)

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–116, which directed the amendment of subsec. (a) by substituting ''Papa Ola Lokahi'' for ''Kamehameha School/Bishop Estate'', was executed by making the substitution for ''Kamehameha Schools/Bishop Estate'' to reflect the probable intent of Congress.

1990—Subsec. (a). Pub. L. 101–644, which directed the general amendment of subsec. (a) of section 338J of the Public Health Service Act, was executed to subsec. (a) of this section, to reflect the probable intent of Congress and the intervening renumbering of section 338J

as 338K by Pub. L. 101–597. Prior to amendment, subsec. (a) read as follows: ''Subject to the availability of funds appropriated under the authority of subsection (d) of this section, the Secretary shall provide scholarship assistance, pursuant to a contract with the Kamehameha Schools/Bishop Estate, to students who—

''(1) meet the requirements of section 254*l*(b) of this title, and

''(2) are Native Hawaiians.''

§ 254t. Demonstration project

(a) Program authorized

The Secretary shall establish a demonstration project to provide for the participation of individuals who are chiropractic doctors or pharmacists in the Loan Repayment Program described in section 254*l*–1 of this title.

(b) Procedure

An individual that receives assistance under this section with regard to the program described in section 254*l*–1 of this title shall comply with all rules and requirements described in such section (other than subparagraphs (A) and (B) of section 254*l*–1(b)(1) of this title) in order to receive assistance under this section.

(c) Limitations

(1) In general

The demonstration project described in this section shall provide for the participation of individuals who shall provide services in rural and urban areas.

(2) Availability of other health professionals

The Secretary may not assign an individual receiving assistance under this section to provide obligated service at a site unless—

(A) the Secretary has assigned a physician (as defined in section 1395x(r) of this title) or other health professional licensed to prescribe drugs to provide obligated service at such site under section 254m or 254n of this title; and

(B) such physician or other health professional will provide obligated service at such site concurrently with the individual receiving assistance under this section.

(3) Rules of construction

(A) Supervision of individuals

Nothing in this section shall be construed to require or imply that a physician or other health professional licensed to prescribe drugs must supervise an individual receiving assistance under the demonstration project under this section, with respect to such project.

(B) Licensure of health professionals

Nothing in this section shall be construed to supersede State law regarding licensure of health professionals.

(d) Designations

The demonstration project described in this section, and any providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of a health professional shortage area under section 254e of this title during fiscal years 2002 through 2004.

(e) Rule of construction

This section shall not be construed to require any State to participate in the project described in this section.

(f) Report

(1) In general

The Secretary shall evaluate the participation of individuals in the demonstration projects under this section and prepare and submit a report containing the information described in paragraph (2) to—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the Senate;

(C) the Committee on Energy and Commerce of the House of Representatives; and

(D) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the House of Representatives.

(2) Content

The report described in paragraph (1) shall detail—

(A) the manner in which the demonstration project described in this section has affected access to primary care services, patient satisfaction, quality of care, and health care services provided for traditionally underserved populations;

(B) how the participation of chiropractic doctors and pharmacists in the Loan Repayment Program might affect the designation of health professional shortage areas; and

(C) whether adding chiropractic doctors and pharmacists as permanent members of the National Health Service Corps would be feasible and would enhance the effectiveness of the National Health Service Corps.

(g) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal years 2002 through 2004.

(2) Fiscal year 2005

If the Secretary determines and certifies to Congress by not later than September 30, 2004, that the number of individuals participating in the demonstration project established under this section is insufficient for purposes of performing the evaluation described in subsection (f)(1), the authorization of appropriations under paragraph (1) shall be extended to include fiscal year 2005.

(July 1, 1944, ch. 373, title III, § 338L, as added Pub. L. 107–251, title III, § 317, Oct. 26, 2002, 116 Stat. 1653.)

PRIOR PROVISIONS

A prior section 254t, act July 1, 1944, ch. 373, title III, § 338L, as added Pub. L. 101–527, § 8, Nov. 6, 1990, 104 Stat. 2328, related to demonstration grants to States for community scholarship programs, prior to repeal by Pub. L. 107–251, title III, § 316, Oct. 26, 2002, 116 Stat. 1653.

§ 254u. Public health departments

(a) In general

To the extent that funds are appropriated under subsection (e), the Secretary shall establish a demonstration project to provide for the participation of individuals who are eligible for the Loan Repayment Program described in section 254*l*–1 of this title and who agree to complete their service obligation in a State health department that provides a significant amount of service to health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local or tribal health department that serves a health professional shortage area or an area at risk of a public health emergency.

(b) Procedure

To be eligible to receive assistance under subsection (a), with respect to the program described in section 254*l*–1 of this title, an individual shall—

(1) comply with all rules and requirements described in such section (other than section 254*l*–1(f)(1)(B)(iv) of this title); and

(2) agree to serve for a time period equal to 2 years, or such longer period as the individual may agree to, in a State, local, or tribal health department, described in subsection (a).

(c) Designations

The demonstration project described in subsection (a), and any healthcare providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of health professional shortage areas under section 254e of this title during fiscal years 2007 through 2010.

(d) Report

Not later than 3 years after December 19, 2006, the Secretary shall submit a report to the relevant committees of Congress that evaluates the participation of individuals in the demonstration project under subsection (a), the impact of such participation on State, local, and tribal health departments, and the benefit and feasibility of permanently allowing such placements in the Loan Repayment Program.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2007 through 2010.

(July 1, 1944, ch. 373, title III, § 338M, as added Pub. L. 109–417, title II, § 203(a), Dec. 19, 2006, 120 Stat. 2848.)

SUBPART IV—HOME HEALTH SERVICES

CODIFICATION

Pub. L. 100–177, title II, § 202(f)(1), Dec. 1, 1987, 101 Stat. 999, substituted ''IV'' for ''III'' as subpart designation.

Pub. L. 97–414, § 6(a), Jan. 4, 1983, 96 Stat. 2057, added heading ''Subpart III—Home Health Services''.

Pub. L. 95–626, title I, § 105(b), title II, § 207(a), Nov. 10, 1978, 92 Stat. 3560, 3585, struck out heading ''Part D—Lepers'' and added heading ''Subpart III—Home Health Services''.

§ 255. Home health services

(a) Purpose; authorization of grants and loans; considerations; conditions on loans; appropriations

(1) For the purpose of encouraging the establishment and initial operation of home health programs to provide home health services in areas in which such services are inadequate or not readily accessible, the Secretary may, in accordance with the provisions of this section, make grants to public and nonprofit private entities and loans to proprietary entities to meet the initial costs of establishing and operating such home health programs. Such grants and loans may include funds to provide training for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) In making grants and loans under this subsection, the Secretary shall—

(A) consider the relative needs of the several States for home health services;

(B) give preference to areas in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or disabled; and

(C) give special consideration to areas with inadequate means of transportation to obtain necessary health services.

(3)(A) No loan may be made to a proprietary entity under this section unless the application of such entity for such loan contains assurances satisfactory to the Secretary that—

(i) at the time the application is made the entity is fiscally sound;

(ii) the entity is unable to secure a loan for the project for which the application is submitted from non-Federal lenders at the rate of interest prevailing in the area in which the entity is located; and

(iii) during the period of the loan, such entity will remain fiscally sound.

(B) Loans under this section shall be made at an interest rate comparable to the rate of interest prevailing on the date the loan is made with respect to the marketable obligations of the United States of comparable maturities, adjusted to provide for administrative costs.

(4) Applications for grants and loans under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and loans under this subsection $5,000,000 for each of the fiscal years ending on September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(b) Grants and contracts for training programs for paraprofessionals; considerations; applications; appropriations

(1) The Secretary may make grants to and enter into contracts with public and private entities to assist them in developing appropriate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) Any program established with a grant or contract under this subsection to train homemaker home health aides shall—

(A) extend for at least forty hours, and consist of classroom instruction and at least

twenty hours (in the aggregate) of supervised clinical instruction directed toward preparing students to deliver home health services;

(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

(C) include training in—

(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and contracts under this subsection $2,000,000 for each of the fiscal years ending September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(c) Report to Congress with respect to grants and loans and training of personnel

The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after January 4, 1983); and

(3) the extent to which standards have been applied to the training of personnel who provide home health services.

(d) "Home health services" defined

For purposes of this section, the term ''home health services'' has the meaning prescribed for the term by section 1395x(m) of this title.

(July 1, 1944, ch. 373, title III, § 339, as added Pub. L. 97–414, § 6(a), Jan. 4, 1983, 96 Stat. 2057; amended Pub. L. 98–555, § 6, Oct. 30, 1984, 98 Stat. 2856.)

REFERENCES IN TEXT

Subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981), referred to in subsec. (c)(1), mean subsections (a) and (b) of section 255 of this title prior to repeal of section 255 by Pub. L. 97–35, title IX, § 902(b), Aug. 13, 1981, 95 Stat. 559, effective Oct. 1, 1981.

PRIOR PROVISIONS

A prior section 255, act July 1, 1944, ch. 373, title III, § 339, as added Nov. 10, 1978, Pub. L. 95–626, title II, § 207(a), 92 Stat. 3585, related to grant authority, etc., for home health services, prior to repeal by Pub. L. 97–35, title IX, § 902(b), (h), Aug. 13, 1981, 95 Stat. 559, 561, eff. Oct. 1, 1981.

Another prior section 339 of act July 1, 1944, ch. 373, title III, formerly § 331, 58 Stat. 698; June 25, 1948, ch. 654, § 4, 62 Stat. 1018; June 25, 1952, ch. 460, 66 Stat. 157; July 12, 1960, Pub. L. 86–624, § 29(b), 74 Stat. 419; renumbered § 339, Oct. 12, 1976, Pub. L. 94–484, title IV, § 407(b)(2), 90 Stat. 2268, which related to reception of persons suffering from leprosy in any hospital, was renumbered section 320 of act July 1, 1944, and transferred to section 247e of this title.

AMENDMENTS

1984—Subsecs. (a)(5), (b)(5). Pub. L. 98–555 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

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.

REPORT TO CONGRESS CONCERNING RESULTS OF STUDIES EVALUATING HOME AND COMMUNITY BASED HEALTH SERVICES; STUDIES OF REIMBURSEMENT METHODOLOGIES; INVESTIGATION OF FRAUD; DEMONSTRATION PROJECTS; HOME HEALTH SERVICES, DEFINED

Pub. L. 97–414, § 6(b)–(f), Jan. 4, 1983, 96 Stat. 2058, 2059, directed Secretary of Health and Human Services to report results of studies evaluating home and community based health services, and any recommendations for legislative action which might improve the provision of such services, to Congress prior to Jan. 1, 1985, to compile and analyze results of significant public or private studies relating to reimbursement methodologies for home health services and to report recommendations to Congress within 180 days after Jan. 4, 1983, to investigate methods available to stem medicare and medicaid fraud and abuse and extent to which such methods are applied and to report results to Congress within 18 months of Jan. 4, 1983, and to develop and carry out demonstration projects commencing no later than Jan. 1, 1984, to test methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services, and to test alternative reimbursement methodologies for home health agencies in order to determine most cost-effective way of providing home health services, and to report to Congress with regard to the demonstrations no later than Jan. 1, 1985; and defined ''home health services'' for purposes of this section.

SUBPART V—HEALTHY COMMUNITIES ACCESS PROGRAM

PRIOR PROVISIONS

A prior subpart VI, consisting of section 256a, related to health services for residents of public housing, prior to repeal by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

§ 256. Grants to strengthen the effectiveness, efficiency, and coordination of services for the uninsured and underinsured

(a) In general

The Secretary may award grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and individuals who are underinsured—

(1) to improve the efficiency of, and coordination among, the providers providing services through such systems;

(2) to assist communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) Eligible entities

To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a consortium—

(A) whose principal purpose is to provide a broad range of coordinated health care services for a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1395x(aa) of this title);

(ii) a hospital with a low-income utilization rate (as defined in section 1396r–4(b)(3) of this title), that is greater than 25 percent;

(iii) a public health department; and

(iv) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) defines a community or geographic area of uninsured and underinsured individuals;

(B) identifies the providers who will participate in the consortium's program under the grant, and specifies each provider's contribution to the care of uninsured and underinsured individuals in the community, including the volume of care the provider provides to beneficiaries under the medicare, medicaid, and State child health insurance programs and to patients who pay privately for services;

(C) describes the activities that the applicant and the consortium propose to perform under the grant to further the objectives of this section;

(D) demonstrates the consortium's ability to build on the current system (as of the date of submission of the application) for serving a community or geographic area of uninsured and underinsured individuals by involving providers who have traditionally provided a significant volume of care for that community;

(E) demonstrates the consortium's ability to develop coordinated systems of care that either directly provide or ensure the prompt provision of a broad range of high-quality, accessible services, including, as appropriate, primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services in a manner that assures continuity of care in the community or geographic area;

(F) provides evidence of community involvement in the development, implementation, and direction of the program that the entity proposes to operate;

(G) demonstrates the consortium's ability to ensure that individuals participating in the program are enrolled in public insurance programs for which the individuals are eligible or know of private insurance programs where available;

(H) presents a plan for leveraging other sources of revenue, which may include State and local sources and private grant funds, and integrating current and proposed new funding sources in a way to assure long-term sustainability of the program;

(I) describes a plan for evaluation of the activities carried out under the grant, including measurement of progress toward the goals and objectives of the program and the use of evaluation findings to improve program performance;

(J) demonstrates fiscal responsibility through the use of appropriate accounting procedures and appropriate management systems;

(K) demonstrates the consortium's commitment to serve the community without regard to the ability of an individual or family to pay by arranging for or providing free or reduced charge care for the poor; and

(L) includes such other information as the Secretary may prescribe.

(c) Limitations

(1) Number of awards

(A) In general

For each of fiscal years 2003, 2004, 2005, and 2006, the Secretary may not make more than 35 new awards under subsection (a) (excluding renewals of such awards).

(B) Rule of construction

This paragraph shall not be construed to affect awards made before fiscal year 2003.

(2) In general

An eligible entity may not receive a grant under this section (including with respect to any such grant made before fiscal year 2003) for more than 3 consecutive fiscal years, except that such entity may receive such a grant award for not more than 1 additional fiscal year if—

(A) the eligible entity submits to the Secretary a request for a grant for such an additional fiscal year;

(B) the Secretary determines that extraordinary circumstances (as defined in para-

graph (3)) justify the granting of such request; and

(C) the Secretary determines that granting such request is necessary to further the objectives described in subsection (a).

(3) Extraordinary circumstances

(A) In general

In paragraph (2), the term ''extraordinary circumstances'' means an event (or events) that is outside of the control of the eligible entity that has prevented the eligible entity from fulfilling the objectives described by such entity in the application submitted under subsection (b)(2).

(B) Examples

Extraordinary circumstances include—

(i) natural disasters or other major disruptions to the security or health of the community or geographic area served by the eligible entity; or

(ii) a significant economic deterioration in the community or geographic area served by such eligible entity, that directly and adversely affects the entity receiving an award under subsection (a).

(d) Priorities

In awarding grants under this section, the Secretary—

(1) shall accord priority to applicants that demonstrate the extent of unmet need in the community involved for a more coordinated system of care; and

(2) may accord priority to applicants that best promote the objectives of this section, taking into consideration the extent to which the application involved—

(A) identifies a community whose geographical area has a high or increasing percentage of individuals who are uninsured;

(B) demonstrates that the applicant has included in its consortium providers, support systems, and programs that have a tradition of serving uninsured individuals and underinsured individuals in the community;

(C) shows evidence that the program would expand utilization of preventive and primary care services for uninsured and underinsured individuals and families in the community, including behavioral and mental health services, oral health services, or substance abuse services;

(D) proposes a program that would improve coordination between health care providers and appropriate social service providers;

(E) demonstrates collaboration with State and local governments;

(F) demonstrates that the applicant makes use of non-Federal contributions to the greatest extent possible; or

(G) demonstrates a likelihood that the proposed program will continue after support under this section ceases.

(e) Use of funds

(1) Use by grantees

(A) In general

Except as provided in paragraphs (2) and (3), a grantee may use amounts provided under this section only for—

(i) direct expenses associated with achieving the greater integration of a health care delivery system so that the system either directly provides or ensures the provision of a broad range of culturally competent services, as appropriate, including primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services; and

(ii) direct patient care and service expansions to fill identified or documented gaps within an integrated delivery system.

(B) Specific uses

The following are examples of purposes for which a grantee may use grant funds under this section, when such use meets the conditions stated in subparagraph (A):

(i) Increases in outreach activities and closing gaps in health care service.

(ii) Improvements to case management.

(iii) Improvements to coordination of transportation to health care facilities.

(iv) Development of provider networks and other innovative models to engage physicians in voluntary efforts to serve the medically underserved within a community.

(v) Recruitment, training, and compensation of necessary personnel.

(vi) Acquisition of technology for the purpose of coordinating care.

(vii) Improvements to provider communication, including implementation of shared information systems or shared clinical systems.

(viii) Development of common processes for determining eligibility for the programs provided through the system, including creating common identification cards and single sliding scale discounts.

(ix) Development of specific prevention and disease management tools and processes.

(x) Translation services.

(xi) Carrying out other activities that may be appropriate to a community and that would increase access by the uninsured to health care, such as access initiatives for which private entities provide non-Federal contributions to supplement the Federal funds provided through the grants for the initiatives.

(2) Direct patient care limitation

Not more than 15 percent of the funds provided under a grant awarded under this section may be used for providing direct patient care and services.

(3) Reservation of funds for national program purposes

The Secretary may use not more than 3 percent of funds appropriated to carry out this section for providing technical assistance to grantees, obtaining assistance of experts and consultants, holding meetings, developing of tools, disseminating of information, evaluation, and carrying out activities that will extend the benefits of programs funded under this section to communities other than the community served by the program funded.

(f) Grantee requirements

(1) Evaluation of effectiveness

A grantee under this section shall—

(A) report to the Secretary annually regarding—

(i) progress in meeting the goals and measurable objectives set forth in the grant application submitted by the grantee under subsection (b); and

(ii) the extent to which activities conducted by such grantee have—

(I) improved the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such grantee;

(II) resulted in the provision of better quality health care for such individuals; and

(III) resulted in the provision of health care to such individuals at lower cost than would have been possible in the absence of the activities conducted by such grantee; and

(B) provide for an independent annual financial audit of all records that relate to the disposition of funds received through the grant.

(2) Progress

The Secretary may not renew an annual grant under this section for an entity for a fiscal year unless the Secretary is satisfied that the consortium represented by the entity has made reasonable and demonstrable progress in meeting the goals and measurable objectives set forth in the entity's grant application for the preceding fiscal year.

(g) Maintenance of effort

With respect to activities for which a grant under this section is authorized, the Secretary may award such a grant only if the applicant for the grant, and each of the participating providers, agree that the grantee and each such provider will maintain its expenditures of non-Federal funds for such activities at a level that is not less than the level of such expenditures during the fiscal year immediately preceding the fiscal year for which the applicant is applying to receive such grant.

(h) Technical assistance

The Secretary may, either directly or by grant or contract, provide any entity that receives a grant under this section with technical and other nonfinancial assistance necessary to meet the requirements of this section.

(i) Evaluation of program

Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the extent to which projects funded under this section have been successful in improving the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such projects, including whether the projects resulted in the provision of better quality health care for such individuals, and whether such care was provided at lower costs, than would have been provided in the absence of such projects.

(j) Demonstration authority

The Secretary may make demonstration awards under this section to historically black health professions schools for the purposes of—

(1) developing patient-based research infrastructure at historically black health professions schools, which have an affiliation, or affiliations, with any of the providers identified in subsection (b)(1)(B);

(2) establishment of joint and collaborative programs of medical research and data collection between historically black health professions schools and such providers, whose goal is to improve the health status of medically underserved populations; or

(3) supporting the research-related costs of patient care, data collection, and academic training resulting from such affiliations.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

***(l)* Date certain for termination of program**

Funds may not be appropriated to carry out this section after September 30, 2006.

(July 1, 1944, ch. 373, title III, § 340, as added Pub. L. 107–251, title IV, § 402, Oct. 26, 2002, 116 Stat. 1655.)

PRIOR PROVISIONS

A prior section 256, act July 1, 1944, ch. 373, title III, § 340, as added July 22, 1987, Pub. L. 100–77, title VI, § 601, 101 Stat. 511; amended Nov. 4, 1988, Pub. L. 100–607, title VIII, §§ 801(a), (c), 802(a), (b)(1), 803, 804, 102 Stat. 3168, 3169; Nov. 7, 1988, Pub. L. 100–628, title VI, §§ 601(a), (c), 602(a), (b)(1), 603, 604, 102 Stat. 3241, 3242; Aug. 16, 1989, Pub. L. 101–93, § 5(t)(1), (3), 103 Stat. 615; Nov. 29, 1990, Pub. L. 101–645, title V, §§ 501–503, 104 Stat. 4724; Oct. 27, 1992, Pub. L. 102–531, title III, § 309(c), 106 Stat. 3501, related to grant program for certain health services for the homeless, prior to repeal by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645, eff. Oct. 1, 1996.

Another prior section 256, act July 1, 1944, ch. 373, title III, § 340, as added Nov. 10, 1978, Pub. L. 95–626, title I, § 115(2), 92 Stat. 3567; amended Dec. 12, 1979, Pub. L. 96–142, title III, § 301(a), 93 Stat. 1073; Aug. 13, 1981, Pub. L. 97–35, title IX, § 903(b)(1), 95 Stat. 561; Jan. 4, 1983, Pub. L. 97–414, § 8(h), 96 Stat. 2061, related to primary care research and demonstration projects to serve medically underserved population, prior to repeal by Pub. L. 97–35, title IX, § 903(c), Aug. 13, 1981, 95 Stat. 561, eff. Oct. 1, 1982.

Another prior section 256, act July 1, 1944, ch. 373, title III, § 340, formerly § 332, 58 Stat. 698; renumbered § 340, Oct. 12, 1976, Pub. L. 94–484, title IV, § 407(b)(2), 90 Stat. 2268, related to apprehension, detention, treatment, and release of persons being treated for leprosy, prior to repeal by Pub. L. 95–626, title I, § 105(b), Nov. 10, 1978, 92 Stat. 3560.

DEMONSTRATION PROJECT TO PROVIDE ACCESS TO AFFORDABLE CARE

Pub. L. 111–148, title X, § 10504, Mar. 23, 2010, 124 Stat. 1004, provided that:

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of this Act [Mar. 23, 2010], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Health Resources and Services Administration, shall establish a 3 year demonstration project in up to 10

States to provide access to comprehensive health care services to the uninsured at reduced fees. The Secretary shall evaluate the feasibility of expanding the project to additional States.

''(b) ELIGIBILITY.—To be eligible to participate in the demonstration project, an entity shall be a State-based, nonprofit, public-private partnership that provides access to comprehensive health care services to the uninsured at reduced fees. Each State in which a participant selected by the Secretary is located shall receive not more than $2,000,000 to establish and carry out the project for the 3-year demonstration period.

''(c) AUTHORIZATION.—There is authorized to be appropriated such sums as may be necessary to carry out this section.''

PURPOSE

Pub. L. 107–251, title IV, § 401, Oct. 26, 2002, 116 Stat. 1655, provided that: ''The purpose of this title [enacting this subpart and subpart X (§ 256f et seq.) of this part and provisions set out as a note under section 1396a of this title] is to provide assistance to communities and consortia of health care providers and others, to develop or strengthen integrated community health care delivery systems that coordinate health care services for individuals who are uninsured or underinsured and to develop or strengthen activities related to providing coordinated care for individuals with chronic conditions who are uninsured or underinsured, through the—

''(1) coordination of services to allow individuals to receive efficient and higher quality care and to gain entry into and receive services from a comprehensive system of care;

''(2) development of the infrastructure for a health care delivery system characterized by effective collaboration, information sharing, and clinical and financial coordination among all providers of care in the community; and

''(3) provision of new Federal resources that do not supplant funding for existing Federal categorical programs that support entities providing services to low-income populations.''

§ 256a. Patient navigator grants

(a) Grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. The Secretary shall coordinate with, and ensure the participation of, the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration programs.

(b) Use of funds

The Secretary shall require each recipient of a grant under this section to use the grant to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of individuals, including by performing each of the following duties:

(1) Acting as contacts, including by assisting in the coordination of health care services and provider referrals, for individuals who are seeking prevention or early detection services for, or who following a screening or early detection service are found to have a symptom, abnormal finding, or diagnosis of, cancer or other chronic disease.

(2) Facilitating the involvement of community organizations in assisting individuals who are at risk for or who have cancer or other chronic diseases to receive better access to high-quality health care services (such as by creating partnerships with patient advocacy groups, charities, health care centers, community hospice centers, other health care providers, or other organizations in the targeted community).

(3) Notifying individuals of clinical trials and, on request, facilitating enrollment of eligible individuals in these trials.

(4) Anticipating, identifying, and helping patients to overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

(5) Coordinating with the relevant health insurance ombudsman programs to provide information to individuals who are at risk for or who have cancer or other chronic diseases about health coverage, including private insurance, health care savings accounts, and other publicly funded programs (such as Medicare, Medicaid, health programs operated by the Department of Veterans Affairs or the Department of Defense, the State children's health insurance program, and any private or governmental prescription assistance programs).

(6) Conducting ongoing outreach to health disparity populations, including the uninsured, rural populations, and other medically underserved populations, in addition to assisting other individuals who are at risk for or who have cancer or other chronic diseases to seek preventative care.

(c) Prohibitions

(1) Referral fees

The Secretary shall require each recipient of a grant under this section to prohibit any patient navigator providing services under the grant from accepting any referral fee, kickback, or other thing of value in return for referring an individual to a particular health care provider.

(2) Legal fees and costs

The Secretary shall prohibit the use of any grant funds received under this section to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

(d) Grant period

(1) In general

Subject to paragraphs (2) and (3), the Secretary may award grants under this section for periods of not more than 3 years.

(2) Extensions

Subject to paragraph (3), the Secretary may extend the period of a grant under this section. Each such extension shall be for a period of not more than 1 year.

(3) Limitations on grant period

In carrying out this section, the Secretary shall ensure that the total period of a grant does not exceed 4 years.

(e) Application

(1) In general

To seek a grant under this section, an eligible entity shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

(2) Contents

At a minimum, the Secretary shall require each such application to outline how the eligible entity will establish baseline measures and benchmarks that meet the Secretary's requirements to evaluate program outcomes.

(3) Minimum core proficiencies

The Secretary shall not award a grant to an entity under this section unless such entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies, as defined by the entity that submits the application, that are tailored for the main focus or intervention of the navigator involved.

(f) Uniform baseline measures

The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(g) Preference

In making grants under this section, the Secretary shall give preference to eligible entities that demonstrate in their applications plans to utilize patient navigator services to overcome significant barriers in order to improve health care outcomes in their respective communities.

(h) Duplication of services

An eligible entity that is receiving Federal funds for activities described in subsection (b) on the date on which the entity submits an application under subsection (e) may not receive a grant under this section unless the entity can demonstrate that amounts received under the grant will be utilized to expand services or provide new services to individuals who would not otherwise be served.

(i) Coordination with other programs

The Secretary shall ensure coordination of the demonstration grant program under this section with existing authorized programs in order to facilitate access to high-quality health care services.

(j) Study; reports

(1) Final report by Secretary

Not later than 6 months after the completion of the demonstration grant program under this section, the Secretary shall conduct a study of the results of the program and submit to the Congress a report on such results that includes the following:

(A) An evaluation of the program outcomes, including—

(i) quantitative analysis of baseline and benchmark measures; and

(ii) aggregate information about the patients served and program activities.

(B) Recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

(2) Interim reports by Secretary

The Secretary may provide interim reports to the Congress on the demonstration grant program under this section at such intervals as the Secretary determines to be appropriate.

(3) Reports by grantees

The Secretary may require grant recipients under this section to submit interim and final reports on grant program outcomes.

(k) Rule of construction

This section shall not be construed to authorize funding for the delivery of health care services (other than the patient navigator duties listed in subsection (b)).

***(l)* Definitions**

In this section:

(1) The term ''eligible entity'' means a public or nonprofit private health center (including a Federally qualified health center (as that term is defined in section 1395x(aa)(4) of this title)), a health facility operated by or pursuant to a contract with the Indian Health Service, a hospital, a cancer center, a rural health clinic, an academic health center, or a nonprofit entity that enters into a partnership or coordinates referrals with such a center, clinic, facility, or hospital to provide patient navigator services.

(2) The term ''health disparity population'' means a population that, as determined by the Secretary, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population.

(3) The term ''patient navigator'' means an individual who has completed a training program approved by the Secretary to perform the duties listed in subsection (b).

(m) Authorization of appropriations

(1) In general

To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2006, $5,000,000 for fiscal year 2007, $8,000,000 for fiscal year 2008, $6,500,000 for fiscal year 2009, $3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.

(2) Availability

The amounts appropriated pursuant to paragraph (1) shall remain available for obligation through the end of fiscal year 2015.

(July 1, 1944, ch. 373, title III, § 340A, as added Pub. L. 109–18, § 2, June 29, 2005, 119 Stat. 340; amended Pub. L. 111–148, title III, § 3510, Mar. 23, 2010, 124 Stat. 537.)

PRIOR PROVISIONS

A prior section 256a, act July 1, 1944, ch. 373, title III, § 340A, as added Nov. 6, 1990, Pub. L. 101–527, § 3, 104 Stat. 2314; amended Oct. 27, 1992, Pub. L. 102–531, title III, § 309(d), 106 Stat. 3502, related to health services for residents of public housing, prior to repeal by Pub. L. 104–299, §§ 4(a)(3), 5, Oct. 11, 1996, 110 Stat. 3645, effective Oct. 1, 1996.

Another prior section 256a, act July 1, 1944, ch. 373, title III, § 340A, as added Nov. 10, 1978, Pub. L. 95–626, title I, § 106(a), 92 Stat. 3560, related to technical assistance demonstration grants and contracts, prior to repeal by Pub. L. 100–77, title VI, § 601, July 22, 1987, 101 Stat. 511.

AMENDMENTS

2010—Subsec. (d)(3). Pub. L. 111–148, § 3510(1), added par. (3) and struck out former par. (3). Prior to amendment, text read as follows: ''In carrying out this section, the Secretary—

''(A) shall ensure that the total period of a grant does not exceed 4 years; and

''(B) may not authorize any grant period ending after September 30, 2010.''

Subsec. (e)(3). Pub. L. 111–148, § 3510(2), added par. (3).

Subsec. (m)(1). Pub. L. 111–148, § 3510(3)(A), substituted ''$3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015'' for ''and $3,500,000 for fiscal year 2010''.

Subsec. (m)(2). Pub. L. 111–148, § 3510(3)(B), substituted ''2015'' for ''2010''.

§ 256a–1. Establishing community health teams to support the patient-centered medical home

(a) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (referred to in this section as ''health teams'') to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants or contracts shall be used to—

(1) establish health teams to provide support services to primary care providers; and

(2) provide capitated payments to primary care providers as determined by the Secretary.

(b) Eligible entities

To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1)(A) be a State or State-designated entity; or

(B) be an Indian tribe or tribal organization, as defined in section 1603 of title 25;

(2) submit a plan for achieving long-term financial sustainability within 3 years;

(3) submit a plan for incorporating prevention initiatives and patient education and care management resources into the delivery of health care that is integrated with community-based prevention and treatment resources, where available;

(4) ensure that the health team established by the entity includes an interdisciplinary, interprofessional team of health care providers, as determined by the Secretary; such team may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers (including substance use disorder prevention and treatment providers), doctors of chiropractic, licensed complementary and alternative medicine practitioners, and physicians' assistants;

(5) agree to provide services to eligible individuals with chronic conditions, as described in section 1396w–4 of this title (as added by section 2703), in accordance with the payment methodology established under subsection (c) of such section; and

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

(c) Requirements for health teams

A health team established pursuant to a grant or contract under subsection (a) shall—

(1) establish contractual agreements with primary care providers to provide support services;

(2) support patient-centered medical homes, defined as a mode of care that includes—

(A) personal physicians or other primary care providers;

(B) whole person orientation;

(C) coordinated and integrated care;

(D) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements;

(E) expanded access to care; and

(F) payment that recognizes added value from additional components of patient-centered care;

(3) collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(4) in collaboration with local health care providers, develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(5) incorporate health care providers, patients, caregivers, and authorized representatives in program design and oversight;

(6) provide support necessary for local primary care providers to—

(A) coordinate and provide access to high-quality health care services;

(B) coordinate and provide access to preventive and health promotion services;

(C) provide access to appropriate specialty care and inpatient services;

(D) provide quality-driven, cost-effective, culturally appropriate, and patient- and family-centered health care;

(E) provide access to pharmacist-delivered medication management services, including medication reconciliation;

(F) provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services;

(G) promote effective strategies for treatment planning, monitoring health outcomes and resource use, sharing information, treatment decision support, and organizing care

to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and

(J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;

(7) provide 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator,[1] assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals,[2] nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 300jj of this title) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 280j–2 of this title.

(d) Requirement for primary care providers

A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

(e) Reporting to Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out by the entity under subsection (c).

(f) Definition of primary care

In this section, the term ''primary care'' means the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

(Pub. L. 111–148, title III, § 3502, title X, § 10321, Mar. 23, 2010, 124 Stat. 513, 952.)

REFERENCES IN TEXT

Section 2703, referred to in subsec. (b)(5), means section 2703 of Pub. L. 111–148.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (c)(2)(A). Pub. L. 111–148, § 10321, inserted ''or other primary care providers'' after ''physicians''.

SUBPART VII—DRUG PRICING AGREEMENTS

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price''), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the ''rebate percentage'' is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security

[1] So in original. The comma probably should be ''and''.

[2] So in original. Probably should be ''hospital,''.

Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the ''rebate percentage'' shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term ''over the counter drug'' means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) "Covered entity" defined

In this section, the term ''covered entity'' means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)]).

(B) An entity receiving a grant under section 256a[1] of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II[1] of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2)[1] of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

[1] See References in Text note below.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. 1396r–8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C. 1396r–8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[2] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[2] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C. 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

(1) In general

In this section, the terms ''average manufacturer price'', ''covered outpatient drug'', and

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

''manufacturer'' have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. 1396r–8(k)].

(2) Covered drug

In this section, the term ''covered drug''—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act [42 U.S.C. 1396r–8(k)(2)]); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act [42 U.S.C. 1396r–8(k)(3)(A)], a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub. L. 111–152, title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).[1]

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[3] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may

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

be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term ''covered outpatient drug'' shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition.

(July 1, 1944, ch. 373, title III, § 340B, as added Pub. L. 102–585, title VI, § 602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub. L. 103–43, title XX, § 2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub. L. 111–148, title II, § 2501(f)(1), title VII, §§ 7101(a)–(d), 7102, Mar. 23, 2010, 124 Stat. 309, 821–823; Pub. L. 111–152, title II, § 2302, Mar. 30, 2010, 124 Stat. 1082; Pub. L. 111–309, title II, § 204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1), (3), (4)(L)(i), (5)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§ 301 et seq.) of this title. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 256a of this title, referred to in subsec. (a)(4)(B), was in the original a reference to section 340A of act July 1, 1944, which was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645. Subsequently, a new section 340A was added to the act of July 1, 1944, by Pub. L. 109–18, § 2, June 29, 2005, 119 Stat. 340, which is also classified to section 256a of this title.

Subpart II of part C of subchapter XXIV, referred to in subsec. (a)(4)(D), was redesignated subpart I of part C of subchapter XXIV of this chapter by Pub. L. 106–345, title III, § 301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff–51 et seq. of this title.

The Native Hawaiian Health Care Act of 1988, referred to in subsec. (a)(4)(H), was Pub. L. 100–579, Oct. 31, 1988, 102 Stat. 2916, and subtitle D of title II of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4222, which were classified generally to chapter 122 (§ 11701 et seq.) of this title prior to being amended generally and renamed the Native Hawaiian Health Care Improvement Act by Pub. L. 102–396. For complete classification of this Act to the Code, see Tables.

The Indian Health Care Improvement Act, referred to in subsec. (a)(4)(I), 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.

Section 247b(j)(2) of this title, referred to in subsec. (a)(4)(K), was repealed and section 247b(j)(1)(B) was redesignated section 247b(j)(2) by Pub. L. 103–183, title III, § 301(b)(1)(A), (C), Dec. 14, 1993, 107 Stat. 2235.

The Prescription Drug Marketing Act, referred to in subsec. (d)(2)(B)(v)(III), probably means the Prescription Drug Marketing Act of 1987, Pub. L. 100–293, Apr. 22, 1988, 102 Stat. 95, which amended sections 331, 333, 353, and 381 of Title 21, Food and Drugs, and enacted provisions set out as notes under sections 301 and 353 of Title 21. For complete classification of this Act to the Code, see Short Title of 1988 Amendments note set out under section 301 of Title 21 and Tables.

CODIFICATION

Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to section 256c of this title.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' and ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, § 7102(b)(1), inserted at end ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

Subsec. (a)(2)(A). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' in introductory provisions.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug'' in introductory provisions.

Subsec. (a)(2)(B)(i). Pub. L. 111–148, § 2501(f)(1)(A), substituted ''1927(c)(3)'' for ''1927(c)(4)''.

Subsec. (a)(4)(L). Pub. L. 111–152, § 2302(1)(B), struck out ''and'' at end of cl. (i), substituted ''; and'' for period at end of cl. (ii), and added cl. (iii).

Pub. L. 111–148, § 7101(c)(1), in cl. (i), inserted ''and'' at end, in cl. (ii), substituted period for ''; and'' at end, and struck out cl. (iii) which read as follows: ''does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.''

Subsec. (a)(4)(M) to (O). Pub. L. 111–148, § 7101(a), added subpars. (M) to (O).

Subsec. (a)(5)(B). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C). Pub. L. 111–152, § 2302(1)(C)(i), (ii), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) read as follows:

''(i) IN GENERAL.—A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

''(ii) INPATIENT DRUGS.—Clause (i) shall not apply to drugs purchased for inpatient use.

''(iii) EXCEPTIONS.—The Secretary shall establish reasonable exceptions to clause (i)—

''(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;

''(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; or

''(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

''(iv) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.—The Secretary shall ensure that a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section shall have multiple options for purchasing covered outpatient drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer,

and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.''

Pub. L. 111–148, §7101(c)(2)(B), added subpar. (C). Former subpar. (C) redesignated (D).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C)(iv). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Subsec. (a)(5)(D). Pub. L. 111–152, §2302(1)(C)(ii), (iii), redesignated subpar. (E) as (D) and substituted ''subparagraph (C)'' for ''subparagraph (D)''. Former subpar. (D) redesignated (C).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §7101(c)(2)(A), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(E). Pub. L. 111–152, §2302(1)(C)(ii), redesignated subpar. (E) as (D).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §§7101(c)(2)(A), 7102(b)(2), redesignated subpar. (D) as (E) and inserted ''after audit as described in subparagraph (D) and'' after ''finds,''.

Subsec. (a)(7). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs'' wherever appearing.

Subsec. (a)(9). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs''.

Subsec. (b). Pub. L. 111–148, §7101(b)(2)(A), which directed substitution of ''Other definitions'' for ''Other definition'' in subsec. heading, designation of existing provisions as par. (1), and insertion of par. (1) heading, was executed by reenacting subsec. heading without change, designating existing provisions as par. (1), and inserting par. (1) heading, to reflect the probable intent of Congress.

Subsec. (b)(2). Pub. L. 111–148, §7101(b)(2)(B), added par. (2).

Subsec. (c). Pub. L. 111–152, §2302(2), struck out subsec. (c). Text read as follows: ''Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.''

Pub. L. 111–148, §7101(d), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: ''A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992.''

Pub. L. 111–148, §2501(f)(1)(B), (C), redesignated subsec. (d) as (c) and struck out former subsec. (c). Text of former subsec. (c) read as follows: ''Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on November 4, 1992.''

Subsec. (d). Pub. L. 111–152, §2302(3), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing and substituted ''(a)(5)(C)'' for ''(a)(5)(D)'' and ''(a)(5)(D)'' for ''(a)(5)(E)'' in two places.

Pub. L. 111–148, §7102(a), which directed general amendment of subsec. (d), was executed by adding subsec. (d) after subsec. (c) to reflect the probable intent of Congress, because no subsec. (d) appeared subsequent to amendment by Pub. L. 111–148, §2501(f)(1)(C). See below.

Pub. L. 111–148, §2501(f)(1)(C), redesignated subsec. (d) as (c).

Subsec. (e). Pub. L. 111–309 substituted ''covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M))'' for ''covered entities described in subparagraph (M)''.

Pub. L. 111–152, §2302(4), added subsec. (e).

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–585, §602(a), which enacted this section.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–309, title II, §204(a)(2), Dec. 15, 2010, 124 Stat. 3289, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152).''

Pub. L. 111–148, title II, §2501(f)(2), Mar. 23, 2010, 124 Stat. 310, provided that: ''The amendments made by this subsection [amending this section] take effect on January 1, 2010.''

Pub. L. 111–148, title VII, §7101(e), Mar. 23, 2010, 124 Stat. 823, provided that:

''(1) IN GENERAL.—The amendments made by this section [amending this section] and section 7102 [amending this section] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

''(2) EFFECTIVENESS.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.''

STUDY OF TREATMENT OF CERTAIN CLINICS AS COVERED ENTITIES ELIGIBLE FOR PRESCRIPTION DRUG DISCOUNTS

Pub. L. 102–585, title VI, §602(b), Nov. 4, 1992, 106 Stat. 4970, directed Secretary of Health and Human Services to conduct a study of feasibility and desirability of including specified entities receiving funds from a State as covered entities eligible for limitations on prices of covered outpatient drugs under 42 U.S.C. 256b(a) and, not later than 1 year after Nov. 4, 1992, to submit a report to Congress on the study, including in the report a description of the entities that were the subject of the study, an analysis of the extent to which such entities procured prescription drugs, and an analysis of the impact of the inclusion of such entities as covered entities on the quality of care provided to and the health status of the patients of such entities.

SUBPART VIII—BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

CODIFICATION

Pub. L. 103–43, title XX, §2008(i)(2)(A)(i), June 10, 1993, 107 Stat. 213, made technical amendment relating to placement of subpart VIII within part D of this subchapter.

§ 256c. Bulk purchases of vaccines for certain programs

(a) Agreements for purchases

(1) In general

Not later than 180 days after October 27, 1992, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations

with manufacturers of vaccines for the purpose of establishing and maintaining agreements under which entities described in paragraph (2) may purchase vaccines from the manufacturers at the prices specified in the agreements.

(2) Relevant entities

The entities referred to in paragraph (1) are entities that provide immunizations against vaccine-preventable diseases with assistance provided under section 254b of this title.

(b) Negotiation of prices

In carrying out subsection (a), the Secretary shall, to the extent practicable, ensure that the prices provided for in agreements under such subsection are comparable to the prices provided for in agreements negotiated by the Secretary on behalf of grantees under section 247b(j)(1) of this title.

(c) Authority of Secretary

In carrying out subsection (a), the Secretary, in the discretion of the Secretary, may enter into the agreements described in such subsection (and may decline to enter into such agreements), may modify such agreements, may extend such agreements, and may terminate such agreements.

(d) Rule of construction

This section may not be construed as requiring any State to reduce or terminate the supply of vaccines provided by the State to any of the entities described in subsection (a)(2).

(July 1, 1944, ch. 373, title III, § 340C, formerly § 340B, as added Pub. L. 102–531, title III, § 305, Oct. 27, 1992, 106 Stat. 3494; renumbered § 340C, Pub. L. 103–43, title XX, § 2008(i)(2)(A)(ii), June 10, 1993, 107 Stat. 213; amended Pub. L. 104–299, § 4(a)(2), Oct. 11, 1996, 110 Stat. 3645.)

AMENDMENTS

1996—Subsec. (a)(2). Pub. L. 104–299 substituted ''with assistance provided under section 254b of this title'' for ''under the programs established in sections 254b, 254c, 256, and 256a of this title.''

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–299 effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as a note under section 233 of this title.

§ 256d. Breast and cervical cancer information

(a) In general

As a condition of receiving grants, cooperative agreements, or contracts under this chapter, each of the entities specified in subsection (c) shall, to the extent determined to be appropriate by the Secretary, make available information concerning breast and cervical cancer.

(b) Certain authorities

In carrying out subsection (a), an entity specified in subsection (c)—

(1) may make the information involved available to such individuals as the entity determines appropriate;

(2) may, as appropriate, provide information under subsection (a) on the need for self-examination of the breasts and on the skills for such self-examinations;

(3) shall provide information under subsection (a) in the language and cultural context most appropriate to the individuals to whom the information is provided; and

(4) shall refer such clients as the entities determine appropriate for breast and cervical cancer screening, treatment, or other appropriate services.

(c) Relevant entities

The entities specified in this subsection are the following:

(1) Entities receiving assistance under section 247b–7[1] of this title (relating to tuberculosis).

(2) Entities receiving assistance under section 247c of this title (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 254b[1] of this title.

(4) Community health centers receiving assistance under section 254c[1] of this title.

(5) Entities receiving assistance under section 254b(h) of this title (relating to homeless individuals).

(6) Entities receiving assistance under section 256a[1] of this title (relating to health services for residents of public housing).

(7) Entities providing services with assistance under subchapter III–A or subchapter XVII.

(8) Entities receiving assistance under section 300 of this title (relating to family planning).

(9) Entities receiving assistance under subchapter XXIV (relating to services with respect to acquired immune deficiency syndrome).

(10) Non-Federal entities authorized under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.].

(July 1, 1944, ch. 373, title III, § 340D, as added Pub. L. 103–183, title I, § 104, Dec. 14, 1993, 107 Stat. 2230; amended Pub. L. 106–310, div. A, title XXV, § 2502(b), Oct. 17, 2000, 114 Stat. 1163; Pub. L. 107–251, title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1664.)

REFERENCES IN TEXT

Section 247b–7 of this title, referred to in subsec. (c)(1), relates to loan repayment program and not to assistance relating to tuberculosis.

Sections 254b and 254c of this title, referred to in subsec. (c)(3), (4), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§ 254b et seq.) of this part by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

Section 256a of this title, referred to in subsec. (c)(6), was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Indian Self-Determination Act, referred to in subsec. (c)(10), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§ 5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

[1] See References in Text note below.

AMENDMENTS

2002—Subsec. (c)(5). Pub. L. 107–251 substituted ''254b(h)'' for ''256''.

2000—Subsec. (c)(1). Pub. L. 106–310 substituted ''section 247b–7 of this title'' for ''section 247b–6 of this title''.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center, considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

SUBPART IX—SUPPORT OF GRADUATE MEDICAL EDUCATION PROGRAMS IN CHILDREN'S HOSPITALS

§ 256e. Program of payments to children's hospitals that operate graduate medical education programs

(a) Payments

The Secretary shall make two payments under this section to each children's hospital for each of fiscal years 2000 through 2005, each of fiscal years 2007 through 2011, and each of fiscal years 2014 through 2018, one for the direct expenses and the other for indirect expenses associated with operating approved graduate medical residency training programs. The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5 which shall govern payments made under this subpart.

(b) Amount of payments

(1) In general

Subject to paragraphs (2) and (3), the amounts payable under this section to a children's hospital for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) Direct expense amount

The amount determined under subsection (c) for direct expenses associated with operating approved graduate medical residency training programs.

(B) Indirect expense amount

The amount determined under subsection (d) for indirect expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

(2) Capped amount

(A) In general

The total of the payments made to children's hospitals under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the funds appropriated under paragraph (1) or (2), respectively, of subsection (f) for such payments for that fiscal year.

(B) Pro rata reductions of payments for direct expenses

If the Secretary determines that the amount of funds appropriated under subsection (f)(1) for a fiscal year is insufficient to provide the total amount of payments otherwise due for such periods under paragraph (1)(A), the Secretary shall reduce the amounts so payable on a pro rata basis to reflect such shortfall.

(3) Annual reporting required

(A) Reduction in payment for failure to report

(i) In general

The amount payable under this section to a children's hospital for a fiscal year (beginning with fiscal year 2008 and after taking into account paragraph (2)) shall be reduced by 25 percent if the Secretary determines that—

(I) the hospital has failed to provide the Secretary, as an addendum to the hospital's application under this section for such fiscal year, the report required under subparagraph (B) for the previous fiscal year; or

(II) such report fails to provide the information required under any clause of such subparagraph.

(ii) Notice and opportunity to provide missing information

Before imposing a reduction under clause (i) on the basis of a hospital's failure to provide information described in clause (i)(II), the Secretary shall provide notice to the hospital of such failure and the Secretary's intention to impose such reduction and shall provide the hospital with the opportunity to provide the required information within a period of 30 days beginning on the date of such notice. If the hospital provides such information within such period, no reduction shall be made under clause (i) on the basis of the previous failure to provide such information.

(B) Annual report

The report required under this subparagraph for a children's hospital for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(i) The types of resident training programs that the hospital provided for residents described in subparagraph (C), such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties, including both medical subspecialties certified by the American Board of Pediatrics (such as pediatric gastroenterology) and non-medical subspecialties approved by other medical certification boards (such as pediatric surgery).

(ii) The number of training positions for residents described in subparagraph (C), the number of such positions recruited to fill, and the number of such positions filled.

(iii) The types of training that the hospital provided for residents described in subparagraph (C) related to the health care needs of different populations, such as children who are underserved for reasons of family income or geographic location, including rural and urban areas.

(iv) The changes in residency training for residents described in subparagraph (C) which the hospital has made during such residency academic year (except that the first report submitted by the hospital under this subparagraph shall be for such changes since the first year in which the hospital received payment under this section), including—

(I) changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes; and

(II) changes for purposes of training the residents in the measurement and improvement of the quality and safety of patient care.

(v) The numbers of residents described in subparagraph (C) who completed their residency training at the end of such residency academic year and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located. Such numbers shall be disaggregated with respect to residents who completed residencies in general pediatrics or internal medicine/pediatrics, subspecialty residencies, and dental residencies.

(C) Residents

The residents described in this subparagraph are those who—

(i) are in full-time equivalent resident training positions in any training program sponsored by the hospital; or

(ii) are in a training program sponsored by an entity other than the hospital, but who spend more than 75 percent of their training time at the hospital.

(D) Report to Congress

Not later than the end of fiscal year 2018, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit a report to the Congress—

(i) summarizing the information submitted in reports to the Secretary under subparagraph (B);

(ii) describing the results of the program carried out under this section; and

(iii) making recommendations for improvements to the program.

(c) Amount of payment for direct graduate medical education

(1) In general

The amount determined under this subsection for payments to a children's hospital for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the hospital's graduate approved medical residency training programs (as determined under section 1395ww(h)(4) of this title during the fiscal year.

(2) Updated per resident amount for direct graduate medical education

The updated per resident amount for direct graduate medical education for a hospital for a fiscal year is an amount determined as follows:

(A) Determination of hospital single per resident amount

The Secretary shall compute for each hospital operating an approved graduate medical education program (regardless of whether or not it is a children's hospital) a single per resident amount equal to the average (weighted by number of full-time equivalent residents) of the primary care per resident amount and the non-primary care per resident amount computed under section 1395ww(h)(2) of this title for cost reporting periods ending during fiscal year 1997.

(B) Determination of wage and non-wage-related proportion of the single per resident amount

The Secretary shall estimate the average proportion of the single per resident amounts computed under subparagraph (A) that is attributable to wages and wage-related costs.

(C) Standardizing per resident amounts

The Secretary shall establish a standardized per resident amount for each such hospital—

(i) by dividing the single per resident amount computed under subparagraph (A) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by dividing the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title for discharges occurring during fiscal year 1999 for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(D) Determination of national average

The Secretary shall compute a national average per resident amount equal to the average of the standardized per resident amounts computed under subparagraph (C) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital.

(E) Application to individual hospitals

The Secretary shall compute for each such hospital that is a children's hospital a per resident amount—

(i) by dividing the national average per resident amount computed under subparagraph (D) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title for discharges

occurring during the preceding fiscal year for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(F) Updating rate

The Secretary shall update such per resident amount for each such children's hospital by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning October 1997 and ending with the midpoint of the Federal fiscal year for which payments are made.

(d) Amount of payment for indirect medical education

(1) In general

The amount determined under this subsection for payments to a children's hospital for indirect expenses associated with the treatment of more severely ill patients and the additional costs associated with the teaching of residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) Factors

In determining the amount under paragraph (1), the Secretary shall—

(A) take into account variations in case mix among children's hospitals and the ratio of the number of full-time equivalent residents in the hospitals' approved graduate medical residency training programs to beds (but excluding beds or bassinets assigned to healthy newborn infants); and

(B) assure that the aggregate of the payments for indirect expenses associated with the treatment of more severely ill patients and the additional costs related to the teaching of residents under this section in a fiscal year are equal to the amount appropriated for such expenses for the fiscal year involved under subsection (f)(2).

(e) Making of payments

(1) Interim payments

The Secretary shall determine, before the beginning of each fiscal year involved for which payments may be made for a hospital under this section, the amounts of the payments for direct graduate medical education and indirect medical education for such fiscal year and shall (subject to paragraph (2)) make the payments of such amounts in 12 equal interim installments during such period. Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.

(2) Withholding

The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis.

(3) Reconciliation

Prior to the end of each fiscal year, the Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made and pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1395*oo* of this title and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1395ww(d)[1] of this title is subject to review under such section.

(f) Authorization of appropriations

(1) Direct graduate medical education

(A) In general

There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(A)—

(i) for fiscal year 2000, $90,000,000;

(ii) for fiscal year 2001, $95,000,000;

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

(iv) for each of fiscal years 2007 through 2011, $110,000,000; and

(v) for each of fiscal years 2014 through 2018, $100,000,000.

(B) Carryover of excess

The amounts appropriated under subparagraph (A) for fiscal year 2000 shall remain available for obligation through the end of fiscal year 2001.

(2) Indirect medical education

There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(B)—

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

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

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

(D) for each of fiscal years 2007 through 2011, $220,000,000; and

(E) for each of fiscal years 2014 through 2018, $200,000,000.

(g) Definitions

In this section:

(1) Approved graduate medical residency training program

The term ''approved graduate medical residency training program'' has the meaning given the term ''approved medical residency

[1] See References in Text note below.

training program'' in section 1395ww(h)(5)(A) of this title.

(2) Children's hospital

The term ''children's hospital'' means a hospital with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1395ww(d)(1)(B)(iii) of this title and its accompanying regulations.

(3) Direct graduate medical education costs

The term ''direct graduate medical education costs'' has the meaning given such term in section 1395ww(h)(5)(C) of this title.

(h) Additional provisions

(1) In general

The Secretary is authorized to make available up to 25 percent of the total amounts in excess of $245,000,000 appropriated under paragraphs (1) and (2) of subsection (f), but not to exceed $7,000,000, for payments to hospitals qualified as described in paragraph (2), for the direct and indirect expenses associated with operating approved graduate medical residency training programs, as described in subsection (a).

(2) Qualified hospitals

(A) In general

To qualify to receive payments under paragraph (1), a hospital shall be a freestanding hospital—

(i) with a Medicare payment agreement and that is excluded from the Medicare inpatient hospital prospective payment system pursuant to section 1395ww(d)(1)(B) of this title and its accompanying regulations;

(ii) whose inpatients are predominantly individuals under 18 years of age;

(iii) that has an approved medical residency training program as defined in section 1395ww(h)(5)(A) of this title; and

(iv) that is not otherwise qualified to receive payments under this section or section 1395ww(h) of this title.

(B) Establishment of residency cap

In the case of a freestanding children's hospital that, on April 7, 2014, meets the requirements of subparagraph (A) but for which the Secretary has not determined an average number of full-time equivalent residents under section 1395ww(h)(4) of this title, the Secretary may establish such number of full-time equivalent residents for the purposes of calculating payments under this subsection.

(3) Payments

Payments to hospitals made under this subsection shall be made in the same manner as payments are made to children's hospitals, as described in subsections (b) through (e).

(4) Payment amounts

The direct and indirect payment amounts under this subsection shall be determined using per resident amounts that are no greater than the per resident amounts used for determining direct and indirect payment amounts under subsection (a).

(5) Reporting

A hospital receiving payments under this subsection shall be subject to the reporting requirements under subsection (b)(3).

(6) Remaining funds

(A) In general

If the payments to qualified hospitals under paragraph (1) for a fiscal year are less than the total amount made available under such paragraph for that fiscal year, any remaining amounts for such fiscal year may be made available to all hospitals participating in the program under this subsection or subsection (a).

(B) Quality bonus system

For purposes of distributing the remaining amounts described in subparagraph (A), the Secretary may establish a quality bonus system, whereby the Secretary distributes bonus payments to hospitals participating in the program under this subsection or subsection (a) that meet standards specified by the Secretary, which may include a focus on quality measurement and improvement, interpersonal and communications skills, delivering patient-centered care, and practicing in integrated health systems, including training in community-based settings. In developing such standards, the Secretary shall collaborate with relevant stakeholders, including program accrediting bodies, certifying boards, training programs, health care organizations, health care purchasers, and patient and consumer groups.

(July 1, 1944, ch. 373, title III, § 340E, as added Pub. L. 106–129, § 4, Dec. 6, 1999, 113 Stat. 1671; amended Pub. L. 106–310, div. A, title XX, § 2001, Oct. 17, 2000, 114 Stat. 1155; Pub. L. 108–490, § 1(a), Dec. 23, 2004, 118 Stat. 3972; Pub. L. 109–307, § 2, Oct. 6, 2006, 120 Stat. 1721; Pub. L. 113–98, §§ 2, 3, Apr. 7, 2014, 128 Stat. 1140.)

REFERENCES IN TEXT

Section 1395ww(d) of this title, referred to in subsec. (e)(3), was in the original ''section 1186(d) of such Act'' and was translated as reading ''section 1886(d) of such Act'', meaning section 1886(d) of the Social Security Act, to reflect the probable intent of Congress, because the Social Security Act does not contain a section 1186 and section 1395ww(d) of this title relates to review of inpatient hospital service payments.

AMENDMENTS

2014—Subsec. (a). Pub. L. 113–98, § 2(a)(1), substituted ''through 2005, each of fiscal years 2007 through 2011, and each of fiscal years 2014 through 2018'' for ''through 2005 and each of fiscal years 2007 through 2011''.

Subsec. (b)(3)(D). Pub. L. 113–98, § 2(b), substituted ''Not later than the end of fiscal year 2018'' for ''Not later than the end of fiscal year 2011'' in introductory provisions.

Subsec. (f)(1)(A)(v). Pub. L. 113–98, § 2(a)(2)(A), added cl. (v).

Subsec. (f)(2)(E). Pub. L. 113–98, § 2(a)(2)(B), added subpar. (E).

Subsec. (h). Pub. L. 113–98, § 3, added subsec. (h).

2006—Subsec. (a). Pub. L. 109–307, § 2(a)(1), inserted ''and each of fiscal years 2007 through 2011'' after ''for each of fiscal years 2000 through 2005''.

Subsec. (b)(1). Pub. L. 109–307, § 2(b)(1), substituted ''paragraphs (2) and (3)'' for ''paragraph (2)'' in introductory provisions.

Subsec. (b)(3). Pub. L. 109–307, §2(b)(2), added par. (3).

Subsec. (c)(2)(E)(ii). Pub. L. 109–307, §2(c)(1), substituted ''applied under section 1395ww(d)(3)(E) of this title for discharges occurring during the preceding fiscal year'' for ''described in subparagraph (C)(ii)''.

Subsec. (e)(1). Pub. L. 109–307, §2(a)(2), substituted ''12'' for ''26''.

Subsec. (e)(2). Pub. L. 109–307, §2(c)(2), struck out first sentence which read as follows: ''The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1).''

Subsec. (e)(3). Pub. L. 109–307, §2(c)(3), substituted ''made and pay'' for ''made to pay''.

Subsec. (f)(1)(A)(iv). Pub. L. 109–307, §2(a)(3), added cl. (iv).

Subsec. (f)(2). Pub. L. 109–307, §2(a)(4)(A), substituted ''subsection (b)(1)(B)'' for ''subsection (b)(1)(A)'' in introductory provisions.

Subsec. (f)(2)(D). Pub. L. 109–307, §2(a)(4)(B)–(D), added subpar. (D).

2004—Subsec. (d)(1). Pub. L. 108–490, §1(a)(1), substituted ''costs associated with'' for ''costs related to''.

Subsec. (d)(2)(A). Pub. L. 108–490, §1(a)(2), inserted ''ratio of the'' after ''hospitals and the'' and ''to beds (but excluding beds or bassinets assigned to healthy newborn infants)'' before semicolon.

2000—Subsec. (a). Pub. L. 106–310, §2001(a), substituted ''2000 through 2005'' for ''2000 and 2001'' and inserted at end ''The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5 which shall govern payments made under this subpart.''.

Subsec. (c)(2)(F). Pub. L. 106–310, §2001(b), substituted ''Federal fiscal year for which payments are made'' for ''hospital's cost reporting period that begins during fiscal year 2000''.

Subsec. (e)(1). Pub. L. 106–310, §2001(c), inserted at end ''Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.''

Subsec. (e)(2). Pub. L. 106–310, §2001(d), inserted ''and indirect'' after ''interim installment for direct'' and inserted at end ''The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis.''

Subsec. (e)(3). Pub. L. 106–310, §2001(e), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: ''At the end of each fiscal year for which payments may be made under this section, the hospital shall submit to the Secretary such information as the Secretary determines to be necessary to determine the percent (if any) of the total amount withheld under paragraph (2) that is due under this section for the hospital for the fiscal year. Based on such determination, the Secretary shall recoup any overpayments made, or pay any balance due. The amount so determined shall be considered a final intermediary determination for purposes of applying section 1395*oo* of this title and shall be subject to review under that section in the same manner as the amount of payment under section 1395ww(d) of this title is subject to review under such section.''

Subsec. (f)(1)(A)(iii). Pub. L. 106–310, §2001(f)(1), added cl. (iii).

Subsec. (f)(2)(C). Pub. L. 106–310, §2001(f)(2), added subpar. (C).

Subsec. (g)(2). Pub. L. 106–310, §2001(g), substituted ''with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1395ww(d)(1)(B)(iii) of this title and its accompanying regulations'' for ''described in section 1395ww(d)(1)(B)(iii) of this title''.

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–490, §1(b), Dec. 23, 2004, 118 Stat. 3972, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to payments for periods beginning with fiscal year 2005.''

SUBPART X—PRIMARY DENTAL PROGRAMS

§ 256f. Designated dental health professional shortage area

In this subpart, the term ''designated dental health professional shortage area'' means an area, population group, or facility that is designated by the Secretary as a dental health professional shortage area under section 254e of this title or designated by the applicable State as having a dental health professional shortage.

(July 1, 1944, ch. 373, title III, §340F, as added Pub. L. 107–251, title IV, §403, Oct. 26, 2002, 116 Stat. 1660.)

§ 256g. Grants for innovative programs

(a) Grant program authorized

The Secretary, acting through the Administrator of the Health Resources and Services Administration, is authorized to award grants to States for the purpose of helping States develop and implement innovative programs to address the dental workforce needs of designated dental health professional shortage areas in a manner that is appropriate to the States' individual needs.

(b) State activities

A State receiving a grant under subsection (a) may use funds received under the grant for—

(1) loan forgiveness and repayment programs for dentists who—

(A) agree to practice in designated dental health professional shortage areas;

(B) are dental school graduates who agree to serve as public health dentists for the Federal, State, or local government; and

(C) agree to—

(i) provide services to patients regardless of such patients' ability to pay; and

(ii) use a sliding payment scale for patients who are unable to pay the total cost of services;

(2) dental recruitment and retention efforts;

(3) grants and low-interest or no-interest loans to help dentists who participate in the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to establish or expand practices in designated dental health professional shortage areas by equipping dental offices or sharing in the overhead costs of such practices;

(4) the establishment or expansion of dental residency programs in coordination with accredited dental training institutions in States without dental schools;

(5) programs developed in consultation with State and local dental societies to expand or establish oral health services and facilities in designated dental health professional shortage areas, including services and facilities for children with special needs, such as—

(A) the expansion or establishment of a community-based dental facility, free-stand-

ing dental clinic, consolidated health center dental facility, school-linked dental facility, or United States dental school-based facility;

(B) the establishment of a mobile or portable dental clinic; and

(C) the establishment or expansion of private dental services to enhance capacity through additional equipment or additional hours of operation;

(6) placement and support of dental students, dental residents, and advanced dentistry trainees;

(7) continuing dental education, including distance-based education;

(8) practice support through teledentistry conducted in accordance with State laws;

(9) community-based prevention services such as water fluoridation and dental sealant programs;

(10) coordination with local educational agencies within the State to foster programs that promote children going into oral health or science professions;

(11) the establishment of faculty recruitment programs at accredited dental training institutions whose mission includes community outreach and service and that have a demonstrated record of serving underserved States;

(12) the development of a State dental officer position or the augmentation of a State dental office to coordinate oral health and access issues in the State; and

(13) any other activities determined to be appropriate by the Secretary.

(c) Application

(1) In general

Each State desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) Assurances

The application shall include assurances that the State will meet the requirements of subsection (d) and that the State possesses sufficient infrastructure to manage the activities to be funded through the grant and to evaluate and report on the outcomes resulting from such activities.

(d) Matching requirement

The Secretary may not make a grant to a State under this section unless that State agrees that, with respect to the costs to be incurred by the State in carrying out the activities for which the grant was awarded, the State will provide non-Federal contributions in an amount equal to not less than 40 percent of Federal funds provided under the grant. The State may provide the contributions in cash or in kind, fairly evaluated, including plant, equipment, and services and may provide the contributions from State, local, or private sources.

(e) Report

Not later than 5 years after October 26, 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether grants provided under this section have increased access to dental services in designated dental health professional shortage areas.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $25,000,000 for the 5-fiscal year period beginning with fiscal year 2008.

(July 1, 1944, ch. 373, title III, § 340G, as added Pub. L. 107–251, title IV, § 403, Oct. 26, 2002, 116 Stat. 1661; amended Pub. L. 110–355, § 5, Oct. 8, 2008, 122 Stat. 3994.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3), 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

2008—Subsec. (f). Pub. L. 110–355 substituted ''$25,000,000'' for ''$50,000,000'' and ''2008'' for ''2002''.

§ 256g–1. Demonstration program to increase access to dental health care services

(a) In general

(1) Authorization

The Secretary is authorized to award grants to 15 eligible entities to enable such entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

(2) Definition

The term ''alternative dental health care providers'' includes community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professional that the Secretary determines appropriate.

(b) Timeframe

The demonstration projects funded under this section shall begin not later than 2 years after March 23, 2010, and shall conclude not later than 7 years after March 23, 2010.

(c) Eligible entities

To be eligible to receive a grant under subsection (a), an entity shall—

(1) be—

(A) an institution of higher education, including a community college;

(B) a public-private partnership;

(C) a federally qualified health center;

(D) an Indian Health Service facility or a tribe or tribal organization (as such terms are defined in section 5304 of title 25);

(E) a State or county public health clinic, a health facility operated by an Indian tribe or tribal organization, or urban Indian organization providing dental services; or

(F) a public hospital or health system;

(2) be within a program accredited by the Commission on Dental Accreditation or within

a dental education program in an accredited institution; and

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

(d) Administrative provisions

(1) Amount of grant

Each grant under this section shall be in an amount that is not less than $4,000,000 for the 5-year period during which the demonstration project[1] being conducted.

(2) Disbursement of funds

(A) Preliminary disbursements

Beginning 1 year after March 23, 2010, the Secretary may disperse to any entity receiving a grant under this section not more than 20 percent of the total funding awarded to such entity under such grant, for the purpose of enabling the entity to plan the demonstration project to be conducted under such grant.

(B) Subsequent disbursements

The remaining amount of grant funds not dispersed under subparagraph (A) shall be dispersed such that not less than 15 percent of such remaining amount is dispersed each subsequent year.

(e) Compliance with State requirements

Each entity receiving a grant under this section shall certify that it is in compliance with all applicable State licensing requirements.

(f) Evaluation

The Secretary shall contract with the Director of the Institute of Medicine to conduct a study of the demonstration programs conducted under this section that shall provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States.

(g) Clarification regarding dental health aide program

Nothing in this section shall prohibit a dental health aide training program approved by the Indian Health Service from being eligible for a grant under this section.

(h) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 340G–1, as added Pub. L. 111–148, title V, § 5304, Mar. 23, 2010, 124 Stat. 621.)

SUBPART XI—SUPPORT OF GRADUATE MEDICAL EDUCATION IN QUALIFIED TEACHING HEALTH CENTERS

CODIFICATION

Subpart is comprised of subpart XI of part D of title III of act July 1, 1944. Another subpart XI of part D of title III of the Act was redesignated subpart XII by Pub. L. 115–63, title III, § 301(c)(1), Sept. 29, 2017, 131 Stat. 1172, and is classified to subpart XII (§ 256i) of this part.

[1] So in original. The word ''is'' probably should appear.

§ 256h. Program of payments to teaching health centers that operate graduate medical education programs

(a) Payments

Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and for indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for expansion of existing or establishment of new approved graduate medical residency training programs.

(b) Amount of payments

(1) In general

Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) Direct expense amount

The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs.

(B) Indirect expense amount

The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.

(2) Capped amount

(A) In general

The total of the payments made to qualified teaching health centers under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the amount of funds appropriated under subsection (g) for such payments for that fiscal year.

(B) Limitation

The Secretary shall limit the funding of full-time equivalent residents in order to ensure the direct and indirect payments as determined under subsection[1] (c) and (d) do not exceed the total amount of funds appropriated in a fiscal year under subsection (g).

(c) Amount of payment for direct graduate medical education

(1) In general

The amount determined under this subsection for payments to qualified teaching health centers for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated national per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the teaching health center's graduate approved medical residency training programs as determined under section 1395ww(h)(4) of this title (without regard to the limitation under subparagraph (F) of such section) during the fiscal year.

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

(2) Updated national per resident amount for direct graduate medical education

The updated per resident amount for direct graduate medical education for a qualified teaching health center for a fiscal year is an amount determined as follows:

(A) Determination of qualified teaching health center per resident amount

The Secretary shall compute for each individual qualified teaching health center a per resident amount—

(i) by dividing the national average per resident amount computed under section 256e(c)(2)(D) of this title into a wage-related portion and a non-wage related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title (but without application of section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note)) during the preceding fiscal year for the teaching health center's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(B) Updating rate

The Secretary shall update such per resident amount for each such qualified teaching health center as determined appropriate by the Secretary.

(d) Amount of payment for indirect medical education

(1) In general

The amount determined under this subsection for payments to qualified teaching health centers for indirect expenses associated with the additional costs of teaching residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) Factors

In determining the amount under paragraph (1), the Secretary shall—

(A) evaluate indirect training costs relative to supporting a primary care residency program in qualified teaching health centers; and

(B) based on this evaluation, assure that the aggregate of the payments for indirect expenses under this section and the payments for direct graduate medical education as determined under subsection (c) in a fiscal year do not exceed the amount appropriated for such expenses as determined in subsection (g).

(3) Interim payment

Before the Secretary makes a payment under this subsection pursuant to a determination of indirect expenses under paragraph (1), the Secretary may provide to qualified teaching health centers a payment, in addition to any payment made under subsection (c), for expected indirect expenses associated with the additional costs of teaching residents for a fiscal year, based on an estimate by the Secretary.

(e) Clarification regarding relationship to other payments for graduate medical education

Payments under this section—

(1) shall be in addition to any payments—

(A) for the indirect costs of medical education under section 1395ww(d)(5)(B) of this title;

(B) for direct graduate medical education costs under section 1395ww(h) of this title; and

(C) for direct costs of medical education under section 1395ww(k) of this title;

(2) shall not be taken into account in applying the limitation on the number of total full-time equivalent residents under subparagraphs (F) and (G) of section 1395ww(h)(4) of this title and clauses (v), (vi)(I), and (vi)(II) of section 1395ww(d)(5)(B) of this title for the portion of time that a resident rotates to a hospital; and

(3) shall not include the time in which a resident is counted toward full-time equivalency by a hospital under paragraph (2) or under section 1395ww(d)(5)(B)(iv) of this title, section 1395ww(h)(4)(E) of this title, or section 256e of this title.

(f) Reconciliation

The Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1395*oo* of this title and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1395ww(d)[2] of this title is subject to review under such section.

(g) Funding

(1) In general

To carry out this section, there are appropriated such sums as may be necessary, not to exceed $230,000,000, for the period of fiscal years 2011 through 2015, $60,000,000 for each of fiscal years 2016 and 2017, and $30,000,000 for the period of the first and second quarters of fiscal year 2018, to remain available until expended.

(2) Administrative expenses

Of the amount made available to carry out this section for any fiscal year, the Secretary may not use more than 5 percent of such amount for the expenses of administering this section.

(h) Annual reporting required

(1) Annual report

The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic

[2] See References in Text note below.

year completed immediately prior to such fiscal year:

(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.

(B) The number of approved training positions for residents described in paragraph (4).

(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.

(D) Other information as deemed appropriate by the Secretary.

(2) Audit authority; limitation on payment

(A) Audit authority

The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).

(B) Limitation on payment

A teaching health center may only receive payment in a cost reporting period for a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the ''base level of primary care residents'' for a teaching health center is the level of such residents as of a base period.

(3) Reduction in payment for failure to report

(A) In general

The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that—

(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center's application under this section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or

(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.

(B) Notice and opportunity to provide accurate and missing information

Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center's failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary's intention to impose such reduction and shall provide the teaching health center with the opportunity to provide the required information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.

(4) Residents

The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.

(i) Regulations

The Secretary shall promulgate regulations to carry out this section.

(j) Definitions

In this section:

(1) Approved graduate medical residency training program

The term ''approved graduate medical residency training program'' means a residency or other postgraduate medical training program—

(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and

(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).

(2) Primary care residency program

The term ''primary care residency program'' has the meaning given that term in section 293*l*–1 of this title.

(3) Qualified teaching health center

The term ''qualified teaching health center'' has the meaning given the term ''teaching health center'' in section 293*l*–1 of this title.

(July 1, 1944, ch. 373, title III, § 340H, as added Pub. L. 111–148, title V, § 5508(c), Mar. 23, 2010, 124 Stat. 670; amended Pub. L. 114–10, title II, § 221(b), Apr. 16, 2015, 129 Stat. 154; Pub. L. 115–63, title III, § 301(a), Sept. 29, 2017, 131 Stat. 1171; Pub. L. 115–96, div. C, title I, § 3101(c), Dec. 22, 2017, 131 Stat. 2048.)

REFERENCES IN TEXT

Section 4410 of the Balanced Budget Act of 1997, referred to in subsec. (c)(2)(A)(ii), is section 4410 of Pub. L. 105–33, which is set out as a note under section 1395ww of this title.

Section 1395ww(d) of this title, referred to in subsec. (f), was in the original ''section 1186(d) of such Act'', and was translated as meaning section 1886(d) of act Aug. 14, 1935, ch. 531, known as the Social Security Act, to reflect the probable intent of Congress. The Social Security Act does not contain a section 1186.

CODIFICATION

Another section 340H of act July 1, 1944, was renumbered section 340I and is classified to section 256i of this title.

AMENDMENTS

2017—Subsec. (g). Pub. L. 115–96 designated existing provisions as par. (1), inserted heading, substituted ''and $30,000,000 for the period of the first and second quarters of fiscal year 2018, to remain available until expended'' for ''and $15,000,000 for the first quarter of fiscal year 2018'', and added par. (2).

Pub. L. 115–63 substituted ''2015, $60,000,000'' for ''2015 and $60,000,000'' and inserted '', and $15,000,000 for the first quarter of fiscal year 2018'' before period at end.

2015—Subsec. (g). Pub. L. 114–10 inserted ''and $60,000,000 for each of fiscal years 2016 and 2017'' before period at end.

SUBPART XII—COMMUNITY-BASED COLLABORATIVE CARE NETWORK PROGRAM

CODIFICATION

Pub. L. 115–63, title III, § 301(c)(1), Sept. 29, 2017, 131 Stat. 1172, redesignated this subpart, which was formerly subpart XI of part D of title III of act July 1, 1944, as subpart XII. Another subpart XI of part D of title III of the Act is classified to subpart XI (§ 256h) of this part.

§ 256i. Community-based collaborative care network program

(a) In general

The Secretary may award grants to eligible entities to support community-based collaborative care networks that meet the requirements of subsection (b).

(b) Community-based collaborative care networks

(1) Description

A community-based collaborative care network (referred to in this section as a ''network'') shall be a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations.

(2) Required inclusion

A network shall include the following providers (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation):

(A) A hospital that meets the criteria in section 1396r–4(b)(1) of this title; and

(B) All Federally qualified health centers (as defined in section 1395x(aa) of this title[1] located in the community.

(3) Priority

In awarding grants, the Secretary shall give priority to networks that include—

(A) the capability to provide the broadest range of services to low-income individuals;

(B) the broadest range of providers that currently serve a high volume of low-income individuals; and

(C) a county or municipal department of health.

(c) Application

(1) Application

A network described in subsection (b) shall submit an application to the Secretary.

(2) Renewal

In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) Use of funds

(1) Use by grantees

Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) Grant funds to HRSA grantees

The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, § 340I, formerly § 340H, as added Pub. L. 111–148, title X, § 10333, Mar. 23, 2010, 124 Stat. 970; renumbered § 340I, Pub. L. 115–63, title III, § 301(c)(2), Sept. 29, 2017, 131 Stat. 1172.)

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS

§ 257. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710

Section, acts July 1, 1944, ch. 373, title III, § 341, 58 Stat. 698; May 8, 1954, ch. 195, § 3, 68 Stat. 80; July 24, 1956, ch. 676, title III, § 302(a), 70 Stat. 622; Pub. L. 89–793, title VI, § 601, Nov. 8, 1966, 80 Stat. 1449; 1967 Reorg. Plan No. 3, § 401, eff. Nov. 3, 1967 (in part), 32 F.R. 11669, 81 Stat. 951; Pub. L. 91–513, title I, § 2(a)(1), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–255, title IV, § 402, Mar. 21, 1972, 86 Stat. 77; Pub. L. 93–198, title IV, § 421, Dec. 24, 1973, 87 Stat. 789; Pub. L. 98–473, title II, § 232(a), Oct. 12, 1984, 98 Stat. 2031; Pub. L. 99–646, § 22(a), Nov. 10, 1986, 100 Stat. 3597; Pub. L. 102–54, § 13(q)(1)(B)(i), June 13, 1991, 105 Stat. 278, related to care and treatment of narcotic addicts.

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed this section) is effective as if included in the enactment of Pub. L. 106–310.

§ 257a. Transferred

CODIFICATION

Section, Pub. L. 91–513, title I, § 4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb–2a of this title.

[1] So in original. A closing parenthesis probably should appear.

§ 258. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710

Section, acts July 1, 1944, ch. 373, title III, § 342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–513, title I, § 2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed this section) is effective as if included in the enactment of Pub. L. 106–310.

§ 258a. Transferred

CODIFICATION

Section, act July 8, 1947, ch. 210, title II, § 201, 61 Stat. 269, which related to transfer of balances in working capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§ 259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710

Section 259, acts July 1, 1944, ch. 373, title III, § 343, 58 Stat. 699; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, § 3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, § 232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, § 344, 58 Stat. 701; June 25, 1948, ch. 654, § 5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, § 302(b), 70 Stat. 622; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, § 345, as added May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, § 302(c), 70 Stat. 622; Pub. L. 91–358, title I, § 155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, § 346, formerly § 345, 58 Stat. 701; renumbered § 346, May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended Pub. L. 91–513, title I, § 2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat. 1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, § 347, as added May 8, 1954, ch. 195, § 4, 68 Stat. 80; amended Pub. L. 91–513, title I, § 2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed sections 259 to 261a of this title) is effective as if included in the enactment of Pub. L. 106–310.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(*o*), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(*o*), (p), 355–1].

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)(5)].

(ii) In this subparagraph, the terms ''qualified indication'' and ''qualified data summary'' have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing in-

vestigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest ⅒ of 1 percent. For purposes of this paragraph, the term ''base quarter'', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:

(1) The term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term ''biosimilar'' or ''biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term ''interchangeable'' or ''interchangeability'', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term ''reference product'' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act [21 U.S.C. 355(*o*), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term ''final court decision'' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance,

with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the ''subsection (k) applicant'') and the sponsor of the application for the reference product (referred to in this subsection as the ''reference product sponsor''), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the ''confidential information'').

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the ''outside counsel''), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such infor-

mation, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the ref-

erence product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (*l*), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(4)[1] [21 U.S.C. 355a(d)(4)] is made later than 9 months prior to the expiration of such period.

(n) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], approval of such application shall not take effect until the interim final rule controlling the biological

[1] See References in Text note below.

product is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

(A) the date an application is approved under subsection (a); or

(B) the date of issuance of the interim final rule controlling the biological product.

(July 1, 1944, ch. 373, title III, § 351, 58 Stat. 702; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, § 2, Sept. 2, 1958, 72 Stat. 1704; Pub. L. 91–515, title II, § 291, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–660, title I, § 105(a), title III, § 315, Nov. 14, 1986, 100 Stat. 3751, 3783; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 104–134, title II, §§ 2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319, 1321–320; Pub. L. 105–115, title I, § 123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323, 2324; Pub. L. 108–155, § 2(b)(3), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title IX, § 901(c), Sept. 27, 2007, 121 Stat. 939; Pub. L. 111–148, title VII, § 7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804, 814, 819; Pub. L. 112–144, title V, § 502(a)(2), July 9, 2012, 126 Stat. 1040; Pub. L. 114–89, § 2(a)(2), Nov. 25, 2015, 129 Stat. 698; Pub. L. 114–255, div. A, title III, § 3031(b), Dec. 13, 2016, 130 Stat. 1100; Pub. L. 115–52, title V, § 505(b)(2)(B), Aug. 18, 2017, 131 Stat. 1046.)

REFERENCES IN TEXT

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, 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.

Sections 526, 527(a), and 505A(d)(4), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(4), respectively, of Title 21, Food and Drugs.

The Controlled Substances Act, referred to in subsec. (n)(1), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

AMENDMENTS

2017—Subsec. (m)(2) to (4). Pub. L. 115–52 substituted ''section 505A(d)(4)'' for ''section 505A(d)(3)''.

2016—Subsec. (a)(2)(E). Pub. L. 114–255 added subpar. (E).

2015—Subsec. (n). Pub. L. 114–89 added subsec. (n).

2012—Subsec. (m)(1). Pub. L. 112–144 substituted ''(f), (h), (i), (j), (k), (*l*), (n), and (p)'' for ''(f), (i), (j), (k), (*l*), (p), and (q)''.

2010—Subsec. (a)(1)(A). Pub. L. 111–148, § 7002(a)(1), inserted ''under this subsection or subsection (k)'' after ''biologics license''.

Subsec. (i). Pub. L. 111–148, § 7002(b), substituted ''In this section:'' for ''In this section,'', designated remainder of existing provisions as par. (1), substituted ''The term'' for ''the term'', inserted ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,'', and added pars. (2) to (4).

Subsecs. (k), (*l*). Pub. L. 111–148, § 7002(a)(2), added subsecs. (k) and (*l*).

Subsec. (m). Pub. L. 111–148, § 7002(g)(1), added subsec. (m).

2007—Subsec. (a)(2)(D). Pub. L. 110–85, § 901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, § 901(c)(2), inserted '', including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act,'' after ''and Cosmetic Act''.

2003—Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997—Subsec. (a). Pub. L. 105–115, § 123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, § 123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.''

Subsec. (c). Pub. L. 105–115, § 123(c), substituted ''biological product.'' for ''virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.''

Subsec. (d). Pub. L. 105–115, § 123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted ''Any violation of paragraph (1)'' for ''Any violation of subparagraph (A)'' and substituted ''this paragraph'' for ''this subparagraph'' wherever appearing, and struck out former par. (1) which read as follows: ''Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.''

Subsec. (i). Pub. L. 105–115, § 123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, § 123(g), added subsec. (j).

1996—Subsec. (h). Pub. L. 104–134, § 2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, § 2102(d)(2), substituted ''in a country listed under section 802(b)(1)'' for ''in a country listed under section 802(b)(A)'' and ''to a country listed under section 802(b)(1)'' for ''to a country listed under section 802(b)(4)''.

1992—Subsec. (c). Pub. L. 102–300, which directed substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'', could not be executed because the words ''Health, Education, and Welfare'' did not ap-

pear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

1986—Subsec. (d). Pub. L. 99–660, § 315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, § 105(a), added subsec. (h).

1970—Subsecs. (a) to (c). Pub. L. 91–515 inserted ''vaccine, blood, blood component or derivative, allergenic product,'' after ''antitoxin'' wherever appearing.

1958—Subsec. (d). Pub. L. 85–881 struck out ''made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary'' after ''regulations'' in first sentence.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–660, title I, § 105(b), Nov. 14, 1986, 100 Stat. 3752, provided that: ''Paragraph (1) of section 351(h) of the Public Health Service Act [former 42 U.S.C. 262(h)(1)] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986].''

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, § 5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. 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.

PRODUCTS PREVIOUSLY APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Pub. L. 111–148, title VII, § 7002(e), Mar. 23, 2010, 124 Stat. 817, provided that:

''(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

''(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

''(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act [Mar. 23, 2010]; and

''(B) such application—

''(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

''(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

''(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

''(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

''(5) DEFINITIONS.—For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).''

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, § 7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818, 819, provided that:

''(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

''(C) AUDIT.—

''(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

''(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

''(II)(aa) such ratio determined under subclause (I); to

''(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

''(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter

the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

''(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.''

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, § 7002(h), Mar. 23, 2010, 124 Stat. 821, provided that: ''If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of—

''(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

''(2) the 12-year period described in subsection (k)(7) of such section 351.''

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, § 7003, Mar. 23, 2010, 124 Stat. 821, provided that:

''(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

''(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.''

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS

Pub. L. 104–132, title V, § 511, Apr. 24, 1996, 110 Stat. 1284, as amended by Pub. L. 107–188, title II, § 204, June 12, 2002, 116 Stat. 647, provided that:

''(a) FINDINGS.—The Congress finds that—

''(1) certain biological agents have the potential to pose a severe threat to public health and safety;

''(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

''(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

''(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

''(b) CRIMINAL ENFORCEMENT.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

''(c) TERRORISM.—[Amended section 2332a of Title 18.]''

§ 262a. Enhanced control of dangerous biological agents and toxins

(a) Regulatory control of certain biological agents and toxins

(1) List of biological agents and toxins

(A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) Criteria

In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

(2) Biennial review

The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for—

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training and appropriate skills to handle such agents and toxins; and

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) Possession and use of listed agents and toxins

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

(d) Registration; identification; database

(1) Registration

Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) Identification; database

Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) Safeguard and security requirements for registered persons

(1) In general

Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) Limiting access to listed agents and toxins

Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) Submitted names; use of databases by attorney general

(A) In general

Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) Certain individuals

For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50).

(C) Notification by Attorney General regarding submitted names

After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) Notifications by Secretary

The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) Expedited review

Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under para-

graph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) Process regarding persons seeking to register

(A) Individuals

Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) Other persons

Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) Review

(A) Administrative review

(i) In general

Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

(ii) Ex parte review

During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) Final agency action

The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5.

(B) Certain procedures

(i) Submission of ex parte materials in judicial proceedings

When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocutory appeal and expedited consideration).

(ii) Disclosure of information

In a review under subparagraph (A), and in any judical[1] proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5.

(8) Notifications regarding theft or loss of agents

Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) Technical assistance for registered persons

The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) Inspections

The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

(g) Exemptions

(1) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c) shall exempt clinical or diagnostic labora-

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

tories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(2) Products

(A) In general

Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

(B) Relevant laws

For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

(i) The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(ii) Section 262 of this title.

(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading ''Bureau of Animal Industry'' in the Act of March 4, 1913; 21 U.S.C. 151–159).

(iv) The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(C) Investigational use

(i) In general

The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) to such product is not necessary to protect public health and safety.

(ii) Certain processes

Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

(3) Public health emergencies

The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) Agricultural emergencies

Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) Disclosure of information

(1) Nondisclosure of certain information

No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by

a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) Covered agencies

For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) Other exemptions

This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection[2] 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) Rule of construction

Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) Disclosures to Congress; other disclosures

This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) Civil money penalty

(1) In general

In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

(2) Applicability of certain provisions

The provisions of section 1320a–7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a–7a(j)(2) of this title, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(j) Notification in event of release

Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (*l*)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) Reports

The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

***(l)* Definitions**

For purposes of this section:

(1) The terms ''biological agent'' and ''toxin'' have the meanings given such terms in section 178 of title 18.

(2) The term ''listed agents and toxins'' means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term ''listed agents or toxins'' means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The term ''overlap agents and toxins'' means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1); and

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term ''overlap agent or toxin'' means a biological agent or toxin that—

(A) is listed pursuant to subsection (a)(1); and

(B) is listed pursuant to section 8401(a)(1) of title 7.

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

(6) The term ''person'' includes Federal, State, and local governmental entities.

(7) The term ''registered person'' means a person registered under regulations under subsection (b) or (c).

(8) The term ''restricted person'' has the meaning given such term in section 175b of title 18.

(m) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.

(July 1, 1944, ch. 373, title III, § 351A, as added Pub. L. 107–188, title II, § 201(a), June 12, 2002, 116 Stat. 637; amended Pub. L. 107–296, title XVII, § 1709(a), Nov. 25, 2002, 116 Stat. 2318.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec.(g)(2)(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. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Act commonly known as the Virus-Serum-Toxin Act, referred to in subsec. (g)(2)(B)(iii), is the eighth paragraph under the heading ''Bureau of Animal Industry'' of act Mar. 4, 1913, ch. 145, 37 Stat. 832, as amended, which is classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (g)(2)(B)(iv), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

Section 6 of the Inspector General Act of 1978, referred to in subsec. (i)(2), is section 6 of Pub. L. 95–452, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2002—Subsec. (e)(1). Pub. L. 107–296 substituted ''collaboration with the Secretary of Homeland Security and'' for ''consultation with''.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107–296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE

Pub. L. 107–188, title II, § 203(b), June 12, 2002, 116 Stat. 647, provided that: ''Subsection (h) of section 351A of the Public Health Service Act [42 U.S.C. 262a(h)], as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, Apr. 24, 1996, 110 Stat. 1214].''

REGULATIONS

Pub. L. 107–188, title II, § 203(a), June 12, 2002, 116 Stat. 647, provided that: ''Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, 42 U.S.C. 262 note] are deemed to have been promulgated under section 351A of the Public Health Service Act [42 U.S.C. 262a], as added by section 201 of this Act. Such regulations, including the list under [former] subsection (d)(1) of such section 511, that were in effect on the day before the date of the enactment of this Act [June 12, 2002] remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act [set out as a note below].''

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 109–417, title II, § 205, Dec. 19, 2006, 120 Stat. 2851, provided that: ''The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

''(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

''(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.''

REPORT TO CONGRESS

Pub. L. 107–188, title II, § 201(b), June 12, 2002, 116 Stat. 646, required the Secretary of Health and Human Services to report to Congress not later than one year after June 12, 2002, on the implementation, compliance, and future plans under this section.

IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pub. L. 107–188, title II, § 202, June 12, 2002, 116 Stat. 646, provided that:

''(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of the enactment of this Act [June 12, 2002], all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act [42 U.S.C. 262a(g)], as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act [42 U.S.C. 262a] shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

''(b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A of the Public Health Service Act [42 U.S.C. 262a], subject to subsection (c). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of—

''(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

''(2) section 351A(i) of the Public Health Service Act [42 U.S.C. 262a(i)] (relating to civil penalties).

''(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act [42 U.S.C. 262a(a)(1)] and that were underway as of the effective date of such rule.''

EX. ORD. NO. 13546. OPTIMIZING THE SECURITY OF BIOLOGICAL SELECT AGENTS AND TOXINS IN THE UNITED STATES

Ex. Ord. No. 13546, July 2, 2010, 75 F.R. 39439, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.

SEC. 2. *Definitions*. (a) ''Select Agent Program'' (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.

(b) ''Select Agent Regulations'' (SAR) means the Federal regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

(c) ''Biological Select Agents and Toxins'' means biological agents and toxins with the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and whose possession, use, and transfer are regulated by the Department of Health and Human Services and the Department of Agriculture under the SAR.

SEC. 3. *Findings*. (a) The use of BSAT presents the risk that BSAT might be lost, stolen, or diverted for malicious purpose. The SAP exists to provide effective regulatory oversight of the possession, use, and transfer of BSAT that reduces the risk of their misuse or mishandling. The absence of clearly defined, risk-based security measures in the SAR/SAP has raised concern about the need for optimized security and for risk management.

(b) In addition, variations in, and limited coordination of, individual executive departments' and agencies' oversight, security practices, and inspections have raised concerns that the cost and complexity of compliance for those who are registered to work with BSAT could discourage research or other legitimate activities.

(c) Understanding that research and laboratory work on BSAT is essential to both public health and national security, it is in the interest of the United States to address these issues.

SEC. 4. *Risk-based Tiering of the Select Agent List*. To help ensure that BSAT are secured according to level of risk, the Secretaries of Health and Human Services and Agriculture shall, through their ongoing review of the biological Select Agents and Toxins List (''Select Agent List'') contained in regulations, and no later than 18 months from the date of this order:

(a) designate a subset of the Select Agent List (Tier 1) that presents the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence;

(b) explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this section to permit tailored risk management practices based upon relevant contextual factors; and

(c) consider reducing the overall number of agents and toxins on the Select Agent List.

SEC. 5. *Revision of Regulations, Rules, and Guidance to Accommodate a Tiered Select Agent List*. Consistent with section 4 of this order, I request that:

(a) The Secretaries of Health and Human Services and Agriculture, no later than 15 months from the date of this order, propose amendments to their respective parts of the SAR that would establish security standards specific to Tier 1 agents and toxins.

(b) The Secretaries of Health and Human Services and Agriculture each, no later than 27 months from the date of this order, promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use, or transfer Tier 1 agents and toxins.

SEC. 6. *Coordination of Federal Oversight for BSAT Security*. To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

(a) no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that:

(i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;

(ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues;

(iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and

(iv) provides for comprehensive and effective Federal oversight of BSAT security; and

(b) no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.

SEC. 7. *Implementation*. (a) Establishment, Operation, and Functions of the Federal Experts Security Advisory Panel.

(i) There is hereby established, within the Department of Health and Human Services for administrative purposes only, the Federal Experts Security Advisory Panel (Panel), which shall make technical and substantive recommendations on BSAT security concerning the SAP.

(ii) The Panel shall consist of representatives from the following, who may consult with additional experts from their department or agency as required:

1. the Department of State;
2. the Department of Defense;
3. the Department of Justice;
4. the Department of Agriculture (Co-Chair);
5. the Department of Commerce;
6. the Department of Health and Human Services (Co-Chair);
7. the Department of Transportation;
8. the Department of Labor;
9. the Department of Energy;
10. the Department of Veterans Affairs;
11. the Department of Homeland Security;
12. the Environmental Protection Agency;
13. the Office of the Director of National Intelligence;
14. the Office of Science and Technology Policy;
15. the Joint Chiefs of Staff; and
16. any other department or agency designated by the Co-Chairs.

(iii) To assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policies set forth in sections 1, 4, 5, and 6 of this order, the Panel shall, no later than 4 months from the date of this order, provide consensus recommendations concerning the SAP on:

1. the designation of Tier 1 agents and toxins;
2. reduction in the number of agents on the Select Agent List;
3. the establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 agents and toxins at registered facilities;
4. the establishment of appropriate practices for physical security and cyber security for facilities that possess Tier 1 agents. The Department of Homeland Security shall Chair a Working Group of the Panel that develops recommended laboratory critical infrastructure security standards in these areas; and
5. other emerging policy issues relevant to the security of BSAT.

Thereafter, the Panel shall continue to provide technical advice concerning the SAP on request.

(iv) If the Panel is unable to reach consensus on recommendations for an issue within its charge, the matter shall be resolved through the interagency policy committee process led by the National Security Staff.

(v) The Secretaries of Health and Human Services and Agriculture and the Attorney General shall report to the Assistant to the President for Homeland Security and Counterterrorism on the consideration and implementation of Panel recommendations concerning the SAP, including a rationale for failure to implement any recommendations.

(vi) The Panel shall be chartered for a period of 4 years subject to renewal through the interagency policy committee process led by the National Security Staff.

(b) To further assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policy set forth in sections 1, 4, 5, and 6 of this order, the National Science Advisory Board for Biosecurity shall provide technical advice and serve as a conduit for public consultation, as needed, on topics of relevance to the SAP.

SEC. 8. *Sharing of Select Agent Program Information.* (a) Consistent with applicable laws and regulations, the Secretaries of Health and Human Services and Agriculture and the Attorney General shall, no later than 6 months from the date of this order, develop a process and the criteria for making SAP information available to executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

(b) SAP information shall continue to be safeguarded properly and handled securely to minimize the risk of disclosing sensitive, personal, and other information protected by the Privacy Act, 5 U.S.C. 552a.

SEC. 9. *General Provisions.* (a) The National Security Staff shall, on a biennial basis, review the implementation and effectiveness of this order and refer to the interagency policy committee process any issues that require further deliberation or adjudication.

(b) Nothing in this order shall be construed to impair or otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

[Reference to the National Security Staff deemed to be a reference to the National Security Council Staff, see Ex. Ord. No. 13657, set out as a note under section 3021 of Title 50, War and National Defense.]

§ 263. Preparation of biological products by Service

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.

(b) The Service may prepare any product described in section 262 of this title for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(July 1, 1944, ch. 373, title III, § 352, 58 Stat. 703.)

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

SUBPART 2—CLINICAL LABORATORIES

§ 263a. Certification of laboratories

(a) "Laboratory" or "clinical laboratory" defined

As used in this section, the term ''laboratory'' or ''clinical laboratory'' means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) Certificate requirement

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) Term

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) Requirements for certificates

(1) In general

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) Requirements for certificates of waiver

(A) In general

A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) Changes

If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) Effect

Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) Examinations and procedures

The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

(4) "Certificate" defined

As used in this section, the term ''certificate'' includes a certificate of waiver issued under paragraph (2).

(e) Accreditation

(1) In general

A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by[1] Secretary,

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f),

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

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

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) Criteria and procedures

The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) Effect of withdrawal of approval

If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval. If an accreditation body withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

(i) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or

(ii) until the effective date of any action taken by the Secretary under subsection (i).

(D) Evaluations

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g) a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body, and

(ii) such other means as the Secretary determines appropriate.

(3) Omitted

(f) Standards

(1) In general

The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

(C) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,

(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3), and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) Considerations

In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (E) of paragraph (1), take into consideration—

(A) the examinations and procedures performed and the methodologies employed,

(B) the degree of independent judgment involved,

(C) the amount of interpretation involved,

(D) the difficulty of the calculations involved,

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and

(G) such other factors as the Secretary considers relevant.

(3) Proficiency testing program

(A) In general

The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be devel-

oped. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

(B) Criteria

The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular examination or procedure or category of examination or procedure over a period of successive quarters.

(C) Approved proficiency testing programs

For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A), the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

(D) Onsite testing

The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the requirements of subsection (d)(5). The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) Training, technical assistance, and enhanced proficiency testing

The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficency[2] testing program,

(ii) to enroll in a program of enhanced proficiency testing, or

(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

(F) Testing results

The Secretary shall establish a system to make the results of the proficiency testing programs subject to the standards established by the Secretary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this subparagraph such explanatory information as may be appropriate to assist in the interpretation of such results.

(4) National standards for quality assurance in cytology services

(A) Establishment

The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

(B) Standards

The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a 24-hour period,

(ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,

(iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

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

(g) Inspections

(1) In general

The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it[3] be submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

(2) Compliance with requirements and standards

The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) Intermediate sanctions

(1) In general

If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i).

(2) Types of sanctions

The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions[4]

[3] So in original. Probably should be ''require it to''.

[4] So in original. Probably should be followed by a period.

(i) Suspension, revocation, and limitation

(1) In general

Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the certificate,

(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate,

(C) has failed to comply with the requirements of subsection (d) or the standards prescribed by the Secretary under subsection (f),

(D) has failed to comply with reasonable requests of the Secretary for—

(i) any information or materials, or

(ii) work on materials,

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f),

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) Action before a hearing

If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) Ineligibility to own or operate laboratories after revocation

No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this

section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) Improper referrals

Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) Injunctions

Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) Judicial review

(1) Petition

Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(*l*) Sanctions

Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, or both.

(m) Fees

(1) Certificate fees

The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) Additional fees

The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

(3) Criteria

(A) Fees under paragraph (1)

Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) Fees under paragraph (2)

Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) Fees imposed under paragraphs (1) and (2)

Fees imposed under paragraphs (1) and (2) shall vary by group or classification of lab-

oratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) Information

On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i), or

(B) which have been the subject of a sanction under subsection (*l*),

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(*o*) Delegation

In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) State laws

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) Consultations

In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

(July 1, 1944, ch. 373, title III, § 353, as added Pub. L. 90–174, § 5(a), Dec. 5, 1967, 81 Stat. 536; amended Pub. L. 100–578, § 2, Oct. 31, 1988, 102 Stat. 2903; Pub. L. 105–115, title I, § 123(h), Nov. 21, 1997, 111 Stat. 2324; Pub. L. 112–202, § 2, Dec. 4, 2012, 126 Stat. 1483.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (i)(3) and (n)(6), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§ 1395 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.

CODIFICATION

Subsec. (e)(3) of this section, which required the Secretary to annually prepare and submit to certain committees of Congress a report describing the results of the evaluation conducted under subsec. (e)(2)(D) of this section, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

2012—Subsec. (d)(1)(E). Pub. L. 112–202, § 2(1), inserted ‘‘, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)’’ before period at end.

Subsec. (i)(3). Pub. L. 112–202, § 2(2)(A), inserted ‘‘, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph’’ after ‘‘issued under this section’’.

Subsec. (i)(4). Pub. L. 112–202, § 2(2)(B), substituted ‘‘may have its certificate revoked’’ for ‘‘shall have its certificate revoked’’.

1997—Subsec. (d)(3). Pub. L. 105–115 amended heading and text of par. (3) generally. Prior to amendment, text read as follows: ‘‘The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

‘‘(A) have been approved by the Food and Drug Administration for home use,

‘‘(B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

‘‘(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.’’

1988—Pub. L. 100–578 substituted ‘‘Certification of laboratories’’ for ‘‘Licensing of laboratories’’ in section catchline, and amended text generally, revising and restating as subsecs. (a) to (q) provisions of former subsecs. (a) to (*l*).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1988 AMENDMENT; EXCEPTIONS; CONTINUING APPLICABILITY

Pub. L. 100–578, § 3, Oct. 31, 1988, 102 Stat. 2914, provided that: ''Subsections (g)(1), (h), (i), (j), (k), (*l*), and (m) of section 353 of the Public Health Service Act [42 U.S.C. 263a], as amended by section 101 [probably means section 2 of Pub. L. 100–578], shall take effect January 1, 1989, except that any reference in such subsections to the standards established under subsection (f) shall be considered a reference to the standards established under subsection (d) of such section 353, as in effect on December 31, 1988. During the period beginning January 1, 1989, and ending December 31, 1989, subsections (a) through (d) and subsection (i) through (*l*) of such section 353 as in effect on December 31, 1988, shall continue to apply to clinical laboratories. The remaining subsections of such section 353, as so amended, shall take effect January 1, 1990, except that subsections (f)(1)(C) and (g)(2) shall take effect July 1, 1991, with respect to laboratories which were not subject to the requirements of such section 353 as in effect on December 31, 1988.''

EFFECTIVE DATE

Pub. L. 90–174, § 5(b), Dec. 5, 1967, 81 Stat. 539, provided that: ''The amendment made by subsection (a) [enacting this section] shall become effective on the first day of the thirteenth month after the month [December 1967] in which it is enacted, except that the Secretary of Health, Education, and Welfare may postpone such effective date for such additional period as he finds necessary, but not beyond the first day of the 19th month after such month [December 1967] in which the amendment is enacted.''

CLIA WAIVER IMPROVEMENTS

Pub. L. 114–255, div. A, title III, § 3057, Dec. 13, 2016, 130 Stat. 1128, provided that:

''(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

''(1) revises 'Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy' of the guidance entitled 'Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices' and dated January 30, 2008; and

''(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

''(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.''

STUDIES

Pub. L. 100–578, § 4, Oct. 31, 1988, 102 Stat. 2914, directed Secretary to conduct studies and submit report to Congress, not later than May 1, 1990, relating to the reliability and quality control procedures of clinical laboratory testing programs and the effect of errors in the testing procedures and results on the diagnosis and treatment of patients.

§ 263a–1. Assisted reproductive technology programs

(a) In general

Effective 2 years after October 24, 1992, each assisted reproductive technology (as defined in section 263a–7[1] of this title) program shall annually report to the Secretary through the Centers for Disease Control—

(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and

(2) the identity of each embryo laboratory (as defined in section 263a–7[1] of this title) used by such program and whether the laboratory is certified under section 263a–2 of this title or has applied for such certification.

(b) Pregnancy success rates

(1) In general

For purposes of subsection (a)(1), the Secretary shall, in consultation with the organizations referenced in subsection (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.

(2) Definition

In developing the definition of pregnancy success rates, the Secretary shall take into account the effect on success rates of age, diagnosis, and other significant factors and shall include in such rates—

(A) the basic live birth rate calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and

(B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.

(c) Consultation

In developing the definition under subsection (b), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.

(Pub. L. 102–493, § 2, Oct. 24, 1992, 106 Stat. 3146.)

REFERENCES IN TEXT

Section 263a–7 of this title, referred to in subsec. (a), was in the original ''section 7'' meaning section 7 of Pub. L. 102–493, which was translated as reading section 8 to reflect the probable intent of Congress, because definitions are contained in section 8 instead of section 7.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Pub. L. 102–493, § 9, Oct. 24, 1992, 106 Stat. 3152, provided that: ''This Act [enacting this section, sections

[1] See References in Text note below.

263a–2 to 263a–7 of this title, and provisions set out as a note under section 201 of this title] shall take effect upon the expiration of 2 years after the date of the enactment of this Act [Oct. 24, 1992].''

§ 263a–2. Certification of embryo laboratories

(a) In general

(1) Development

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a ''certification program'') to be carried out by the States.

(2) Consultation

In developing the certification program under paragraph (1), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with the assisted reproductive technology programs.

(b) Distribution

The Secretary shall distribute a description of the certification program to—

(1) the Governor of each State,

(2) the presiding officers of each State legislature,

(3) the public health official of each State, and

(4) the official responsible in each State for the operation of the State's contract with the Secretary under section 1395aa of this title,

and shall encourage such officials to assist in the State adopting such program.

(c) Requirements

The certification program shall include the following requirements:

(1) Administration

The certification program shall be administered by the State and shall provide for the inspection and certification of embryo laboratories in the State by the State or by approved accreditation organizations.

(2) Application requirements

The certification program shall provide for the submission of an application to a State by an embryo laboratory for certification, in such form as may be specified by the State. Such an application shall include—

(A) assurances satisfactory to the State that the embryo laboratory will be operated in accordance with the standards under subsection (d),

(B) a report to the State identifying the assisted reproductive technology programs with which the laboratory is associated, and

(C) such other information as the State finds necessary.

An embryo laboratory which meets the requirements of section 263a of this title shall, for the purposes of subparagraph (A) be considered in compliance with the standards referred to in such subparagraph which are the same as the standards in effect under section 263a of this title.

(d) Standards

The certification program shall include the following standards developed by the Secretary:

(1) A standard to assure consistent performance of procedures by each embryo laboratory certified under the certification program or by an approved accreditation organization in a State which has not adopted the certification program.

(2) A standard for a quality assurance and a quality control program to assure valid, reliable, and reproduceable[1] procedures in the laboratory.

(3) A standard for the maintenance of records (on a program by program basis) on laboratory tests and procedures performed, including the scientific basis of, and the methodology used for, the tests, procedures, and preparation of any standards or controls, criteria for acceptable and unacceptable outcomes, criteria for sample rejection, and procedures for safe sample disposal.

(4) A standard for the maintenance of written records on personnel and facilities necessary for proper and effective operation of the laboratory, schedules of preventive maintenance, function verification for equipment, and the release of such records to the State upon demand.

(5) A standard for the use of such personnel who meet such qualifications as the Secretary may develop.

(e) Certification under State programs

A State may qualify to adopt the certification program if the State has submitted an application to the Secretary to adopt such program and the Secretary has approved the application. Such an application shall include—

(1) assurances by the State satisfactory to the Secretary that the certification program within the State meets the requirements of this section,

(2) an agreement to make such reports as the Secretary may require, and

(3) information about any proposed use of accreditation organizations under subsection (g).[2]

(f) Use of accreditation organizations

A State which has adopted the certification program may use accreditation organizations approved under section 263a–3 of this title to inspect and certify embryo laboratories.

(g) Inspections

(1) In general

A State which qualifies to adopt the certification program within the State shall conduct inspections in accordance with paragraph (2) to determine if laboratories in the State meet the requirements of such program. Such inspections shall be carried out by the State or by accreditation organizations used by the State under subsection (g).[2]

(2) Requirements

Inspections carried out under paragraph (1) shall—

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

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

(A) be periodic and unannounced, or

(B) be announced in such circumstances as the Secretary determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (B), the Secretary shall make public, in such manner as to facilitate comment from any person (including any Federal or other public agency), a proposal indicating the circumstances under which announced inspections would be permitted.

(3) Results

The specific findings, including deficiencies, identified in an inspection carried out under paragraph (1) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than 60 days after the date of the inspection.

(h) Validation inspections

(1) In general

The Secretary may enter and inspect, during regular hours of operation, embryo laboratories—

(A) which have been certified by a State under the certification program, or

(B) which have been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title,

for the purpose of determining whether the laboratory is being operated in accordance with the standards in subsection (d).

(2) Access to facilities and records

In conducting an inspection of an embryo laboratory under paragraph (1), the Secretary shall have access to all facilities, equipment, materials, records, and information which the Secretary determines is necessary to determine if such laboratory is being operated in accordance with the standards in subsection (d). As part of such an inspection, the Secretary may copy any material, record, or information inspected or require it to be submitted to the Secretary. Such an inspection may be made only upon the presentation of identification to the owner, operator, or agent in charge of the laboratory being inspected.

(3) Failure to comply

If the Secretary determines as a result of an inspection under paragraph (1) that the embryo laboratory is not in compliance with the standards in subsection (d), the Secretary shall—

(A) notify the State in which the laboratory is located and, if appropriate, the accreditation organization which certified the laboratory,

(B) make available to the public the results of the inspection,

(C) conduct additional inspections of other embryo laboratories under paragraph (1) to determine if—

(i) such State in carrying out the certification program is reliably identifying the deficiencies of such laboratory, or

(ii) the accreditation organization which certified such laboratories is reliably identifying such deficencies,[3] and

(D) if the Secretary determines—

(i) that such State in carrying out the certification program has not met the requirements applicable to such program, or

(ii) the accreditation organization which certified such laboratory has not met the requirements of section 263a–3 of this title,

the Secretary may revoke the approval of the State certification program or revoke the approval of such accreditation organization.

(i) Limitation

(1) Secretary

In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(2) State

In adopting the certification program, a State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(j) Term

The term of a certification issued by a State or an accreditation organization in a State shall be prescribed by the Secretary in the certification program and shall be valid for a period of time to be defined by the Secretary through the public comment process described in subsection (h)(2).[4] The Secretary shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified laboratory or changes in the administration of such a laboratory.

(Pub. L. 102–493, § 3, Oct. 24, 1992, 106 Stat. 3146.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–3. Accreditation organizations

(a) Approval of accreditation organizations

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories.

[3] So in original. Probably should be ''deficiencies,''.

[4] So in original. Probably should be subsection ''(g)(2)''.

The procedures shall require an application to the Secretary by an accreditation organization for approval. An accreditation organization which has received such an approval—

(1) may be used by States in the certification program under section 263a–2 of this title to inspect and certify embryo laboratories, or

(2) may certify embryo laboratories in States which have not adopted such a certification program.

(b) Criteria and procedures

The criteria and procedures promulgated under subsection (a) shall include—

(1) requirements for submission of such reports and the maintenance of such records as the Secretary or a State may require, and

(2) requirements for the conduct of inspections under section 263a–2(h)[1] of this title.

(c) Evaluations

The Secretary shall evaluate annually the performance of each accreditation organization approved by the Secretary by—

(1) inspecting under section 263a–2(i)[2] of this title a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such organization, and

(2) such other means as the Secretary determines to be appropriate.

(d) Transition

If the Secretary revokes approval under section 263a–2(i)(3)(D)[3] of this title of an accreditation organization after an evaluation under subsection (c), the certification of any embryo laboratory accredited by the organization shall continue in effect for 60 days after the laboratory is notified by the Secretary of the withdrawal of approval, except that the Secretary may extend the period during which the certification shall remain in effect if the Secretary determines that the laboratory submitted an application to another approved accreditation organization for certification after receipt of such notice in a timely manner.

(Pub. L. 102–493, § 4, Oct. 24, 1992, 106 Stat. 3150.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–4. Certification revocation and suspension

(a) In general

A certification issued by a State or an accreditation organization for an embryo laboratory shall be revoked or suspended if the State or organization finds, on the basis of inspections and after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory—

(1) has been guilty of misrepresentation in obtaining the certification,

(2) has failed to comply with any standards under section 263a–2 of this title applicable to the certification, or

(3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.

(b) Effect

If the certification of an embryo laboratory is revoked or suspended, the certification of the laboratory shall continue in effect for 60 days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, the laboratory may apply for recertification after one year after the date of the revocation or suspension.

(Pub. L. 102–493, § 5, Oct. 24, 1992, 106 Stat. 3150.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–5. Publication

The Secretary, through the Centers for Disease Control, shall not later than 3 years after October 24, 1992, and annually thereafter publish and distribute to the States and the public—

(1)(A)[1] pregnancy success rates reported to the Secretary under section 263a–1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report, and

(B) from information reported under section 263a–1(a)(2) of this title—

(i) the identity of each embryo laboratory in a State which has adopted the certification program under such program and whether such laboratory is certified under section 263a–2 of this title,

(ii) the identity of each embryo laboratory in a State which has not adopted such certification program and which has been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title, and

(iii) in the case of an embryo laboratory which is not certified under section 263a–2 of this title or certified by an accreditation organization approved by the Secretary under

[1] So in original. Probably should be section ''263a–2(g)''.

[2] So in original. Probably should be section ''263a–2(h)''.

[3] So in original. Probably should be section ''263a–2(h)(3)(D)''.

[1] So in original. No par. (2) has been enacted.

section 263a–3 of this title, whether the laboratory applied for certification.

(Pub. L. 102–493, § 6, Oct. 24, 1992, 106 Stat. 3151.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–6. Fees

The Secretary may require the payment of fees for the purpose of, and in an amount sufficient to cover the cost of, administering sections 263a–1 to 263a–7 of this title. A State operating a program under section 263a–2 of this title may require the payment of fees for the purpose of, and in an amount sufficient to cover the costs of, administering its program.

(Pub. L. 102–493, § 7, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original ''this Act'', meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–7. Definitions

For purposes of sections 263a–1 to 263a–7 of this title:

(1) Assisted reproductive technology

The term ''assisted reproductive technology'' means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).

(2) Embryo laboratory

The term ''embryo laboratory'' means a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation.

(3) Secretary

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

(Pub. L. 102–493, § 8, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original ''this Act'', meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

SUBPART 3—MAMMOGRAPHY FACILITIES

PRIOR PROVISIONS

A prior subpart 3 of part F of title III of the Public Health Service Act, comprising this subpart, was renumbered subchapter C of chapter V of the Federal Food, Drug, and Cosmetic Act, by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779, and is classified to part C (§ 360hh et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs.

§ 263b. Certification of mammography facilities

(a) Definitions

As used in this section:

(1) Accreditation body

The term ''accreditation body'' means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit mammography facilities.

(2) Certificate

The term ''certificate'' means the certificate described in subsection (b)(1).

(3) Facility

(A) In general

The term ''facility'' means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) Activities

For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing

conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f).

(4) Inspection

The term ''inspection'' means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) Mammogram

The term ''mammogram'' means a radiographic image produced through mammography.

(6) Mammography

The term ''mammography'' means radiography of the breast.

(7) Survey

The term ''survey'' means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E).

(8) Review physician

The term ''review physician'' means a physician as prescribed by the Secretary under subsection (f)(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.

(b) Certificate requirement

(1) Certificate

No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs[1] (1) or (2) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility; or

(B) a provisional certificate or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a temporary renewal certificate, provisional certificate, or a limited provisional certificate.

(2) Examination or procedure

A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) Temporary renewal certificate

The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) Limited provisional certificate

The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) Provisional certificate

The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90

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

days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be taken to qualify the facility for certification under subsection (b)(1).

(d) Application for certificate

(1) Submission

The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E); and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary under subsection (f) to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g);

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) Appeal

If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(3) Effect of denial

If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) Accreditation

(1) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) Standards

The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1);

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) Assurances

The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) Regulations

Not later than 9 months after October 27, 1992, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) Withdrawal of approval

(A) In general

The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

(B) Effect of withdrawal

If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certificate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

(3) Accreditation

To be accredited by an approved accreditation body a facility shall meet—

(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

(B) such other standards which the accreditation body may require.

(4) Compliance

To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

(A) make onsite visits on an annual basis of a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

(5) Revocation of accreditation

If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

(6) Evaluation and report

(A) Evaluation

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(ii) such additional means as the Secretary determines to be appropriate.

(B) Report

The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) Quality standards

(1) In general

The standards referred to in subsection (d)(1)(B)(i) are standards established by the Secretary which include—

(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

(i)(I) be licensed by a State to perform radiological procedures; or

(II) be certified as qualified to perform radiological procedures by an organization described in paragraph (2)(A); and

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform mammograms;

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after October 27, 1992, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

(II) such written report shall be provided to the patient's physicians (if any);

(III) if such a physician is not available or if there is no such physician, the written report shall be sent directly to the patient; and

(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) shall not be construed to limit a patient's access to the patient's medical records.

(2) Certification of personnel

The Secretary shall by regulation—

(A) specify organizations eligible to certify individuals to perform radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) Inspections

(1) Annual inspections

(A) In general

The Secretary may enter and inspect facilities to determine compliance with the certification requirements under subsection (b) and the standards established under subsection (f). The Secretary shall, if feasible, delegate to a State or local agency the authority to make such inspections.

(B) Identification

The Secretary, or State or local agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected.

(C) Scope of inspection

In conducting inspections, the Secretary or State or local agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State or local agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State or local agency, any of the materials, records, or information.

(D) Qualifications of inspectors

Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State or local agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

(E) Frequency

The Secretary or State or local agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually, subject to paragraph (6).

(F) Records and annual reports

The Secretary or a State or local agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such

a State or local agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) Inspection of accredited facilities

The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

(3) Inspection of facilities inspected by State or local agencies

The Secretary shall inspect annually facilities inspected by State or local agencies acting on behalf of the Secretary to assure a reasonable performance by such State or local agencies.

(4) Timing

The Secretary, or State or local agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) Limited reinspection

Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

(6) Demonstration program

(A) In general

The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) Requirements

Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f). The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(h) Sanctions

(1) In general

In order to promote voluntary compliance with this section, the Secretary may, in lieu of taking the actions authorized by subsection (i), impose one or more of the following sanctions:

(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

(B) Payment for the cost of onsite monitoring.

(2) Patient information

If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

(3) Civil money penalties

The Secretary may assess civil money penalties in an amount not to exceed $10,000 for—

(A) failure to obtain a certificate as required by subsection (b),

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii),

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

(D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

(4) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) Suspension and revocation

(1) In general

The certificate of a facility issued under subsection (c) may be suspended or revoked if the Secretary finds, after providing, except as pro-

vided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) has been guilty of misrepresentation in obtaining the certificate;

(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) or the standards established by the Secretary under subsection (f);

(C) has failed to comply with reasonable requests of the Secretary (or of an accreditation body approved pursuant to subsection (e)) for any record, information, report, or material that the Secretary (or such accreditation body or State carrying out certification program requirements pursuant to subsection (q)) concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f);

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State or local officer or employee duly designated by the State or local agency, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

(E) has violated or aided and abetted in the violation of any provision of, or regulation promulgated under, this section; or

(F) has failed to comply with a sanction imposed under subsection (h).

(2) Action before a hearing

(A) In general

The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

(B) Hearing

If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the facility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

(3) Ineligibility to own or operate facilities after revocation

If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

(j) Injunctions

If the Secretary determines that—

(1) continuation of any activity related to the provision of mammography by a facility would constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

(2) a facility is operating without a certificate as required by subsection (b), the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

(k) Judicial review

(1) Petition

If the Secretary imposes a sanction on a facility under subsection (h) or suspends or revokes the certificate of a facility under subsection (i), the owner or operator of the facility may, not later than 60 days after the date the action of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary with the return of the additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set the action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(*l*) Information

(1) In general

Not later than October 1, 1996, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under subsection (h), together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under subsection (i), together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary has taken action under subsection (j), together with a statement of the reasons for the action;

(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

(F) against which a State has taken adverse action; and

(G) that meets such other measures of performance as the Secretary may develop.

(2) Date

The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

(3) Explanatory information

The information to be compiled under paragraph (1) shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraph.

(m) State laws

Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

(n) National Advisory Committee

(1) Establishment

In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the ''Advisory Committee'').

(2) Composition

The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

(A) physicians,

(B) practitioners, and

(C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, at least 2 industry representatives with expertise in mammography equipment, and at least 2 practicing physicians who provide mammography services.

(3) Functions and duties

The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;

(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;

(C) advise the Secretary in the development of regulations with respect to sanctions;

(D) assist in developing procedures for monitoring compliance with standards under subsection (f);

(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;

(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) on access to the services of such facilities in such areas;

(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E);

(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and

(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) Meetings

The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least annually.

(5) Chairperson

The Secretary shall appoint a chairperson of the Advisory Committee.

(*o*) Consultations

In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of developing stand-

ards, regulations, evaluations, and procedures for compliance and oversight.

(p) Breast cancer screening surveillance research grants

(1) Research

(A) Grants

The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) Use of funds

Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) Grant application

To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) Report

A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) Establishment

The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) Standards and procedures

The Secretary shall establish standards and procedures for the operation of the breast cancer screening surveillance system, including procedures to maintain confidentiality of patient records.

(4) Information

The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5.

(q) State program

(1) In general

The Secretary may, upon application, authorize a State—

(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f),

with respect to mammography facilities operating within the State.

(2) Approval

The Secretary may approve an application under paragraph (1) if the Secretary determines that—

(A) the State has enacted laws and issued regulations relating to mammography facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) the State has provided satisfactory assurances that the State—

(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

(ii) will devote adequate funds to the administration and enforcement of such requirements, and

(iii) will provide the Secretary with such information and reports as the Secretary may require.

(3) Authority of Secretary

In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f);

(B) the Secretary may take action under subsections (h), (i), and (j); and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3).

(4) Withdrawal of approval

(A) In general

The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Sec-

retary shall promulgate regulations for the implementation of this subparagraph.

(B) Effect of withdrawal

If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility certified by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) Funding

(1) Fees

(A) In general

The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) Deposit and appropriations

(i) Deposit and availability

Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitation.

(ii) Appropriations

Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) Authorization of appropriations

There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

(July 1, 1944, ch. 373, title III, § 354, as added Pub. L. 102–539, § 2, Oct. 27, 1992, 106 Stat. 3547; amended Pub. L. 105–248, §§ 2–13, Oct. 9, 1998, 112 Stat. 1864–1867; Pub. L. 108–365, §§ 2–4, Oct. 25, 2004, 118 Stat. 1738–1740.)

PRIOR PROVISIONS

A prior section 263b, act July 1, 1944, ch. 373, title III, § 354, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1173; amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), 104 Stat. 4529; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779, set forth Congressional declaration of purpose, prior to repeal by Pub. L. 101–629, § 19(a)(3), Nov. 28, 1990, 104 Stat. 4530.

Sections 263c to 263n, act July 1, 1944, ch. 373, title III, §§ 355–360F, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174, and amended, which related to electronic product radiation control, were renumbered sections 531 to 542, respectively, of the Federal Food, Drug, and Cosmetic Act by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, and are classified to sections 360hh to 360ss, respectively, of Title 21, Food and Drugs.

AMENDMENTS

2004—Subsec. (b)(1). Pub. L. 108–365, § 2(1)(C), substituted ''temporary renewal certificate, provisional certificate, or a limited provisional certificate'' for ''provisional certificate'' in concluding provisions.

Subsec. (b)(1)(A). Pub. L. 108–365, § 2(1)(A), inserted ''or a temporary renewal certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (1) or (2) of subsection (c)'' for ''subsection (c)(1)'' in cl. (i).

Subsec. (b)(1)(B). Pub. L. 108–365, § 2(1)(B), inserted ''or a limited provisional certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (3) and (4) of subsection (c)'' for ''subsection (c)(2)'' in cl. (i).

Subsec. (c)(2) to (4). Pub. L. 108–365, § 2(2), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (n)(2). Pub. L. 108–365, § 3(1), reenacted subpar. (C) without change, added concluding provisions, and struck out former concluding provisions which read as follows: ''whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least 2 practicing physicians who provide mammography services.''

Subsec. (n)(4). Pub. L. 108–365, § 3(2), substituted ''annually'' for ''biannually''.

Subsec. (r)(2). Pub. L. 108–365, § 4, substituted ''2007'' for ''2002'' in subpars. (A) and (B).

1998—Subsec. (a)(4). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State''.

Subsec. (a)(8). Pub. L. 105–248, § 4(b), added par. (8).

Subsec. (d)(2)(B). Pub. L. 105–248, § 3, substituted ''part 498 of title 42, Code of Federal Regulations'' for ''42 C.F.R. 498 and in effect on October 27, 1992''.

Subsec. (e)(1)(B)(i)(I), (II). Pub. L. 105–248, § 4(a)(1), substituted ''review physicians'' for ''practicing physicians''.

Subsec. (e)(1)(B)(ii). Pub. L. 105–248, § 4(a)(2), substituted ''relationship'' for ''financial relationship''.

Subsec. (f)(1)(G)(i). Pub. L. 105–248, § 5, added cl. (i) and struck out former cl. (i) which read as follows: ''a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

''(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, or longer if mandated by State law; or

''(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and''.

Subsec. (f)(1)(G)(ii)(IV). Pub. L. 105–248, § 6, added subcl. (IV) and struck out former subcl. (IV) which read as follows: ''if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and''.

Subsec. (g)(1). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State'' wherever appearing.

Subsec. (g)(1)(A). Pub. L. 105–248, § 7, in first sentence, struck out ''certified'' before ''facilities'' and inserted ''the certification requirements under subsection (b) and'' after ''compliance with''.

Subsec. (g)(1)(E). Pub. L. 105–248, §8(1), inserted '', subject to paragraph (6)'' before period at end.

Subsec. (g)(3). Pub. L. 105–248, §9(1), (2), inserted ''or local'' after ''State'' in heading and in two places in text.

Subsec. (g)(4). Pub. L. 105–248, §9(1), inserted ''or local'' after ''State''.

Subsec. (g)(6). Pub. L. 105–248, §8(2), added par. (6).

Subsec. (h)(2). Pub. L. 105–248, §10(a), added par. (2) and redesignated former par. (2) as (3).

Subsec. (h)(3). Pub. L. 105–248, §10(a)(1), (b), redesignated par. (2) as (3), added subpar. (C), and redesignated former subpar. (C) as (D). Former par. (3) redesignated (4).

Subsec. (h)(4). Pub. L. 105–248, §10(a)(1), (c), redesignated par. (3) as (4) and substituted ''paragraphs (1) through (3)'' for ''paragraphs (1) and (2)''.

Subsec. (i)(1)(C). Pub. L. 105–248, §11, inserted ''(or of an accreditation body approved pursuant to subsection (e))'' after ''of the Secretary'' and inserted ''(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q))'' after ''that the Secretary''.

Subsec. (i)(1)(D). Pub. L. 105–248, §9(3), inserted ''or local'' after ''any State'' and ''or local agency'' after ''by the State''.

Subsec. (i)(2)(A). Pub. L. 105–248, §12, substituted ''has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—'' and cls. (i) and (ii) for ''makes the finding described in paragraph (1) and determines that—

''(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) of this section presents a serious risk to human health; or

''(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1).''

Subsec. (q)(4)(B). Pub. L. 105–248, §13, substituted ''certified'' for ''accredited''.

Subsec. (r)(2)(A). Pub. L. 105–248, §2, substituted ''subsection (p)'' for ''subsection (q)'' and ''2002'' for ''1997''.

Subsec. (r)(2)(B). Pub. L. 105–248, §2, substituted ''fiscal years'' for ''fiscal year'' and ''2002'' for ''1997''.

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.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees 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 committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 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.

REGULATIONS

Pub. L. 103–183, title VII, §707, Dec. 14, 1993, 107 Stat. 2241, provided that: ''The Secretary of Health and Human Services is authorized to issue interim final regulations—

''(1) under which the Secretary may approve accreditation bodies under section 354(e) of the Public Health Service Act (42 U.S.C. 263b(e)); and

''(2) establishing quality standards under section 354(f) of the Public Health Service Act (42 U.S.C. 263b(f)).''

STUDY

Section 3 of Pub. L. 102–539 directed Comptroller General of United States to conduct a study of the certification program authorized by this section to determine if the program has resulted in improvement of quality and accessibility of mammography services, and if the program has reduced the frequency of poor quality mammography and improved early detection of breast cancer, with Comptroller General, not later than 3 years from Oct. 27, 1992, submit to Congress an interim report of results of study and, not later than 5 years from such date to submit a final report.

PART G—QUARANTINE AND INSPECTION

§ 264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[1].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

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[1] So in original. The comma probably should not appear.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term ''State'' includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term ''qualifying stage'', with respect to a communicable disease, means that such disease—

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

(July 1, 1944, ch. 373, title III, § 361, 58 Stat. 703; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–624, § 29(c), July 12, 1960, 74 Stat. 419; Pub. L. 94–317, title III, § 301(b)(1), June 23, 1976, 90 Stat. 707; Pub. L. 107–188, title I, § 142(a)(1), (2), (b)(1), (c), June 12, 2002, 116 Stat. 626, 627.)

AMENDMENTS

2002—Pub. L. 107–188, § 142(a)(1), (2), (b)(1), and (c), which directed certain amendments to section 361 of the Public Health Act, was executed by making the amendments to this section, which is section 361 of the Public Health Service Act, to reflect the probable intent of Congress. See below.

Subsec. (b). Pub. L. 107–188, § 142(a)(1), substituted ''Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,'' for ''Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General''.

Subsec. (d). Pub. L. 107–188, § 142(a)(2), (b)(1), substituted in first sentence ''Regulations'' for ''On recommendation of the National Advisory Health Council, regulations'', ''in a qualifying stage'' for ''in a communicable stage'' in two places, designated existing text as par. (1) and substituted ''(A)'' and ''(B)'' for ''(1)'' and ''(2)'', respectively, and added par. (2).

Subsec. (e). Pub. L. 107–188, § 142(c), added subsec. (e).

1976—Subsec. (d). Pub. L. 94–317 inserted provision defining ''State'' to include, in addition to the several States, only the District of Columbia.

1960—Subsec. (c). Pub. L. 86–624 struck out reference to Territory of Hawaii.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

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.

EVALUATION OF PUBLIC HEALTH AUTHORITIES

Pub. L. 110–392, title I, § 121, Oct. 13, 2008, 122 Stat. 4200, provided that:

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Comprehensive Tuberculosis Elimination Act of 2008 [Oct. 13, 2008], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine.

''(b) CONTENTS OF EVALUATION.—The report described in subsection (a) shall include—

''(1) an evaluation of the effectiveness of current policies to detain patients with active tuberculosis;

''(2) an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis; and

''(3) specific legislative recommendations for changes to Federal laws, if any.

''(c) UPDATE OF QUARANTINE REGULATIONS.—Not later than 240 days after the date of enactment of this Act [Oct. 13, 2008], the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of title 42, Code of Federal Regulations.''

EXECUTIVE ORDER NO. 12452

Ex. Ord. No. 12452, Dec. 22, 1983, 48 F.R. 56927, which specified certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of such diseases, was revoked by Ex. Ord. No. 13295, § 5, Apr. 4, 2003, 68 F.R. 17255, set out below.

EX. ORD. NO. 13295. REVISED LIST OF QUARANTINABLE COMMUNICABLE DISEASES

Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, as amended by Ex. Ord. No. 13375, § 1, Apr. 1, 2005, 70 F.R. 17299; Ex. Ord. No. 13674, § 1, July 31, 2014, 79 F.R. 45671, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)), it is hereby ordered as follows:

SECTION 1. Based upon the recommendation of the Secretary of Health and Human Services (the ''Sec-

retary''), in consultation with the Surgeon General, and for the purpose of specifying certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, the following communicable diseases are hereby specified pursuant to section 361(b) of the Public Health Service Act:

(a) Cholera; Diphtheria; infectious Tuberculosis; Plague; Smallpox; Yellow Fever; and Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named).

(b) Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza.

(c) Influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

SEC. 2. The Secretary, in the Secretary's discretion, shall determine whether a particular condition constitutes a communicable disease of the type specified in section 1 of this order.

SEC. 3. The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the Secretary.

SEC. 4. This order is not intended to, and does not, create any right or benefit enforceable at law or equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

SEC. 5. Executive Order 12452 of December 22, 1983, is hereby revoked.

§ 265. Suspension of entries and imports from designated places to prevent spread of communicable diseases

Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

(July 1, 1944, ch. 373, title III, § 362, 58 Stat. 704.)

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

DELEGATION OF FUNCTIONS

For assignment of functions of President under this section, see section 3 of Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, set out as a note under section 264 of this title.

§ 266. Special quarantine powers in time of war

To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 264 of this title, the Secretary, in consultation with the Surgeon General, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

(July 1, 1944, ch. 373, title III, § 363, 58 Stat. 704; Pub. L. 107–188, title I, § 142(a)(3), (b)(2), June 12, 2002, 116 Stat. 626, 627.)

AMENDMENTS

2002—Pub. L. 107–188, which directed substitution of ''the Secretary, in consultation with the Surgeon General,'' for ''the Surgeon General, on recommendation of the National Advisory Health Council,'' and striking out of ''in a communicable stage'' after ''(1) to be infected with such disease'', in section 363 of the Public Health Act, was executed to this section, which is section 363 of the Public Health Service Act, to reflect the probable intent of Congress.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

TERMINATION OF WAR AND EMERGENCIES

Joint Res. July 25, 1947, ch. 327, § 3, 61 Stat. 451, provided that in the interpretation of this section, the date July 25, 1947, shall be deemed to be the date of termination of any state of war theretofore declared by Congress and of the national emergencies proclaimed by the President on Sept. 8, 1939, and May 27, 1941.

§ 267. Quarantine stations, grounds, and anchorages

(a) Control and management

Except as provided in title II of the Act of June 15, 1917, as amended [50 U.S.C. 191 et seq.], the Surgeon General shall control, direct, and manage all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof. With the approval of the President he shall from time to time select suit-

able sites for and establish such additional stations, grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of communicable diseases into the States and possessions of the United States.

(b) Hours of inspection

The Surgeon General shall establish the hours during which quarantine service shall be performed at each quarantine station, and, upon application by any interested party, may establish quarantine inspection during the twenty-four hours of the day, or any fraction thereof, at such quarantine stations as, in his opinion, require such extended service. He may restrict the performance of quarantine inspection to hours of daylight for such arriving vessels as cannot, in his opinion, be satisfactorily inspected during hours of darkness. No vessel shall be required to undergo quarantine inspection during the hours of darkness, unless the quarantine officer at such quarantine station shall deem an immediate inspection necessary to protect the public health. Uniformity shall not be required in the hours during which quarantine inspection may be obtained at the various ports of the United States.

(c) Overtime pay for employees of Service

The Surgeon General shall fix a reasonable rate of extra compensation for overtime services of employees of the United States Public Health Service, Foreign Quarantine Division, performing overtime duties including the operation of vessels, in connection with the inspection or quarantine treatment of persons (passengers and crews), conveyances, or goods arriving by land, water, or air in the United States or any place subject to the jurisdiction thereof, hereinafter referred to as ''employees of the Public Health Service'', when required to be on duty between the hours of 6 o'clock postmeridian and 6 o'clock antemeridian (or between the hours of 7 o'clock postmeridian and 7 o'clock antemeridian at stations which have a declared workday of from 7 o'clock antemeridian to 7 o'clock postmeridian), or on Sundays or holidays, such rate, in lieu of compensation under any other provision of law, to be fixed at two times the basic hourly rate for each hour that the overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian, and two times the basic hourly rate for each overtime hour worked on Sundays or holidays. As used in this subsection, the term ''basic hourly rate'' shall mean the regular basic rate of pay which is applicable to such employees for work performed within their regular scheduled tour of duty.

(d) Payment of extra compensation to United States; bond or deposit to assure payment; deposit of moneys to credit of appropriation

(1) The said extra compensation shall be paid to the United States by the owner, agent, consignee, operator, or master or other person in charge of any conveyance, for whom, at his request, services as described in this subsection (hereinafter referred to as overtime service) are performed. If such employees have been ordered to report for duty and have so reported, and the requested services are not performed by reason of circumstances beyond the control of the employees concerned, such extra compensation shall be paid on the same basis as though the overtime services had actually been performed during the period between the time the employees were ordered to report for duty and did so report, and the time they were notified that their services would not be required, and in any case as though their services had continued for not less than one hour. The Surgeon General with the approval of the Secretary of Health and Human Services may prescribe regulations requiring the owner, agent, consignee, operator, or master or other person for whom the overtime services are performed to file a bond in such amounts and containing such conditions and with such sureties, or in lieu of a bond, to deposit money or obligations of the United States in such amount, as will assure the payment of charges under this subsection, which bond or deposit may cover one or more transactions or all transactions during a specified period: *Provided*, That no charges shall be made for services performed in connection with the inspection of (1) persons arriving by international highways, ferries, bridges, or tunnels, or the conveyances in which they arrive, or (2) persons arriving by aircraft or railroad trains, the operations of which are covered by published schedules, or the aircraft or trains in which they arrive, or (3) persons arriving by vessels operated between Canadian ports and ports on Puget Sound or operated on the Great Lakes and connecting waterways, the operations of which are covered by published schedules, or the vessels in which they arrive.

(2) Moneys collected under this subsection shall be deposited in the Treasury of the United States to the credit of the appropriation charged with the expense of the services, and the appropriations so credited shall be available for the payment of such compensation to the said employees for services so rendered.

(July 1, 1944, ch. 373, title III, § 364, 58 Stat. 704; Pub. L. 85–58, ch. VII, § 701, June 21, 1957, 71 Stat. 181; Pub. L. 85–580, title II, § 201, Aug. 1, 1958, 72 Stat. 467; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

AMENDMENTS

1958—Subsec. (c). Pub. L. 85–580 increased rate of pay for each hour that overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian from one and one-half times the basic hourly rate to two times the basic hourly rate.

1957—Subsecs. (c), (d). Pub. L. 85–58 added subsecs. (c) and (d).

TRANSFER OF FUNCTIONS

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (d) pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

For assignment of functions of President under subsec. (a) of this section, see section 3 of Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, set out as a note under section 264 of this title.

§ 268. Quarantine duties of consular and other officers

(a) Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and necessary traveling expenses, shall be allowed any such officer by reason of such services.

(July 1, 1944, ch. 373, title III, § 365, 58 Stat. 705; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Reference to Secretary of Health, Education, and Welfare substituted for reference to Federal Security Administrator pursuant to section 5 of Reorg. Plan No. 1, of 1953, set out as a note under section 3501 of this title, which transferred functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. 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.

§ 269. Bills of health

(a) Detail of medical officer; conditions precedent to issuance; consular officer to receive fees

Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or medical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

(b) Collectors of customs to receive originals; duplicate copies as part of ship's papers

Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

(c) Regulations to secure sanitary conditions of vessels

The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

(d) Vessels from ports near frontier

The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

(e) Compliance with regulations

It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be pro-

curable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

(July 1, 1944, ch. 373, title III, § 366, 58 Stat. 705.)

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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.

All offices of collector of customs, comptroller of customs, surveyor of customs, and appraiser of merchandise of Bureau of Customs of Department of the Treasury to which appointments were required to be made by the President with the advice and consent of the Senate ordered abolished, with such offices to be terminated not later than December 31, 1966, by Reorg. Plan No. 1, of 1965, eff. May 25, 1965, 30 F.R. 7035, 79 Stat. 1317, set out in the Appendix to Title 5, Government Organization and Employees. All functions of offices eliminated were already vested in Secretary of the Treasury by Reorg. Plan No. 26 of 1950, eff. July 31, 1950, 15 F.R. 4935, 64 Stat. 1280, set out in the Appendix to Title 5.

§ 270. Quarantine regulations governing civil air navigation and civil aircraft

The Surgeon General is authorized to provide by regulations for the application to air navigation and aircraft of any of the provisions of sections 267 to 269 of this title and regulations prescribed thereunder (including penalties and forfeitures for violations of such sections and regulations), to such extent and upon such conditions as he deems necessary for the safeguarding of the public health.

(July 1, 1944, ch. 373, title III, § 367, 58 Stat. 706.)

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§ 271. Penalties for violation of quarantine laws

(a) Penalties for persons violating quarantine laws

Any person who violates any regulation prescribed under sections 264 to 266 of this title, or any provision of section 269 of this title or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than $1,000 or by imprisonment for not more than one year, or both.

(b) Penalties for vessels violating quarantine laws

Any vessel which violates section 269 of this title, or any regulations thereunder or under section 267 of this title, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than $5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) Remittance or mitigation of forfeitures

With the approval of the Secretary, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

(July 1, 1944, ch. 373, title III, § 368, 58 Stat. 706; June 25, 1948, ch. 646, § 1, 62 Stat. 909; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, substituted ''United States attorney'' for ''United States district attorney''. See section 541 of Title 28, Judiciary and Judicial Procedure, and Historical and Revision note thereunder.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary 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. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

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.

§ 272. Administration of oaths by quarantine officers

Medical officers of the United States, when performing duties as quarantine officers at any

port or place within the United States, are authorized to take declarations and administer oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

(July 1, 1944, ch. 373, title III, § 369, 58 Stat. 706.)

PART H—ORGAN TRANSPLANTS

PRIOR PROVISIONS

A prior part H related to grants to Alaska for mental health, prior to the general revision of part H by Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2342.

Another prior part H, entitled ''National Library of Medicine'', as added by act Aug. 3, 1956, ch. 907, 70 Stat. 960, was redesignated part I and classified to section 275 et seq. of this title, prior to repeal by Pub. L. 99–158.

§ 273. Organ procurement organizations

(a) Grant authority of Secretary

(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

(b) Qualified organizations

(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2)[1] and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;[2]

(E) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(F) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(G) has a board of directors or an advisory board which—

(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatability[3] or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (3)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (3), and

(iii) has no authority over any other activity of the organization.

(2)(A) Not later than 90 days after November 16, 1990, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).[1]

(B) Not later than 1 year after November 16, 1990, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

[1] See References in Text note below.

[2] So in original. The semicolon probably should be a comma.

[3] So in original. Probably should be ''histocompatibility''.

(B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 274(b)(2)(E) of this title, including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV),

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 274 of this title,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) Pancreata islet cell transplantation or research

Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).

(July 1, 1944, ch. 373, title III, § 371, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2342; amended Pub. L. 100–607, title IV, § 402(a), (c)(1), (2), (d), Nov. 4, 1988, 102 Stat. 3114, 3115; Pub. L. 101–616, title II, §§ 201(a)–(c)(1), (d), (e), 206(b), Nov. 16, 1990, 104 Stat. 3283, 3285; Pub. L. 106–505, title VII, § 701(c), Nov. 13, 2000, 114 Stat. 2347; Pub. L. 106–554, § 1(a)(1) [title II, § 219(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–29; Pub. L. 108–216, § 9, Apr. 5, 2004, 118 Stat. 590; Pub. L. 108–362, § 2, Oct. 25, 2004, 118 Stat. 1703; Pub. L. 113–51, § 2(a)(2), (3), Nov. 21, 2013, 127 Stat. 579, 580.)

REFERENCES IN TEXT

Paragraph (2), referred to in subsec. (b)(1), meaning paragraph (2) of subsec. (b) of this section, was redesignated paragraph (3) by section 201(d)(1) of Pub. L. 101–616. See 1990 Amendment note below.

The Social Security Act, referred to in subsec. (b)(1)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§ 1395 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.

Paragraph (1)(E), referred to in subsec. (b)(2)(A), meaning paragraph (1)(E) of subsec. (b) of this section, was redesignated paragraph (1)(F) by section 701(c)(1) of Pub. L. 106–505 and section 1(a)(1) [title II, § 219(b)(1)] of Pub. L. 106–554. See 2000 Amendment note below.

PRIOR PROVISIONS

A prior section 273, act July 1, 1944, ch. 373, title III, § 371, as added July 28, 1956, ch. 772, title II, § 201, 70 Stat. 709, authorized grants to the Territory of Alaska for an integrated mental health program, prior to repeal by Pub. L. 86–70, § 31(b)(1), June 25, 1959, 73 Stat. 148, effective July 1, 1959.

A prior section 371 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 960, was renumbered section 381 and classified to section 275 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2013—Subsec. (b)(1)(E), (F). Pub. L. 113–51, § 2(a)(3)(A), (B), redesignated subpars. (F) and (G) as (E) and (F), respectively, and struck out former subpar. (E) which read as follows: ''has procedures to obtain payment for non-renal organs provided to transplant centers,''.

Subsec. (b)(1)(G). Pub. L. 113–51, § 2(a)(3)(C), which directed the substitution of ''(G) has a director'' for ''(H) has a director'', was executed by substituting ''(G) has a board of directors'' for ''(H) has a board of directors'' to reflect the probable intent of Congress. Former subpar. (G) redesignated (F).

Subsec. (b)(1)(G)(i)(V), (ii). Pub. L. 113–51, § 2(a)(3)(D), which directed the amendment of subpar. (H) by substituting ''paragraph (3)(G)'' for ''paragraph (2)(G)'' in cl. (i)(V) and ''paragraph (3)'' for ''paragraph (2)'' in cl. (ii), was executed by making the substitutions in subpars. (G)(i)(V) and (G)(ii), respectively, to reflect the probable intent of Congress and the redesignation of subpar. (H) as (G) by Pub. L. 113–51, § 2(a)(3)(C). See above.

Subsec. (b)(3)(C). Pub. L. 113–51, § 2(a)(2), substituted ''including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)'' for ''including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome''.

2004—Subsec. (a)(3). Pub. L. 108–216 struck out par. (3) which read as follows: ''The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors.''

Subsec. (c). Pub. L. 108–362 added subsec. (c).

2000—Subsec. (b)(1)(D) to (H). Pub. L. 106–505 and Pub. L. 106–554 amended par. (1) identically, adding subpar. (D), redesignating former subpars. (D) to (G) as (E) to (H), respectively, and realigning margins of subpar. (F).

1990—Pub. L. 101–616, § 201(a), substituted ''Organ procurement organizations'' for ''Assistance for organ procurement organizations'' in section catchline.

Subsec. (a)(3). Pub. L. 101–616, § 201(b)(1), substituted ''may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects'' for ''may make grants for special projects''.

Subsec. (a)(4). Pub. L. 101–616, § 201(b)(2), struck out par. (4) which set forth factors to consider in making grants.

Subsec. (b)(1)(E). Pub. L. 101–616, § 201(c)(1), amended subpar. (E) generally. Prior to amendment, subpar. (E) read as follows: ''has a defined service area which is a geographical area of sufficient size such that (unless the service area comprises an entire State) the organization can reasonably expect to procure organs from not less than 50 donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,''.

Subsec. (b)(1)(G)(i)(III). Pub. L. 101–616, § 201(e), made technical correction to Pub. L. 100–607, § 402(c)(2). See 1988 Amendment note below.

Subsec. (b)(2), (3). Pub. L. 101–616, § 201(d), added par. (2) and redesignated former par. (2) as (3).

Subsec. (c). Pub. L. 101–616, § 206(b), struck out subsec. (c) which authorized appropriations for subsec. (a) grants for fiscal years 1988 through 1990.

1988—Subsec. (a)(2). Pub. L. 100–607, § 402(a)(1), inserted ''consolidation,'' after ''initial operation,''.

Subsec. (a)(3). Pub. L. 100–607, § 402(a)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (a)(4). Pub. L. 100–607, § 402(a)(2), redesignated former par. (3) as (4).

Subsec. (a)(4)(C). Pub. L. 100–607, § 402(a)(3), added subpar. (C).

Subsec. (b)(1)(E). Pub. L. 100–607, § 402(c)(1)(A), substituted ''size such that'' for ''size which'', and ''the organization can reasonably expect to procure organs from not less than 50 donors each year'' for ''will include at least fifty potential organ donors each year''.

Subsec. (b)(1)(G)(i)(III). Pub. L. 100–607, § 402(c)(2), as amended by Pub. L. 101–616, § 201(e), inserted ''or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility'' before comma at end.

Subsec. (b)(2)(C). Pub. L. 100–607, § 402(c)(1)(B), substituted ''274(b)(2)(E) of this title, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,'' for ''274(b)(2)(D) of this title,''.

Subsec. (b)(2)(E). Pub. L. 100–607, § 402(c)(1)(C), substituted ''organs equitably among transplant patients'' for ''organs among transplant centers and patients''.

Subsec. (b)(2)(K). Pub. L. 100–607, § 402(c)(1)(D), added subpar. (K).

Subsec. (c). Pub. L. 100–607, § 402(d), amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: ''For grants under subsection (a) of this section there are authorized to be appropriated $5,000,000 for fiscal year 1985, $8,000,000 for fiscal year 1986, and $12,000,000 for fiscal year 1987.''

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–616, title II, § 207, Nov. 16, 1990, 104 Stat. 3286, provided that: ''Except as otherwise provided in this title, the amendments made by this title [enacting sections 274f and 274g of this title, amending this section and sections 274 and 274b to 274d of this title, and repealing provisions set out as a note below] shall become effective on October 1, 1990, or on the date of the enactment of this Act [Nov. 16, 1990], whichever occurs later.''

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–607, title IV, § 402(c)(3), Nov. 4, 1988, 102 Stat. 3115, as amended by Pub. L. 101–274, Apr. 23, 1990, 104 Stat. 139, which provided that the amendment made by section 402(c)(1)(A) of Pub. L. 100–607, amending this section, was not to apply to an organ procurement organization designated under section 1320b–8(b) of this title until Jan. 1, 1992, was repealed by Pub. L. 101–616, title II, § 201(c)(2), Nov. 16, 1990, 104 Stat. 3283.

SHORT TITLE

For short title of Pub. L. 98–507, which enacted this part as the ''National Organ Transplant Act'', see section 1 of Pub. L. 98–507, set out as a Short Title of 1984 Amendments note under section 201 of this title.

SEVERABILITY

Pub. L. 101–616, title III, § 301, Nov. 16, 1990, 104 Stat. 3286, provided that: ''If any provision of this Act [enacting sections 274f, 274g, 274k, and 274*l* of this title, amending this section and sections 274 to 274d of this title, enacting provisions set out as notes under this section and sections 274 and 274k of this title, and repealing provisions set out as a note above], amendment made by this Act, or application of the provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions or amendments to any person or circumstance shall not be affected.''

CERTIFICATION OF ORGAN PROCUREMENT ORGANIZATIONS

Pub. L. 106–505, title VII, § 701(b), Nov. 13, 2000, 114 Stat. 2346, and Pub. L. 106–554, § 1(a)(1) [title II, § 219(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–28, provided that: ''Congress makes the following findings:

''(1) Organ procurement organizations play an important role in the effort to increase organ donation in the United States.

''(2) The current process for the certification and recertification of organ procurement organizations conducted by the Department of Health and Human Services has created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.

''(3) The General Accounting Office [now Government Accountability Office], the Institute of Medicine, and the Harvard School of Public Health have identified substantial limitations in the organ procurement organization certification and recertification process and have recommended changes in that process.

''(4) The limitations in the recertification process include:

''(A) An exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.

''(B) A lack of due process to appeal to the Secretary of Health and Human Services for recertification on either substantive or procedural grounds.

''(5) The Secretary of Health and Human Services has the authority under section 1138(b)(1)(A)(i) of the Social Security Act (42 U.S.C. 1320b–8(b)(1)(A)(i)) to extend the period for recertification of an organ procurement organization from 2 to 4 years on the basis of its past practices in order to avoid the inappropriate disruption of the nation's organ system.

''(6) The Secretary of Health and Human Services can use the extended period described in paragraph (5) for recertification of all organ procurement organizations to—

''(A) develop improved performance measures that would reflect organ donor potential and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and

''(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals.''

STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS

Pub. L. 106–310, div. A, title XXI, § 2101(b), Oct. 17, 2000, 114 Stat. 1156, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall provide for a study to determine the costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs. The Secretary may carry out the study directly or through a grant to the Institute of Medicine (or other public or nonprofit private entity).

''(2) RECOMMENDATIONS REGARDING CERTAIN ISSUES.—The Secretary shall ensure that, in addition to making

determinations under paragraph (1), the study under such paragraph makes recommendations regarding the following issues:

''(A) The costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans, health insurance and government programs cover such costs.

''(B) The extent of denial of organs to be released for transplant by coroners and medical examiners.

''(C) The special growth and developmental issues that children have pre- and post-organ transplantation.

''(D) Other issues that are particular to the special health and transplantation needs of children.

''(3) REPORT.—The Secretary shall ensure that, not later than December 31, 2001, the study under paragraph (1) is completed and a report describing the findings of the study is submitted to the Congress.''

STUDY ON HOSPITAL AGREEMENTS WITH ORGAN PROCUREMENT AGENCIES

Pub. L. 103–432, title I, § 155(b), Oct. 31, 1994, 108 Stat. 4439, directed Office of Technology Assessment to conduct study to determine efficacy and fairness of requiring a hospital to enter into agreement under subsec. (b)(3)(A) of this section with organ procurement agency for service area in which such hospital is located and impact of such requirement on efficacy and fairness of organ procurement and distribution, and to submit to Congress, not later than 2 years after Oct. 31, 1994, report containing findings of such study and implications of such findings with respect to policies affecting organ procurement and distribution.

TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

Pub. L. 98–507, title I, §§ 101–105, Oct. 19, 1984, 98 Stat. 2339–2342, directed Secretary of Health and Human Services, not later than 90 days after Oct. 19, 1984, to establish a Task Force on Organ Transplantation to conduct comprehensive examinations, prepare an assessment and report, and submit advice as to regulation of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, with the final report due not later than 12 months after the Task Force is established and the Task Force to terminate 3 months thereafter.

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

Pub. L. 98–507, title IV, § 401, Oct. 19, 1984, 98 Stat. 3268, directed Secretary of Health and Human Services to hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors not later than 9 months after Oct. 19, 1984, and if the conference found that it was feasible to establish a national registry of voluntary donors of bone marrow and that such a registry was likely to be effective in matching donors with recipients, the Secretary was to establish a registry of voluntary donors of bone marrow not later than six months after the completion of the conference, and further directed the Secretary, acting through the Assistant Secretary for Health, to study the establishment and implementation of the registry to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the implementation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry was needed and appropriate, and to report the results of the study to Congress not later than two years after the date the registry was established.

§ 273a. National living donor mechanisms

The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.

(July 1, 1944, ch. 373, title III, § 371A, as added Pub. L. 108–216, § 7, Apr. 5, 2004, 118 Stat. 589.)

§ 273b. Report on the long-term health effects of living organ donation

Not later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation.

(Pub. L. 110–144, § 3, Dec. 21, 2007, 121 Stat. 1814.)

CODIFICATION

Section was enacted as part of the Charlie W. Norwood Living Organ Donation Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 274. Organ procurement and transplantation network

(a) Contract authority of Secretary; limitation; available appropriations

The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $7,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

(b) Functions

(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professionals regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants,

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,

(K) work actively to increase the supply of donated organs,

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network,

(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children,

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation, and

(O) provide that for purposes of this paragraph, the term ''children'' refers to individuals who are under the age of 18.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as ''HIV''), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 274f–5 of this title; or

(ii) if the Secretary has determined under section 274f–5(c) of this title that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 274f–5(c) of this title.

(c) Consideration of critical comments

The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

(July 1, 1944, ch. 373, title III, § 372, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2344; amended Pub. L. 100–607, title IV, § 403, Nov. 4, 1988, 102 Stat. 3115; Pub. L. 101–616, title II, § 202(a)–(c), Nov. 16, 1990, 104 Stat. 3283, 3284; Pub. L. 106–310, div. A, title XXI, § 2101(a), Oct. 17, 2000, 114 Stat. 1156; Pub. L. 110–426, § 2, Oct. 15, 2008, 122 Stat. 4835; Pub. L. 113–51, § 2(a)(1), Nov. 21, 2013, 127 Stat. 579.)

PRIOR PROVISIONS

A prior section 274, act July 1, 1944, ch. 373, title III, § 372, as added July 28, 1956, ch. 772, title II, § 201, 70 Stat. 710; amended June 25, 1959, Pub. L. 86–70, § 31(b)(2)–(4), 73 Stat. 148, related to grants to Alaska for a mental health program and payment for construction of hospital facilities, prior to the general revision of this part by section 201 of Pub. L. 98–507.

Another section 372 of act July 1, 1944, added by act Aug. 3, 1956, ch. 941, § 1, 70 Stat. 960, which related to functions of National Library of Medicine, was renumbered section 382 and classified to section 276 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2013—Subsec. (b)(2)(E). Pub. L. 113–51, § 2(a)(1)(A), struck out '', including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome'' after ''organs''.

Subsec. (b)(3). Pub. L. 113–51, § 2(a)(1)(B), added par. (3).

2008—Subsec. (a). Pub. L. 110–426 substituted ''$7,000,000'' for ''$2,000,000''.

2000—Subsec. (b)(2)(M) to(O). Pub. L. 106–310 added subpars. (M) to (O).

1990—Subsec. (b)(1)(A). Pub. L. 101–616, § 202(a)(1), substituted ''that has an expertise in organ procurement and transplantation'' for ''which is not engaged in any activity unrelated to organ procurement''.

Subsec. (b)(1)(B). Pub. L. 101–616, § 202(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public.''

Subsec. (b)(2)(D). Pub. L. 101–616, § 202(b)(1), inserted ''nationwide'' after ''organizations in the'' and ''equitably among transplant patients'' after ''organs''.

Subsec. (b)(2)(F). Pub. L. 101–616, § 202(c), substituted ''compatibility'' for ''compatability''.

Subsec. (b)(2)(K), (L). Pub. L. 101–616, § 202(b)(2)–(4), added subpars. (K) and (L).

1988—Subsec. (b)(2)(B), (C). Pub. L. 100–607, § 403(a)(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (b)(2)(D). Pub. L. 100–607, § 403(a)(1), (2), redesignated former subpar. (C) as (D) and substituted ''organs'' for ''organs which cannot be placed within the

service areas of the organizations''. Former subpar. (D) redesignated (E).

Subsec. (b)(2)(E). Pub. L. 100–607, § 403(a)(1), (3), redesignated former subpar. (D) as (E) and inserted ''including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,'' after ''organs,''. Former subpar. (E) redesignated (F).

Subsec. (b)(2)(F). Pub. L. 100–607, § 403(a)(1), (4), redesignated former subpar. (E) as (F) and inserted ''(and, to the extent practicable, among regions or on a national basis)'' after ''basis''. Former subpar. (F) redesignated (G).

Subsec. (b)(2)(G) to (I). Pub. L. 100–607, § 403(a)(1), redesignated former subpars. (F) to (H) as (G) to (I), respectively.

Subsec. (b)(2)(J). Pub. L. 100–607, § 403(a)(5), added subpar. (J).

Subsec. (c). Pub. L. 100–607, § 403(b), added subsec. (c).

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–616, title II, § 202(d), Nov. 16, 1990, 104 Stat. 3284, provided that: ''The amendments made by subsection (a) [amending this section] shall become effective on December 31, 1990.''

REPORT; LIMITATION ON AMENDMENT BY PUB. L. 110–426

Pub. L. 110–426, § 3, Oct. 15, 2008, 122 Stat. 4835, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall request that the Executive Director of the Organ Procurement and Transplantation Network submit to Congress, not later than 1 year after the date of enactment of this Act [Oct. 15, 2008], a report that shall include—

''(1) the identity of transplant programs that have become inactive or have closed since the heart allocation policy change of 2006;

''(2) the distance to the next closest operational heart transplant center from such inactivated or closed programs and an evaluation of whether or not access to care has been reduced to the population previously serviced by such inactive or closed program;

''(3) the number of patients with rural zip codes that received transplants after the heart allocation policy change of 2006 as compared with the number of such patients that received such transplants prior to such heart allocation policy change;

''(4) a comparison of the number of transplants performed, the mortality rate for individuals on the transplant waiting lists, and the post-transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006; and

''(5) specifically with respect to allosensitized patients, a comparison of the number of heart transplants performed, the mortality rate for individuals on the heart transplant waiting lists, and the post heart transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006.

''(b) LIMITATION ON FUNDING.—The increase provided for in the amendment made by section 2 [amending this section] shall not apply with respect to contracts entered into under section 372(a) of the Public Health Service Act (42 U.S.C. 274(a)) after the date that is 1 year after the date of enactment of this Act [Oct. 15, 2008] if the Executive Director of the Organ Procurement and Transplantation Network fails to submit the report under subsection (a).''

§ 274a. Scientific registry

The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 274d of this title an analysis of information derived from the registry.

(July 1, 1944, ch. 373, title III, § 373, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100–607, title IV, § 404, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title I, § 101(b), Nov. 16, 1990, 104 Stat. 3282.)

PRIOR PROVISIONS

A prior section 373 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 960, which related to a Board of Regents of National Library of Medicine, was renumbered section 383 and classified to section 277 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101–616 struck out ''and bone marrow registry'' after ''Scientific registry'' in section catchline and struck out subsec. (a) designation and subsec. (b) which directed establishment of bone marrow registry and authorized appropriations for fiscal years 1989 and 1990 for such purpose.

1988—Pub. L. 100–607 inserted ''and bone marrow registry'' in section catchline, designated existing text as subsec. (a), and added subsec. (b).

§ 274b. General provisions respecting grants and contracts

(a) Application requirement

No grant may be made under this part or contract entered into under section 274 or 274a of this title unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b) Special considerations and priority; planning and establishment grants

(1) A grant for planning under section 273(a)(1) of this title may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

(2) Grants under section 273(a)(2) of this title may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 273(a)(3) of this title may be made for not more than 3 years.

(c) Determination of grant amount; terms of payment; recordkeeping; access for purposes of audits and examination of records

(1) The Secretary shall determine the amount of a grant or contract made under section 273 or 274a of this title. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 273 or 274a of this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount

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

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 273 or 274a of this title that are pertinent to such grant or contract.

(d) "Transplant center" and "organ" defined

For purposes of this part:

(1) The term ''transplant center'' means a health care facility in which transplants of organs are performed.

(2) The term ''organ'' means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 274a of this title, such term includes bone marrow.

(July 1, 1944, ch. 373, title III, § 374, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100–607, title IV, § 402(b), Nov. 4, 1988, 102 Stat. 3114; Pub. L. 101–616, title II, § 203, Nov. 16, 1990, 104 Stat. 3284.)

PRIOR PROVISIONS

A prior section 374 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 961, which related to acceptance and administration of gifts to National Library of Medicine and to establishment of memorials to donors, was renumbered section 384 and classified to section 278 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Subsec. (a). Pub. L. 101–616, § 203(1), substituted ''No grant may be made under this part'' for ''No grant may be made under section 273 or 274a of this title''.

Subsec. (b). Pub. L. 101–616, § 203(2), redesignated par. (2) as (1) and substituted ''section 273(a)(1)'' for ''section 273'', struck out former par. (1) which set forth factors in considering applications for section 273 grants, redesignated par. (3) as (2) and substituted ''section 273(a)(2)'' for ''paragraphs (2) and (3) of section 273(a)'', and added par. (3).

Subsec. (c). Pub. L. 101–616, § 203(3), inserted ''or contract'' after ''grant'' wherever appearing and ''and contracts'' after ''grants'' wherever appearing.

1988—Subsec. (b)(3). Pub. L. 100–607 substituted ''paragraphs (2) and (3) of section 273(a) of this title'' for ''section 273 of this title for the establishment, initial operation, or expansion of organ procurement organizations''.

§ 274c. Administration

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.],

(2) conduct a program of public information to inform the public of the need for organ donations,

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 274 of this title, and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information—

(i) to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

(July 1, 1944, ch. 373, title III, § 375, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100–607, title IV, § 405, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title II, § 204, Nov. 16, 1990, 104 Stat. 3285.)

REFERENCES IN TEXT

The Social Security Act, referred to in par. (1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§ 1395 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.

PRIOR PROVISIONS

A prior section 375 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 962, which related to definitions, was renumbered section 385 and classified to section 279 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101–616, § 204(a), struck out '', during fiscal years 1985 through 1990,'' after ''The Secretary shall''.

Par. (3). Pub. L. 101–616, § 204(b)(1), struck out ''receiving funds under section 273 of this title'' after ''organ procurement organizations''.

Par. (4). Pub. L. 101–616, § 204(b)(2), amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.''

1988—Pub. L. 100–607, in introductory provisions, substituted ''1985 through 1990'' for ''1985, 1986, 1987, and 1988'' and, in par. (4), substituted ''not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report'' for ''one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report''.

§ 274d. Report

Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.[1] a report on the scientific

[1] So in original. The period probably should be a comma.

and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

(July 1, 1944, ch. 373, title III, § 376, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100–607, title IV, § 406, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title II, § 205, Nov. 16, 1990, 104 Stat. 3285.)

PRIOR PROVISIONS

A prior section 376 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 962, which related to Library facilities, was renumbered section 386 and classified to section 280 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101–616 substituted ''Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.'' for ''The Secretary shall, not later than October 1 of each year, publish''.

1988—Pub. L. 100–607 substituted ''shall, not later than October 1 of each year,'' for ''shall annually''.

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.

§ 274e. Prohibition of organ purchases

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.

(b) Penalties

Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (a):

(1) The term ''human organ'' means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term ''valuable consideration'' does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term ''interstate commerce'' has the meaning prescribed for it by section 321(b) of title 21.

(4) The term ''human organ paired donation'' means the donation and receipt of human organs under the following circumstances:

(A) An individual (referred to in this paragraph as the ''first donor'') desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the ''first patient''), but such donor is biologically incompatible as a donor for such patient.

(B) A second individual (referred to in this paragraph as the ''second donor'') desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the ''second patient''), but such donor is biologically incompatible as a donor for such patient.

(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.

(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.

(E) All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group.

(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the human organs referred to in such subparagraph.

(Pub. L. 98–507, title III, § 301, Oct. 19, 1984, 98 Stat. 2346; Pub. L. 100–607, title IV, § 407, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 110–144, § 2, Dec. 21, 2007, 121 Stat. 1813.)

CODIFICATION

Section was enacted as part of the National Organ Transplant Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110–144, § 2(1), inserted at end ''The preceding sentence does not apply with respect to human organ paired donation.''

Subsec. (c)(4). Pub. L. 110–144, § 2(2), added par. (4).

1988—Subsec. (c)(1). Pub. L. 100–607 amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''The term 'human organ' means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation.''

DETERMINATION ON THE DEFINITION OF HUMAN ORGAN

Pub. L. 114–104, § 4, Dec. 18, 2015, 129 Stat. 2218, provided that: ''Not later than one year after the date of

enactment of this Act [Dec. 18, 2015], the Secretary of Health and Human Services shall issue determinations with respect to the inclusion of peripheral blood stem cells and umbilical cord blood in the definition of human organ.''

NO IMPACT ON SOCIAL SECURITY TRUST FUND

Pub. L. 110–144, § 4, Dec. 21, 2007, 121 Stat. 1814, provided that: ''Nothing in this Act [see Short Title of 2007 Amendment note set out under section 201 of this title] (or an amendment made by this Act) shall be construed to alter or amend the Social Security Act (42 U.S.C. 301 et seq.) (or any regulation promulgated under that Act).''

§ 274f. Reimbursement of travel and subsistence expenses incurred toward living organ donation

(a) In general

The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 273 of this title, or other public or private entities for the purpose of—

(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as ''donating individuals''); and

(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) Preference

The Secretary shall, in carrying out subsection (a), give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses.

(c) Certain circumstances

The Secretary may, in carrying out subsection (a), consider—

(1) the term ''donating individuals'' as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs; and

(2) the term ''qualifying expenses'' as including the expenses of having relatives or other individuals, not to exceed 2, accompany or assist the donating individual for purposes of subsection (a) (subject to making payment for only those types of expenses that are paid for a donating individual).

(d) Relationship to payments under other programs

An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

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

(2) by an entity that provides health services on a prepaid basis; or

(3) by the recipient of the organ.

(e) Definitions

For purposes of this section:

(1) The term ''donating individuals'' has the meaning indicated for such term in subsection (a)(1), subject to subsection (c)(1).

(2) The term ''qualifying expenses'' means the expenses authorized for purposes of subsection (a), subject to subsection (c)(2).

(f) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $5,000,000 for each of the fiscal years 2005 through 2009.

(July 1, 1944, ch. 373, title III, § 377, as added Pub. L. 101–616, title II, § 206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 108–216, § 3, Apr. 5, 2004, 118 Stat. 584.)

AMENDMENTS

2004—Pub. L. 108–216 amended section catchline and text generally, substituting provisions relating to reimbursement of travel and subsistence expenses incurred toward living organ donation for provisions requiring the Comptroller General to study and report on organ procurement and allocation.

§ 274f–1. Public awareness; studies and demonstrations

(a) Organ donation public awareness program

The Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.

(b) Studies and demonstrations

The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.

(c) Grants to States

(1) In general

The Secretary may make grants to States for the purpose of assisting States in carrying out organ donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the State, including living donors.

(2) Eligibility

To be eligible to receive a grant under this subsection, a State shall—

(A) submit an application to the Department in the form prescribed;

(B) establish yearly benchmarks for improvement in organ donation rates in the State; and

(C) report to the Secretary on an annual basis a description and assessment of the State's use of funds received under this subsection, accompanied by an assessment of initiatives for potential replication in other States.

(3) Use of funds

Funds received under this subsection may be used by the State, or in partnership with other public agencies or private sector institutions,

for education and awareness efforts, information dissemination, activities pertaining to the State donor registry, and other innovative donation specific initiatives, including living donation.

(d) Educational activities

The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals in issues surrounding organ, tissue, and eye donation including evidence-based proven methods to approach patients and their families, cultural sensitivities, and other relevant issues.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $15,000,000 for fiscal year 2005, and such sums as may be necessary for each of the fiscal years 2006 through 2009. Such authorization of appropriations is in addition to any other authorizations of appropriations that are available for such purpose.

(July 1, 1944, ch. 373, title III, § 377A, as added Pub. L. 108–216, § 4, Apr. 5, 2004, 118 Stat. 585.)

§ 274f–2. Grants regarding hospital organ donation coordinators

(a) Authority

(1) In general

The Secretary may award grants to qualified organ procurement organizations and hospitals under section 273 of this title to establish programs coordinating organ donation activities of eligible hospitals and qualified organ procurement organizations under section 273 of this title. Such activities shall be coordinated to increase the rate of organ donations for such hospitals.

(2) Eligible hospital

For purposes of this section, the term ''eligible hospital'' means a hospital that performs significant trauma care, or a hospital or consortium of hospitals that serves a population base of not fewer than 200,000 individuals.

(b) Administration of coordination program

A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that the program under such subsection will be carried out jointly—

(1) by representatives from the eligible hospital and the qualified organ procurement organization with respect to which the grant is made; and

(2) by such other entities as the representatives referred to in paragraph (1) may designate.

(c) Requirements

Each entity receiving a grant under subsection (a) shall—

(1) establish joint organ procurement organization and hospital designated leadership responsibility and accountability for the project;

(2) develop mutually agreed upon overall project performance goals and outcome measures, including interim outcome targets; and

(3) collaboratively design and implement an appropriate data collection process to provide ongoing feedback to hospital and organ procurement organization leadership on project progress and results.

(d) Rule of construction

Nothing in this section shall be construed to interfere with regulations in force on April 5, 2004.

(e) Evaluations

Within 3 years after the award of grants under this section, the Secretary shall ensure an evaluation of programs carried out pursuant to subsection (a) in order to determine the extent to which the programs have increased the rate of organ donation for the eligible hospitals involved.

(f) Matching requirement

The Secretary may not award a grant to a qualifying organ donation entity under this section unless such entity agrees that, with respect to costs to be incurred by the entity in carrying out activities for which the grant was awarded, the entity shall contribute (directly or through donations from public or private entities) non-Federal contributions in cash or in kind, in an amount equal to not less than 30 percent of the amount of the grant awarded to such entity.

(g) Funding

For the purpose of carrying out this section, there are authorized to be appropriated $3,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, § 377B, as added Pub. L. 108–216, § 4, Apr. 5, 2004, 118 Stat. 586.)

§ 274f–3. Studies relating to organ donation and the recovery, preservation, and transportation of organs

(a) Development of supportive information

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

(b) Activities

In carrying out subsection (a), the Secretary shall—

(1) conduct or support evaluation research to determine whether interventions, technologies, or other activities improve the effectiveness, efficiency, or quality of existing organ donation practice;

(2) undertake or support periodic reviews of the scientific literature to assist efforts of professional societies to ensure that the clinical practice guidelines that they develop reflect the latest scientific findings;

(3) ensure that scientific evidence of the research and other activities undertaken under this section is readily accessible by the organ procurement workforce; and

(4) work in coordination with the appropriate professional societies as well as the Organ Procurement and Transplantation Network and other organ procurement and transplantation organizations to develop evidence and promote the adoption of such proven practices.

(c) Research and dissemination

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, as appropriate, shall provide support for research and dissemination of findings, to—

(1) develop a uniform clinical vocabulary for organ recovery;

(2) apply information technology and telecommunications to support the clinical operations of organ procurement organizations;

(3) enhance the skill levels of the organ procurement workforce in undertaking quality improvement activities; and

(4) assess specific organ recovery, preservation, and transportation technologies.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, § 377C, as added Pub. L. 108–216, § 5, Apr. 5, 2004, 118 Stat. 587.)

§ 274f–4. Report relating to organ donation and the recovery, preservation, and transportation of organs

(a) In general

Not later than December 31, 2005, and every 2 years thereafter, the Secretary shall report to the appropriate committees of Congress on the activities of the Department carried out pursuant to this part, including an evaluation describing the extent to which the activities have affected the rate of organ donation and recovery.

(b) Requirements

To the extent practicable, each report submitted under subsection (a) shall—

(1) evaluate the effectiveness of activities, identify effective activities, and disseminate such findings with respect to organ donation and recovery;

(2) assess organ donation and recovery activities that are recently completed, ongoing, or planned; and

(3) evaluate progress on the implementation of the plan required under subsection (c)(5).

(c) Initial report requirements

The initial report under subsection (a) shall include the following:

(1) An evaluation of the organ donation practices of organ procurement organizations, States, other countries, and other appropriate organizations including an examination across all populations, including those with low organ donation rates, of—

(A) existing barriers to organ donation; and

(B) the most effective donation and recovery practices.

(2) An evaluation of living donation practices and procedures. Such evaluation shall include an assessment of issues relating to informed consent and the health risks associated with living donation (including possible reduction of long-term effects).

(3) An evaluation of—

(A) federally supported or conducted organ donation efforts and policies, as well as federally supported or conducted basic, clinical, and health services research (including research on preservation techniques and organ rejection and compatibility); and

(B) the coordination of such efforts across relevant agencies within the Department and throughout the Federal Government.

(4) An evaluation of the costs and benefits of State donor registries, including the status of existing State donor registries, the effect of State donor registries on organ donation rates, issues relating to consent, and recommendations regarding improving the effectiveness of State donor registries in increasing overall organ donation rates.

(5) A plan to improve federally supported or conducted organ donation and recovery activities, including, when appropriate, the establishment of baselines and benchmarks to measure overall outcomes of these programs. Such plan shall provide for the ongoing coordination of federally supported or conducted organ donation and research activities.

(July 1, 1944, ch. 373, title III, § 377D, as added Pub. L. 108–216, § 6, Apr. 5, 2004, 118 Stat. 588.)

§ 274f–5. Criteria, standards, and regulations with respect to organs infected with HIV

(a) In general

Not later than 2 years after November 21, 2013, the Secretary shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with human immunodeficiency virus (in this section referred to as ''HIV'') into individuals who are infected with HIV before receiving such organ.

(b) Corresponding changes to standards and regulations applicable to research

Not later than 2 years after November 21, 2013, to the extent determined by the Secretary to be necessary to allow the conduct of research in accordance with the criteria developed under subsection (a)—

(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 274(b)(2)(E) of this title; and

(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(c) Revision of standards and regulations generally

Not later than 4 years after November 21, 2013, and annually thereafter, the Secretary,[1] shall—

(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine

[1] So in original. The comma probably should not appear.

whether the results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and Transplantation Network to revise such standards, consistent with section 274 of this title and in a way that ensures the changes will not reduce the safety of organ transplantation; and

(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(July 1, 1944, ch. 373, title III, § 377E, as added Pub. L. 113–51, § 2(b), Nov. 21, 2013, 127 Stat. 580.)

§ 274g. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(July 1, 1944, ch. 373, title III, § 378, as added Pub. L. 101–616, title II, § 206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 105–196, § 4(1), July 16, 1998, 112 Stat. 636.)

AMENDMENTS

1998—Pub. L. 105–196 made technical amendment relating to placement of section within part H of this subchapter.

PART H–1—Stephanie Tubbs Jones Gift of Life Medal

CODIFICATION

Part was enacted as part of the Stephanie Tubbs Jones Gift of Life Medal Act of 2008, and not as part of the Public Health Service Act which comprises this chapter.

§ 274i. Eligibility requirements for Stephanie Tubbs Jones Gift of Life Medal

(a) In general

Subject to the provisions of this section and the availability of funds under this part, any organ donor, or the family of any organ donor, shall be eligible for a Stephanie Tubbs Jones Gift of Life Medal (hereafter in this part referred to as a ''medal'').

(b) Documentation

The Secretary of Health and Human Services shall direct the entity operating the Organ Procurement and Transplantation Network to—

(1) establish an application procedure requiring the relevant organ procurement organization through which an individual or family of the individual made an organ donation, to submit to such entity documentation supporting the eligibility of the individual or the family, respectively, to receive a medal;

(2) determine through the documentation provided and, if necessary, independent investigation whether the individual or family, respectively, is eligible to receive such a medal; and

(3) arrange for the presentation to the relevant organ procurement organization all medals struck pursuant to section 274i–2 of this title to individuals or families that are determined to be eligible to receive medals.

(c) Limitation

(1) In general

Except as provided in paragraph (2), only 1 medal may be presented to a family under subsection (b). Such medal shall be presented to the donating family member, or in the case of a deceased donor, the family member who signed the consent form authorizing, or who otherwise authorized, the donation of the organ involved.

(2) Exception

In the case of a family in which more than 1 member is an organ donor, a medal may be presented for each such organ donor.

(Pub. L. 110–413, § 2, Oct. 14, 2008, 122 Stat. 4338.)

§ 274i–1. Solicitation of donations; prohibition on use of Federal funds

(a) In general

The Organ Procurement and Transplantation Network may collect funds to offset expenditures relating to the issuance of medals authorized under this part.

(b) Payment of funds

(1) In general

Except as provided in paragraph (2), all funds received by the Organ Procurement and Transplantation Network under subsection (a) shall be promptly paid by the Organ Procurement and Transplantation Network to the Secretary of Health and Human Services for purposes of purchasing medals under this part for distribution and paying the administrative costs of the Secretary of Health and Human Services and the Secretary of the Treasury in carrying out this part.

(2) Limitation

Not more than 7 percent of any funds received under subsection (a) may be used to pay administrative costs, and fundraising costs to solicit funds under subsection (a), incurred by the Organ Procurement and Transplantation Network in carrying out this part.

(c) Prohibition on use of Federal funds

No Federal funds (including amounts appropriated for use by the Organ Procurement and Transplantation Network) may be used for purposes of carrying out this part, including purchasing medals under this part or paying the administrative costs of the Secretary of Health and Human Services or the Secretary of the Treasury in carrying out this part.

(Pub. L. 110–413, § 3, Oct. 14, 2008, 122 Stat. 4339.)

§ 274i–2. Design and production of medal

(a) In general

Subject to the provisions of this section, the Secretary of the Treasury shall design and strike the Stephanie Tubbs Jones Gift of Life Medals, each of which shall—

(1) weigh 250 grams;

(2) have a diameter of 3 inches; and

(3) consist of bronze.

(b) Design

(1) In general

The design of the medals shall commemorate the compassion and courage manifested by and the sacrifices made by organ donors and their families, and the medals shall bear suitable emblems, devices, and inscriptions.

(2) Selection

The design of medals struck under this section shall be—

(A) selected by the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, the Organ Procurement and Transplantation Network, interested members of the family of Stephanie Tubbs Jones, Dr. William H. Frist, and the Commission of Fine Arts; and

(B) reviewed by the Citizens Coin Advisory Committee.

(c) National medals

The medals struck pursuant to this section are national medals for purposes of chapter 51 of title 31.

(d) Striking and delivery of minimum-sized lots

The Secretary of the Treasury shall strike and deliver to the Secretary of Health and Human Services no fewer than 100 medals at any time pursuant to an order by such Secretary.

(e) Cost of medals

Medals struck under this section and sold to the Secretary of Health and Human Services for distribution in accordance with this part shall be sold to the Secretary of Health and Human Services at a price sufficient to cover the cost of designing and striking the medals, including labor, materials, dies, use of machinery, and overhead expenses.

(f) No expenditures in advance of receipt of fund

(1) In general

The Secretary of the Treasury shall not strike or distribute any medals under this part until such time as the Secretary of Health and Human Services certifies that sufficient funds have been received by such Secretary to cover the cost of the medals ordered.

(2) Design in advance of order

Notwithstanding paragraph (1), the Secretary of the Treasury may begin designing the medal at any time after October 14, 2008, and take such other action as may be necessary to be prepared to strike such medals upon receiving the certification described in such paragraph, including preparing dies and striking test pieces.

(Pub. L. 110–413, § 4, Oct. 14, 2008, 122 Stat. 4339.)

§ 274i–3. Medals not treated as valuable consideration

A medal under this part shall not be treated as valuable consideration for purposes of section 274e(a) of this title.

(Pub. L. 110–413, § 5, Oct. 14, 2008, 122 Stat. 4340.)

§ 274i–4. Definitions

For purposes of this part:

(1) Organ

The term ''organ'' has the meaning given such term in section 121.2 of title 42, Code of Federal Regulations.

(2) Organ procurement organization

The term ''organ procurement organization'' means a qualified organ procurement organization described in section 273(b)(1) of this title.

(3) Organ Procurement and Transplantation Network

The term ''Organ Procurementand[1] Transplantation Network'' means the Organ Procurement and Transplantation Network established under section 274 of this title.

(Pub. L. 110–413, § 6, Oct. 14, 2008, 122 Stat. 4340.)

PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

CODIFICATION

Pub. L. 109–129, § 3(e), Dec. 20, 2005, 119 Stat. 2562, substituted ''C.W. Bill Young Cell Transplantation Program'' for ''National Bone Marrow Donor Registry'' in part heading.

Pub. L. 101–616, title I, § 101(a)(2), Nov. 16, 1990, 104 Stat. 3279, added part I ''National Bone Marrow Donor Registry'' and redesignated former part I ''Biomedical Ethics'' as J.

Pub. L. 99–158, §§ 3(b), 11, Nov. 20, 1985, 99 Stat. 879, 883, added part I ''Biomedical Ethics'', and repealed former part I ''National Library of Medicine''.

Pub. L. 91–212, § 10(a)(2), Mar. 13, 1970, 84 Stat. 66, redesignated part H ''National Library of Medicine'', as I.

§ 274k. National Program

(a) Establishment

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the ''Program''), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Pro-

[1] So in original. Probably should be ''Procurement and''.

gram shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and

(B) one additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.

(b) Accreditation

The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) Informed consent

The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) Functions

(1) Bone marrow functions

With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

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

(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

(E) carry out informational and educational activities in accordance with subsection (e);

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

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

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) Cord blood functions

(A) In general

With respect to cord blood, the Program shall—

(i) operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

(ii) consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

(iii) allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;

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

(vi) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

(vii) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

(viii) with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

(B) Efforts to increase collection of high quality cord blood units

In carrying out subparagraph (A)(iv), not later than 1 year after October 8, 2010, and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the ''inventory goal''), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate. If the Secretary cannot identify a project as described in the preceding sentence, the Secretary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding collection of high quality cord blood units, including remote collection, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public.

(C) Definition

In this paragraph, the term ''remote collection'' means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support.

(3) Single point of access; standard data

(A) Single point of access

The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A)(i), cells from bone marrow donors and cord blood units through a single point of access.

(B) Standard data

The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) Definition

The term ''qualified cord blood bank'' means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) Bone marrow recruitment; priorities; information and education

(1) Recruitment; priorities

The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) Information and education regarding recruitment; testing and enrollment

(A) In general

The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

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

(B) Priorities

In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) Transplantation as treatment option

In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) Implementation of subsection

The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(f) Bone marrow criteria, standards, and procedures

The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) Cord blood recruitment; priorities; information and education

(1) Recruitment; priorities

The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) Information and education regarding recruitment; testing and donation

(A) In general

In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) Priorities

In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) Transplantation as treatment option

In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) Implementation of subsection

The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) Patient advocacy and case management for bone marrow and cord blood

(1) In general

The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the ''Office'').

(2) General functions

The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct, a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

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

(i) The resources available through the Program.

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

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) Case management

(A) In general

In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) Postsearch functions

In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) Comment procedures

The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

(j) Consultation

In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) Contracts

(1) Application

To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) Considerations

In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

***(l)* Eligibility**

Entities eligible to receive a contract under this section shall include private nonprofit entities.

(m) Records

(1) Recordkeeping

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

(2) Examination of records

The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) Penalties for disclosure

Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, or both.

(July 1, 1944, ch. 373, title III, § 379, as added Pub. L. 101–616, title I, § 101(a)(2), Nov. 16, 1990, 104 Stat. 3279; amended Pub. L. 105–196, § 2(a), (b)(1), (c)–(g), July 16, 1998, 112 Stat. 631–635; Pub. L. 109–129, § 3(a), Dec. 20, 2005, 119 Stat. 2553; Pub. L. 111–264, § 2(b), Oct. 8, 2010, 124 Stat. 2791; Pub. L. 114–104, § 2(a), Dec. 18, 2015, 129 Stat. 2216.)

REFERENCES IN TEXT

Section 2 of the Stem Cell Therapeutic and Research Act of 2005, referred to in subsec. (d)(2)(A)(iv), (B), is section 2 of Pub. L. 109–129, Dec. 20, 2005, 119 Stat. 2550, which is set out as a note under this section.

AMENDMENTS

2015—Subsec. (d)(2)(B). Pub. L. 114–104 substituted ''collection of high quality cord blood units, including remote collection,'' for ''remote collection of high quality cord blood units,''.

2010—Subsec. (a)(6). Pub. L. 111–264, § 2(b)(1), added par. (6) and struck out former par. (6) which read as follows: ''The Secretary, acting through the Advisory Council, shall submit to the Congress—

''(A) an annual report on the activities carried out under this section; and

''(B) not later than 6 months after December 20, 2005, a report of recommendations on the scientific factors necessary to define a cord blood unit as a high-quality unit.''

Subsec. (d)(2). Pub. L. 111–264, §2(b)(2)(A), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (H) as cls. (i) to (viii), respectively, of subpar. (A), added cl. (iv) and struck out former cl. (iv) which related to studies and demonstration and outreach projects for the purpose of increasing cord blood donation, and added subpars. (B) and (C).

Subsec. (d)(3)(A). Pub. L. 111–264, §2(b)(2)(B), substituted ''(2)(A)(i)'' for ''(2)(A)''.

Subsec. (f)(5)(A). Pub. L. 111–264, §2(b)(3), added subpar. (A) and struck out former subpar. (A) which read as follows: ''require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and''.

2005—Pub. L. 109–129 amended section generally, substituting provisions relating to the C.W. Bill Young Cell Transplantation Program for provisions relating to the National Bone Marrow Donor Registry.

1998—Subsec. (a). Pub. L. 105–196, §2(a), substituted ''(referred to in this part as the 'Registry') that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets'' for ''(referred to in this part as the 'Registry') that meets'' and substituted ''under the direction of a board of directors meeting the following requirements:'' and pars. (1) to (4) for ''under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public.''

Subsec. (b)(2) to (8). Pub. L. 105–196, §2(b)(1), added pars. (2) to (7), redesignated former par. (7) as (8), and struck out former pars. (2) to (6) which read as follows:

''(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

''(3) increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the Registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group;

''(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

''(5) recruit potential bone marrow donors;

''(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and''.

Subsecs. (c), (d). Pub. L. 105–196, §2(c), (d), added subsecs. (c) and (d). Former subsecs. (c) and (d) redesignated (e) and (f), respectively.

Subsec. (e). Pub. L. 105–196, §2(c), redesignated subsec. (c) as (e). Former subsec. (e) redesignated (g).

Subsec. (e)(4). Pub. L. 105–196, §2(e), added par. (4) and struck out former par. (4) which read as follows: ''standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning—

''(A) the resources available through the Registry;

''(B) all other marrow donor registries meeting the standards described in this paragraph; and

''(C) in the case of the Registry—

''(i) the comparative costs of all charges by marrow transplant centers incurred by patients prior to transplantation; and

''(ii) the success rates of individual marrow transplant centers;''.

Subsec. (f). Pub. L. 105–196, §2(c), (g)(1), redesignated subsec. (d) as (f) and substituted ''subsection (e)'' for ''subsection (c)''. Former subsec. (f) redesignated (h).

Subsecs. (g) to (i). Pub. L. 105–196, §2(c), redesignated subsecs. (e) to (g) as (g) to (i), respectively. Former subsecs. (h) and (i) redesignated (j) and (k), respectively.

Subsec. (j). Pub. L. 105–196, §2(c), redesignated subsec. (h) as (j) and struck out heading and text of former subsec. (j). Text read as follows: ''There are authorized to be appropriated to carry out this section $15,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.''

Subsec. (k). Pub. L. 105–196, §2(c), (g)(2), redesignated subsec. (i) as (k) and substituted ''subsection (e)(5)(A)'' for ''subsection (c)(5)(A)'' and ''subsection (e)(5)(B)'' for ''subsection (c)(5)(B)''.

Subsec. (*l*). Pub. L. 105–196, §2(f), added subsec. (*l*).

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–196, §7, July 16, 1998, 112 Stat. 637, provided that: ''This Act [see Short Title of 1998 Amendment note set out under section 201 of this title] takes effect October 1, 1998, or upon the date of the enactment of this Act [July 16, 1998], whichever occurs later.''

SAVINGS PROVISION

Pub. L. 101–616, title I, §102, Nov. 16, 1990, 104 Stat. 3282, provided that:

''(a) IN GENERAL.—This title [enacting this section and section 274*l* of this title and amending section 274a of this title], and the amendments made by this title, shall not affect any legal document, including any order, regulation, grant, or contract, in effect on the date of enactment of this Act [Nov. 16, 1990], or any administrative proceeding or lawsuit pending on the date, that relates to the bone marrow registry established under section 373(b) of the Public Health Service Act [42 U.S.C. 274a(b)] (as it existed before the amendment made by section 101(b) of this Act).

''(b) CONTINUED EFFECT.—A legal document described in subsection (a) or an order issued in a lawsuit described in subsection (a) shall continue in effect until modified, terminated, or revoked.

''(c) PROCEEDINGS.—In any administrative proceeding or lawsuit described in subsection (a), parties shall take appeals, and officials shall hold proceedings and render judgments, in the same manner and with the same effect as if this title had not been enacted.''

CORD BLOOD INVENTORY

Pub. L. 109–129, §2, Dec. 20, 2005, 119 Stat. 2550, as amended by Pub. L. 111–264, §2(a), Oct. 8, 2010, 124 Stat. 2789; Pub. L. 114–104, §3, Dec. 18, 2015, 129 Stat. 2217, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into contracts with qualified cord blood banks to assist in the collection and maintenance of the inventory goal of at least 150,000 new units of high-quality cord blood to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program and to carry out the requirements of subsection (b).

''(b) REQUIREMENTS.—The Secretary shall require each recipient of a contract under this section—

''(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor, as determined by the Secretary pursuant to section 379(c) of the Public Health Service Act [42 U.S.C. 274k(c)], in a manner that complies with applicable Federal and State regulations;

''(2) to encourage donation from a genetically diverse population;

''(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

''(4) to make cord blood units that are collected, but not appropriate for clinical use, available for peer-reviewed research;

''(5) to make data available, as required by the Secretary and consistent with section 379(d)(3) of the Public Health Service Act (42 U.S.C. 274k(d)(3)), as amended by this Act, in a standardized electronic for-

mat, as determined by the Secretary, for the C.W. Bill Young Cell Transplantation Program; and

''(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act [42 U.S.C. 274*l*], as amended by this Act.

''(c) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood bank shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. At a minimum, an application for a contract under this section shall include a requirement that the applicant—

''(1) will participate in the C.W. Bill Young Cell Transplantation Program for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section;

''(2) will make cord blood units collected pursuant to this section available through the C.W. Bill Young Cell Transplantation Program in perpetuity or for such time as determined viable by the Secretary;

''(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

''(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and

''(5) if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational or does not meet the requirements of section 379(d)(4) of the Public Health Service Act [42 U.S.C. 274k(d)(4)] (as added by this Act) and as a result may not distribute the units, transfer the units collected pursuant to this section to another qualified cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

''(d) DURATION OF CONTRACTS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section. The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2), (3), and (4).

''(2) EXTENSIONS.—The Secretary may extend the period of funding under a contract under this section to exceed a period of 5 years if—

''(A) the Secretary finds that the inventory goal described in subsection (a) has not yet been met;

''(B) the Secretary does not receive an application for a contract under this section meeting the requirements under subsection (c) from any qualified cord blood bank that has not previously entered into a contract under this section; or

''(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.

''(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

''(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

''(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

''(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.

''(4) CONSIDERATION OF BEST SCIENCE.—The Secretary shall take into consideration the best scientific information available in order to maximize the number of cord blood units available for transplant when entering into contracts under this section, or when extending a period of funding under such a contract under paragraph (2).

''(5) CONSIDERATION OF BANKED UNITS OF CORD BLOOD.—In extending contracts pursuant to paragraph (3), and determining new allocation amounts for the next contract period or contract extension for such cord blood bank, the Secretary shall take into account the number of cord blood units banked in the National Cord Blood Inventory by a cord blood bank during the previous contract period, in addition to consideration of the ability of such cord blood bank to increase the collection and maintenance of additional, genetically diverse cord blood units.

''(e) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

''(f) DEFINITIONS.—In this section:

''(1) The term 'C.W. Bill Young Cell Transplantation Program' means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act [42 U.S.C. 274k], as amended by this Act.

''(2) The term 'cord blood donor' means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

''(3) The term 'cord blood unit' means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

''(4) The term 'qualified cord blood bank' has the meaning given to that term in section 379(d)(4) of the Public Health Service Act [42 U.S.C. 274k(d)(4)], as amended by this Act.

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

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) [sic; there is no par. (2)] AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $20,000,000 for fiscal year 2015 and $23,000,000 for each of fiscal years 2016 through 2020.''

REPORT OF INSPECTOR GENERAL; PLAN REGARDING RELATIONSHIP BETWEEN REGISTRY AND DONOR CENTERS

Pub. L. 105–196, § 2(b)(2), July 16, 1998, 112 Stat. 632, directed the Secretary of Health and Human Services to ensure that, not later than 1 year after July 16, 1998, the National Bone Marrow Donor Registry (under this section) developed, evaluated, and implemented a plan to effectuate efficiencies in the relationship between such Registry and donor centers.

STUDY BY GAO

Pub. L. 105–196, § 5, July 16, 1998, 112 Stat. 636, provided that the Comptroller General was to conduct a study of the National Bone Marrow Donor Registry under this section to determine the extent to which the Registry had increased the representation of racial and ethnic minority groups among potential donors enrolled with the Registry and whether the extent of increase resulted in a level of representation that met the standard established in subsec. (c)(1)(A) of this section, the extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, had been utilizing the Registry, the number of patients for whom the Registry began a preliminary but not complete search process and the reasons underlying such circumstances, the extent to which the plan required in section 2(b)(2) of Pub. L. 105–196 (42 U.S.C. 274k note) had been implemented, and the extent to which the Reg-

istry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities had been complying with subsec. (e) of this section; and provided that a report describing the findings of this study was to be submitted to Congress not later than Oct. 1, 2001, and not before Jan. 1, 2001.

COMPLIANCE WITH NEW REQUIREMENTS FOR OFFICE OF PATIENT ADVOCACY

Pub. L. 105–196, §6, July 16, 1998, 112 Stat. 636, provided that with respect to requirements for the office of patient advocacy under subsec. (d) of this section, the Secretary of Health and Human Services was to ensure that, not later than 180 days after Oct. 1, 1998, such office was in compliance with all requirements that were additional to the requirements under this section in effect with respect to patient advocacy on the day before July 16, 1998.

§ 274*l*. Stem cell therapeutic outcomes database

(a) Establishment

The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

(b) Information

The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) Annual report on patient outcomes

The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) Publicly available data

The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 274k of this title[1] donor registries, and cord blood banks.

(July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 105–196, §3, July 16, 1998, 112 Stat. 635; amended Pub. L. 109–129, §3(b), Dec. 20, 2005, 119 Stat. 2561.)

PRIOR PROVISIONS

A prior section 274*l*, act July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 101–616, title I, §101(a)(2), Nov. 16, 1990, 104 Stat. 3282, related to study by General Accounting Office, prior to repeal by Pub. L. 105–196, §§3, 7, July 16, 1998, 112 Stat. 635, 637, effective Oct. 1, 1998.

AMENDMENTS

2005—Pub. L. 109–129, amended section generally, substituting provisions relating to the stem cell therapeutic outcomes database for provisions relating to the bone marrow scientific registry.

EFFECTIVE DATE

Section effective Oct. 1, 1998, see section 7 of Pub. L. 105–196, set out as an Effective Date of 1998 Amendment note under section 274k of this title.

[1] So in original. Probably should be followed by a comma.

§ 274*l*–1. Definitions

In this part:

(1) The term ''Advisory Council'' means the advisory council established by the Secretary under section 274k(a)(1) of this title.

(2) The term ''bone marrow'' means the cells found in adult bone marrow and peripheral blood.

(3) The term ''outcomes database'' means the database established by the Secretary under section 274*l* of this title.

(4) The term ''Program'' means the C.W. Bill Young Cell Transplantation Program established under section 274k of this title.

(July 1, 1944, ch. 373, title III, §379A–1, as added Pub. L. 109–129, §3(c), Dec. 20, 2005, 119 Stat. 2562.)

§ 274m. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $33,000,000 for fiscal year 2015 and $30,000,000 for each of fiscal years 2016 through 2020.

(July 1, 1944, ch. 373, title III, §379B, as added Pub. L. 105–196, §4(2), July 16, 1998, 112 Stat. 636; amended Pub. L. 109–129, §3(d), Dec. 20, 2005, 119 Stat. 2562; Pub. L. 111–264, §2(d), Oct. 8, 2010, 124 Stat. 2792; Pub. L. 114–104, §2(b), Dec. 18, 2015, 129 Stat. 2216.)

AMENDMENTS

2015—Pub. L. 114–104 struck out ''$30,000,000 for each of fiscal years 2011 through 2014 and'' after ''to be appropriated'' and inserted ''and $30,000,000 for each of fiscal years 2016 through 2020'' after ''fiscal year 2015''.

2010—Pub. L. 111–264 substituted ''$30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015.'' for ''$34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010.''

2005—Pub. L. 109–129 amended section generally. Prior to amendment, section read as follows: ''For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.''

EFFECTIVE DATE

Section effective Oct. 1, 1998, see section 7 of Pub. L. 105–196, set out as an Effective Date of 1998 Amendment note under section 274k of this title.

§ 275. Repealed. Pub. L. 103–43, title I, § 121(a), June 10, 1993, 107 Stat. 133

Section, act July 1, 1944, ch. 373, title III, §381, as added Nov. 20, 1985, Pub. L. 99–158, §11, 99 Stat. 883; amended Nov. 4, 1988, Pub. L. 100–607, title I, §157(a), 102 Stat. 3059, established the Biomedical Ethics Board and provided for its membership, functions, reports to Congress, etc., and provided for appointment of a Biomedical Ethics Advisory Committee to assist the Biomedical Ethics Board.

A prior section 275, act July 1, 1944, ch. 373, title III, §381, formerly §371, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §381, Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), 84 Stat. 66, established a National Library of

Medicine in the Public Health Service and stated the congressional purposes for such establishment, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

§§ 276 to 280a–1. Repealed. Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879

Section 276, act July 1, 1944, ch. 373, title III, §382, formerly §372, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §382 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (b)(1), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(1), 85 Stat. 463, related to functions of Secretary with regard to acquisition, etc., of materials and rules for public access to materials.

Section 277, act July 1, 1944, ch. 373, title III, §383, formerly §373, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; amended Oct. 22, 1965, Pub. L. 89–291, §4, 79 Stat. 1067; renumbered §383 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(2), 85 Stat. 464; Nov. 9, 1978, Pub. L. 95–622, title II, §212, 92 Stat. 3421, related to establishment, etc., of Board of Regents.

Section 278, act July 1, 1944, ch. 373, title III, §384, formerly §374, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 961; renumbered §384 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Apr. 26, 1983, Pub. L. 98–24, §2(a)(2), 97 Stat. 176, related to acceptance and administration of gifts and establishment of memorials to donors.

Section 279, act July 1, 1944, ch. 373, title III, §385, formerly §375, as added Aug. 3, 1956, ch. 907 §1, 70 Stat. 962; renumbered §385 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (b)(2), 84 Stat. 66, defined ''medicine'' and ''medical''.

Section 280, act July 1, 1944, ch. 373, title III, §386, formerly §376, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; renumbered §386 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(3), 85 Stat. 464, authorized appropriations for erection and equipment of Library.

Section 280a, act July 1, 1944, ch. 373, title III, §387, formerly §377, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; amended 1970 Reorg. Plan No. 2 §102, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085; renumbered §387, Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), 84 Stat. 66, related to transfer of Armed Forces Medical Library to Public Health Service for use in administration of part I.

Section 280a–1, act July 1, 1944, ch. 373, title III, §388, formerly §378, as added Oct. 22, 1965, Pub. L. 89–291, §3, 79 Stat. 1067; renumbered §388 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(4), 85 Stat. 464, related to establishment of regional branches.

PART J—PREVENTION AND CONTROL OF INJURIES

CODIFICATION

Pub. L. 103–183, title II, §203(a)(1), Dec. 14, 1993, 107 Stat. 2232, substituted ''Prevention and Control of Injuries'' for ''Injury Control'' in part heading.

Pub. L. 103–43, title XX, §2008(i)(2)(B)(i), June 10, 1993, 107 Stat. 213, redesignated part K ''Injury Control'' as J. Former part J ''Biomedical Ethics'', consisting of section 275, was repealed by Pub. L. 103–43, title I, §121(a), June 10, 1993, 107 Stat. 133.

Pub. L. 101–616, title I, §101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part I ''Biomedical Ethics'' as J. Former part J ''Injury Control'' redesignated K.

§ 280b. Research

(a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries;

(2) make grants to, or enter into cooperative agreements or contracts with, public and nonprofit private entities (including academic institutions, hospitals, and laboratories) and individuals for the conduct of such research; and

(3) make grants to, or enter into cooperative agreements or contracts with, academic institutions for the purpose of providing training on the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall collect and disseminate, through publications and other appropriate means, information concerning the practical applications of research conducted or assisted under subsection (a). In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools.

(July 1, 1944, ch. 373, title III, §391, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3633; amended Pub. L. 101–558, §2(a), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §312(d)(3), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103–183, title II, §203(b)(2), Dec. 14, 1993, 107 Stat. 2232.)

PRIOR PROVISIONS

A prior section 280b, act July 1, 1944, ch. 373, title III, §390, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, §§4(b), 5(b), 6(b), 84 Stat. 64, 65; July 23, 1974, Pub. L. 93–353, title II, §§201(a), (b), 202(a), 88 Stat. 371, 372; Aug. 1, 1977, Pub. L. 95–83, title II, §202, 91 Stat. 386; Nov. 9, 1978, Pub. L. 95–622, title II, §211, 92 Stat. 3420; Aug. 13, 1981, Pub. L. 97–35, title IX, §925(a), 95 Stat. 569, set forth findings and declaration of policy and authorized appropriations with regard to assistance to medical libraries, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

A prior section 391 of act July 1, 1944, ch. 373, title III, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, §10(b)(3), 84 Stat. 66; July 23, 1974, Pub. L. 93–353, title II, §202(b), 88 Stat. 372, which defined ''sciences related to health'', ''National Medical Libraries Assistance Advisory Board'', ''Board'', and ''medical library'', was classified to section 280b–1 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–183 inserted at end ''In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools.''

1992—Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control'' in subsecs. (a) and (b).

1990—Subsec. (a)(2). Pub. L. 101–558, §2(a)(1), inserted '', or enter into cooperative agreements or contracts with,'' after ''grants to''.

Subsec. (a)(3). Pub. L. 101–558, §2(a)(2), added par. (3).

FINDINGS AND PURPOSES

Pub. L. 99–649, §2, Nov. 10, 1986, 100 Stat. 3633, provided that:

''(a) The Congress finds and declares that:

''(1) Injury is one of the principal public health problems in America, and causes over 140,000 deaths per year.

''(2) Injury rates are particularly high for children and the elderly.

''(3) Injury causes 50 percent of all deaths for children over the age of one year and two-thirds of all deaths for children over the age of 15 years, and is the leading cause of death for individuals under the age of 44 years. Individuals over the age of 65 years have the highest fatality rates for many injuries.

''(4) Injury control has not been given high priority in the United States, and the research being conducted on injury control and the number of personnel involved in injury control activities are not adequate.

''(b) The purposes of this Act [enacting this part] are—

''(1) to promote research into the causes, diagnosis, treatment, prevention, and control of injuries and rehabilitation from injuries;

''(2) to promote cooperation between specialists in fields involved in injury research; and

''(3) to promote coordination between Federal, State, and local governments and public and private entities in order to achieve a reduction in deaths from injuries.''

§ 280b–1. Prevention and control activities

(a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) assist States and political subdivisions of States in activities for the prevention and control of injuries; and

(2) encourage regional activities between States designed to reduce injury rates.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, may—

(1) enter into agreements between the Service and public and private community health agencies which provide for cooperative planning of activities to deal with problems relating to the prevention and control of injuries;

(2) work in cooperation with other Federal agencies, and with public and nonprofit private entities, to promote activities regarding the prevention and control of injuries; and

(3) make grants to States and, after consultation with State health agencies, to other public or nonprofit private entities for the purpose of carrying out demonstration projects for the prevention and control of injuries at sites that are not subject to the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.], including homes, elementary and secondary schools, and public buildings.

(July 1, 1944, ch. 373, title III, § 392, as added Pub. L. 99–649, § 3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, § 2(b), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §§ 301, 312(d)(4), Oct. 27, 1992, 106 Stat. 3482, 3504; Pub. L. 103–183, title II, § 203(a)(2), (b)(1), Dec. 14, 1993, 107 Stat. 2232.)

REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in subsec. (b)(3), is Pub. L. 91–596, Dec. 29, 1970, 84 Stat. 1590, as amended, which is classified principally to chapter 15 (§ 651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables.

PRIOR PROVISIONS

A prior section 280b–1, act July 1, 1944, ch. 373, title III, § 391, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, § 10(b)(3), 84 Stat. 66; July 23, 1974, Pub. L. 93–353, title II, § 202(b), 88 Stat. 372, defined ''sciences related to health'', ''National Medical Libraries Assistance Advisory Board'', ''Board'', and ''medical library'', prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

A prior section 392 of act July 1, 1944, ch. 373, title III, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, § 10(b)(4), (d)(2)(A), 84 Stat. 66, 67; July 23, 1974, Pub. L. 93–353, title II, § 202(c), 88 Stat. 372, which related to composition, functions, etc., of the National Medical Libraries Assistance Advisory Board, was classified to section 280b–2 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1993—Pub. L. 103–183, § 203(a)(2)(A), substituted ''Prevention and control activities'' for ''Control activities'' in section catchline.

Subsec. (a)(1). Pub. L. 103–183, § 203(a)(2)(B), inserted ''and control'' after ''prevention''.

Subsec. (b)(1). Pub. L. 103–183, § 203(a)(2)(C), substituted ''the prevention and control of injuries'' for ''injuries and injury control''.

Subsec. (b)(2). Pub. L. 103–183, § 203(b)(1), substituted ''to promote activities regarding the prevention and control of injuries; and'' for ''to promote injury control. In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools; and''.

1992—Pub. L. 102–531, § 312(d)(4), substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control'' in introductory provisions of subsecs. (a) and (b).

Subsec. (b)(1). Pub. L. 102–531, § 301(1), struck out ''and'' after semicolon at end.

Subsec. (b)(2). Pub. L. 102–531, § 301(2), inserted sentence requiring Secretary to disseminate information on injury control to the public, including through elementary and secondary schools and substituted ''; and'' for period at end.

Subsec. (b)(3). Pub. L. 102–531, § 301(3), added par. (3).

1990—Subsec. (b)(2). Pub. L. 101–558 amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''work in cooperation with Federal, State, and local agencies to promote injury control.''

§ 280b–1a. Interpersonal violence within families and among acquaintances

(a) With respect to activities that are authorized in sections 280b and 280b–1 of this title, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out such activities with respect to interpersonal violence within families and among acquaintances. Activities authorized in the preceding sentence include the following:

(1) Collecting data relating to the incidence of such violence.

(2) Making grants to public and nonprofit private entities for the evaluation of programs whose purpose is to prevent such violence, including the evaluation of demonstration projects under paragraph (6).

(3) Making grants to public and nonprofit private entities for the conduct of research on identifying effective strategies for preventing such violence.

(4) Providing to the public information and education on such violence, including information and education to increase awareness of the public health consequences of such violence.

(5) Training health care providers as follows:

(A) To identify individuals whose medical conditions or statements indicate that the individuals are victims of such violence.

(B) To routinely determine, in examining patients, whether the medical conditions or statements of the patients so indicate.

(C) To refer individuals so identified to entities that provide services regarding such violence, including referrals for counseling, housing, legal services, and services of community organizations.

(6) Making grants to public and nonprofit private entities for demonstration projects with respect to such violence, including with respect to prevention.

(b) For purposes of this part, the term ''interpersonal violence within families and among acquaintances'' includes behavior commonly referred to as domestic violence, sexual assault, spousal abuse, woman battering, partner abuse, elder abuse, and acquaintance rape.

(July 1, 1944, ch. 373, title III, § 393, as added Pub. L. 103–183, title II, § 201(2), Dec. 14, 1993, 107 Stat. 2231.)

PRIOR PROVISIONS

A prior section 393 of act July 1, 1944, was renumbered section 394 and is classified to section 280b–2 of this title.

Another prior section 393 of act July 1, 1944, was renumbered section 394 and was classified to section 280b–4 of this title.

§ 280b–1b. Use of allotments for rape prevention education

(a) Permitted use

The Secretary, acting through the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, shall award targeted grants to States to be used for rape prevention and education programs conducted by rape crisis centers, State, territorial or tribal sexual assault coalitions, and other public and private nonprofit entities for—

(1) educational seminars;

(2) the operation of hotlines;

(3) training programs for professionals;

(4) the preparation of informational material;

(5) education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;

(6) education to increase awareness about drugs and alcohol used to facilitate rapes or sexual assaults; and

(7) other efforts to increase awareness of the facts about, or to help prevent, sexual assault, including efforts to increase awareness in underserved communities and awareness among individuals with disabilities (as defined in section 12102 of this title).

(b) Collection and dissemination of information on sexual assault

The Secretary shall, through the National Resource Center on Sexual Assault established under the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, provide resource information, policy, training, and technical assistance to Federal, State, local, and Indian tribal agencies, as well as to State sexual assault coalitions and local sexual assault programs and to other professionals and interested parties on issues relating to sexual assault, including maintenance of a central resource library in order to collect, prepare, analyze, and disseminate information and statistics and analyses thereof relating to the incidence and prevention of sexual assault.

(c) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section $50,000,000 for each of fiscal years 2014 through 2018.

(2) National sexual violence resource center allotment

Of the total amount made available under this subsection in each fiscal year, not less than $1,500,000 shall be available for allotment under subsection (b).

(3) Baseline funding for States, the District of Columbia, and Puerto Rico

A minimum allocation of $150,000 shall be awarded in each fiscal year for each of the States, the District of Columbia, and Puerto Rico. A minimum allocation of $35,000 shall be awarded in each fiscal year for each Territory. Any unused or remaining funds shall be allotted to each State, the District of Columbia, and Puerto Rico on the basis of population.

(d) Limitations

(1) Supplement not supplant

Amounts provided to States under this section shall be used to supplement and not supplant other Federal, State, and local public funds expended to provide services of the type described in subsection (a).

(2) Studies

A State may not use more than 2 percent of the amount received by the State under this section for each fiscal year for surveillance studies or prevalence studies.

(3) Administration

A State may not use more than 5 percent of the amount received by the State under this section for each fiscal year for administrative expenses.

(July 1, 1944, ch. 373, title III, § 393A, formerly § 393B, as added Pub. L. 106–386, div. B, title IV, § 1401(a), Oct. 28, 2000, 114 Stat. 1512; amended Pub. L. 109–162, title III, § 302, Jan. 5, 2006, 119 Stat. 3004; renumbered § 393C, Pub. L. 110–202, § 2(1), Apr. 23, 2008, 122 Stat. 697; renumbered § 393A, Pub. L. 110–206, § 2(1), Apr. 28, 2008, 122 Stat. 714; Pub. L. 113–4, title III, § 301, Mar. 7, 2013, 127 Stat. 84.)

CODIFICATION

Section was formerly classified to section 280b–1c of this title. Pub. L. 110–206, which directed the renumbering of ''the section 393B (42 U.S.C. 280b–1c)'' of act July 1, 1944, ''relating to the use of allotments for rape prevention education'' as section 393A and the transfer of that section so as to appear after section 393 of that Act, was executed by renumbering section 393C of that Act as 393A and transferring the renumbered provisions

to this section, to reflect the probable intent of Congress and the renumbering of section 393B as 393C by section 2(1) of Pub. L. 110–202.

PRIOR PROVISIONS

A prior section 393A of act July 1, 1944, was renumbered section 393B and is classified to section 280b–1c of this title.

AMENDMENTS

2013—Subsec. (a). Pub. L. 113–4, §301(1)(A), inserted '', territorial or tribal'' after ''crisis centers, State'' in introductory provisions.

Subsec. (a)(6). Pub. L. 113–4, §301(1)(B), inserted ''and alcohol'' after ''about drugs''.

Subsec. (c)(1). Pub. L. 113–4, §301(2)(A), substituted ''$50,000,000 for each of fiscal years 2014 through 2018'' for ''$80,000,000 for each of fiscal years 2007 through 2011''.

Subsec. (c)(3). Pub. L. 113–4, §301(2)(B), added par. (3).

2006—Subsec. (c). Pub. L. 109–162 reenacted heading without change and amended text generally. Prior to amendment, text contained provisions in par. (1) authorizing appropriations for fiscal years 2001 through 2005 and in par. (2) directing an allotment under subsec. (b) of this section.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–4 not effective until the beginning of the fiscal year following Mar. 7, 2013, see section 4 of Pub. L. 113–4, set out as a note under section 2261 of Title 18, Crimes and Criminal Procedure.

§ 280b–1c. Prevention of traumatic brain injury

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out projects to reduce the incidence of traumatic brain injury. Such projects may be carried out by the Secretary directly or through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(b) Certain activities

Activities under subsection (a) may include—

(1) the conduct of research into identifying effective strategies for the prevention of traumatic brain injury;

(2) the implementation of public information and education programs for the prevention of such injury and for broadening the awareness of the public concerning the public health consequences of such injury; and

(3) the implementation of a national education and awareness campaign regarding such injury (in conjunction with the program of the Secretary regarding health-status goals for 2020, commonly referred to as Healthy People 2020), including—

(A) the national dissemination of information on—

(i) incidence and prevalence; and

(ii) information relating to traumatic brain injury and the sequelae of secondary conditions arising from traumatic brain injury upon discharge from hospitals and emergency departments; and

(B) the provision of information in primary care settings, including emergency rooms and trauma centers, concerning the availability of State level services and resources.

(c) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding traumatic brain injury.

(d) "Traumatic brain injury" defined

For purposes of this section, the term ''traumatic brain injury'' means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(July 1, 1944, ch. 373, title III, §393B, formerly §393A, as added Pub. L. 104–166, §1, July 29, 1996, 110 Stat. 1445; amended Pub. L. 106–310, div. A, title XIII, §1301(a), Oct. 17, 2000, 114 Stat. 1137; renumbered §393B and amended Pub. L. 110–206, §§2(2), 3(a), Apr. 28, 2008, 122 Stat. 714; Pub. L. 113–196, §2(a), Nov. 26, 2014, 128 Stat. 2052.)

CODIFICATION

Section was formerly classified to section 280b–1b of this title.

PRIOR PROVISIONS

Prior sections 393B of act July 1, 1944, were renumbered sections 393A and 393C and are classified to sections 280b–1b and 280b–1d, respectively, of this title.

AMENDMENTS

2014—Subsec. (b)(3). Pub. L. 113–196 substituted ''2020, commonly referred to as Healthy People 2020'' for ''2010, commonly referred to as Healthy People 2010'' in introductory provisions.

2008—Subsec. (b)(3)(A)(ii). Pub. L. 110–206, §3(a), substituted ''from hospitals and emergency departments'' for ''from hospitals and trauma centers''.

2000—Subsec. (b)(3). Pub. L. 106–310, §1301(a)(1), added par. (3).

Subsec. (d). Pub. L. 106–310, §1301(a)(2), substituted ''anoxia due to trauma'' for ''anoxia due to near drowning'' and inserted '', after consultation with States and other appropriate public or nonprofit private entities'' after ''Secretary determines necessary''.

§ 280b–1d. National program for traumatic brain injury surveillance and registries

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—

(1) demographic information about each traumatic brain injury;

(2) information about the circumstances surrounding the injury event associated with each traumatic brain injury;

(3) administrative information about the source of the collected information, dates of hospitalization and treatment, and the date of injury; and

(4) information characterizing the clinical aspects of the traumatic brain injury, including the severity of the injury, outcomes of the injury, the types of treatments received, and the types of services utilized.

(b) Report

Not later than 18 months after April 28, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit to the relevant committees of Congress a report that contains the findings derived from an evaluation concerning activities and procedures that can be implemented by the Centers for Disease Control and Prevention to improve the collection and dissemination of compatible epidemiological studies on the incidence and prevalence of traumatic brain injury in individuals who were formerly in the military. The report shall include recommendations on the manner in which such agencies can further collaborate on the development and improvement of traumatic brain injury diagnostic tools and treatments.

(July 1, 1944, ch. 373, title III, § 393C, formerly § 393B, as added Pub. L. 106–310, div. A, title XIII, § 1301(b), Oct. 17, 2000, 114 Stat. 1137; renumbered § 393C and amended Pub. L. 110–206, §§ 2(3), 3(b), (c), Apr. 28, 2008, 122 Stat. 714, 715.)

PRIOR PROVISIONS

A prior section 393C of act July 1, 1944, was renumbered section 393A and is classified to section 280b–1b of this title.

AMENDMENTS

2008—Pub. L. 110–206, § 3(b)(1), inserted ''surveillance and'' after ''National program for traumatic brain injury'' in section catchline.

Subsec. (a). Pub. L. 110–206, § 3(b)(2), in introductory provisions, substituted ''may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—'' for ''may make grants to States or their designees to operate the State's traumatic brain injury registry, and to academic institutions to conduct applied research that will support the development of such registries, to collect data concerning—''.

Subsec. (b). Pub. L. 110–206, § 3(c), added subsec. (b).

§ 280b–1e. Study on traumatic brain injury

(a) Study

The Secretary, acting through the Director of the Centers for Disease Control and Prevention with respect to paragraph (1) and in consultation with the Director of the National Institutes of Health and other appropriate entities with respect to paragraphs (2), (3), and (4), may conduct a study with respect to traumatic brain injury for the purpose of carrying out the following:

(1) In collaboration with appropriate State and local health-related agencies—

(A) determining the incidence of traumatic brain injury and prevalence of traumatic brain injury related disability and the clinical aspects of the disability in all age groups and racial and ethnic minority groups in the general population of the United States, including institutional settings, such as nursing homes, correctional facilities, psychiatric hospitals, child care facilities, and residential institutes for people with developmental disabilities; and

(B) reporting national trends in traumatic brain injury.

(2) Identifying common therapeutic interventions which are used for the rehabilitation of individuals with such injuries, and, subject to the availability of information, including an analysis of—

(A) the effectiveness of each such intervention in improving the functioning, including return to work or school and community participation, of individuals with brain injuries;

(B) the comparative effectiveness of interventions employed in the course of rehabilitation of individuals with brain injuries to achieve the same or similar clinical outcome; and

(C) the adequacy of existing measures of outcomes and knowledge of factors influencing differential outcomes.

(3) Identifying interventions and therapies that can prevent or remediate the development of secondary neurologic conditions related to traumatic brain injury.

(4) Developing practice guidelines for the rehabilitation of traumatic brain injury at such time as appropriate scientific research becomes available.

(b) Dates certain for reports

If the study is conducted under subsection (a), the Secretary shall, not later than 3 years after April 28, 2008, submit to Congress a report describing findings made as a result of carrying out such subsection (a).

(c) Definition

For purposes of this section, the term ''traumatic brain injury'' means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma including near drowning. The Secretary may revise the definition of such term as the Secretary determines necessary.

(July 1, 1944, ch. 373, title III, § 393C–1, as added Pub. L. 110–206, § 4, Apr. 28, 2008, 122 Stat. 715.)

§ 280b–1f. Prevention of falls among older adults

(a) Public education

The Secretary may—

(1) oversee and support a national education campaign to be carried out by a nonprofit organization with experience in designing and implementing national injury prevention programs, that is directed principally to older adults, their families, and health care providers, and that focuses on reducing falls among older adults and preventing repeat falls; and

(2) award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, for the purpose of organizing State-level coalitions of appropriate State and local agencies, safety, health, senior citizen, and other organizations to design and carry out local education campaigns, focusing on reducing falls among older adults and preventing repeat falls.

(b) Research

(1) In general

The Secretary may—

(A) conduct and support research to—

(i) improve the identification of older adults who have a high risk of falling;

(ii) improve data collection and analysis to identify fall risk and protective factors;

(iii) design, implement, and evaluate the most effective fall prevention interventions;

(iv) improve strategies that are proven to be effective in reducing falls by tailoring these strategies to specific populations of older adults;

(v) conduct research in order to maximize the dissemination of proven, effective fall prevention interventions;

(vi) intensify proven interventions to prevent falls among older adults;

(vii) improve the diagnosis, treatment, and rehabilitation of elderly fall victims and older adults at high risk for falls; and

(viii) assess the risk of falls occurring in various settings;

(B) conduct research concerning barriers to the adoption of proven interventions with respect to the prevention of falls among older adults;

(C) conduct research to develop, implement, and evaluate the most effective approaches to reducing falls among high-risk older adults living in communities and long-term care and assisted living facilities; and

(D) evaluate the effectiveness of community programs designed to prevent falls among older adults.

(2) Educational support

The Secretary, either directly or through awarding grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, may provide professional education for physicians and allied health professionals, and aging service providers in fall prevention, evaluation, and management.

(c) Demonstration projects

The Secretary may carry out the following:

(1) Oversee and support demonstration and research projects to be carried out by qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in the following areas:

(A) A multistate demonstration project assessing the utility of targeted fall risk screening and referral programs.

(B) Programs designed for community-dwelling older adults that utilize multicomponent fall intervention approaches, including physical activity, medication assessment and reduction when possible, vision enhancement, and home modification strategies.

(C) Programs that are targeted to new fall victims who are at a high risk for second falls and which are designed to maximize independence and quality of life for older adults, particularly those older adults with functional limitations.

(D) Private sector and public-private partnerships to develop technologies to prevent falls among older adults and prevent or reduce injuries if falls occur.

(2)(A) Award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to design, implement, and evaluate fall prevention programs using proven intervention strategies in residential and institutional settings.

(B) Award 1 or more grants, contracts, or cooperative agreements to 1 or more qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in order to carry out a multistate demonstration project to implement and evaluate fall prevention programs using proven intervention strategies designed for single and multifamily residential settings with high concentrations of older adults, including—

(i) identifying high-risk populations;

(ii) evaluating residential facilities;

(iii) conducting screening to identify high-risk individuals;

(iv) providing fall assessment and risk reduction interventions and counseling;

(v) coordinating services with health care and social service providers; and

(vi) coordinating post-fall treatment and rehabilitation.

(3) Award 1 or more grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to conduct evaluations of the effectiveness of the demonstration projects described in this subsection.

(d) Priority

In awarding grants, contracts, or cooperative agreements under this section, the Secretary may give priority to entities that explore the use of cost-sharing with respect to activities funded under the grant, contract, or agreement to ensure the institutional commitment of the recipients of such assistance to the projects funded under the grant, contract, or agreement. Such non-Federal cost sharing contributions may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Study of effects of falls on health care costs

(1) In general

The Secretary may conduct a review of the effects of falls on health care costs, the potential for reducing falls, and the most effective strategies for reducing health care costs associated with falls.

(2) Report

If the Secretary conducts the review under paragraph (1), the Secretary shall, not later than 36 months after April 23, 2008, submit to Congress a report describing the findings of the Secretary in conducting such review.

(July 1, 1944, ch. 373, title III, § 393D, as added Pub. L. 110–202, § 2(2), Apr. 23, 2008, 122 Stat. 697.)

§ 280b–2. General provisions

(a) Advisory committee

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to advise the Secretary and such Director with respect to the prevention and control of injuries.

(b) Technical assistance

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may provide technical assistance to public and nonprofit private entities with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(c) Biennial report

Not later than February 1 of 1995 and of every second year thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this part during the preceding 2 fiscal years. Such report shall include a description of such activities that were carried out with respect to interpersonal violence within families and among acquaintances and with respect to rural areas.

(July 1, 1944, ch. 373, title III, § 394, formerly § 393, as added Pub. L. 99–649, § 3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, § 2(c), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, § 312(d)(5), Oct. 27, 1992, 106 Stat. 3504; renumbered § 394 and amended Pub. L. 103–183, title II, §§ 201(1), 202, Dec. 14, 1993, 107 Stat. 2231, 2232.)

PRIOR PROVISIONS

A prior section 280b–2, act July 1, 1944, ch. 373, title III, § 392, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, § 10(b)(4), (d)(2)(A), 84 Stat. 66, 67; July 23, 1974, Pub. L. 93–353, title II, § 202(c), 88 Stat. 372, related to composition, functions, etc., of National Medical Libraries Assistance Advisory Board, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

A prior section 394 of act July 1, 1944, was renumbered section 394A and is classified to section 280b–3 of this title.

AMENDMENTS

1993—Pub. L. 103–183, § 202, amended section generally. Prior to amendment, section read as follows: ''By not later than September 30, 1992, the Secretary, through the Director of the Centers for Disease Control and Prevention, shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities conducted or supported under this part. The report shall include—

''(1) information regarding the practical applications of research conducted pursuant to subsection (a) of section 280b of this title, including information that has not been disseminated under subsection (b) of such section; and

''(2) information on such activities regarding the prevention and control of injuries in rural areas, including information regarding injuries that are particular to rural areas.''

1992—Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control'' in introductory provisions.

1990—Pub. L. 101–558 amended section generally. Prior to amendment, section read as follows: ''By January 1, 1989, the Secretary, through the Director of the Centers for Disease Control, shall prepare and transmit to the Congress a report analyzing the incidence and causes of childhood injuries in the United States and containing recommendations for such legislation with respect to injury control as the Secretary considers appropriate.''

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.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees 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 committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 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.

§ 280b–3. Authorization of appropriations

(a) In general

For the purpose of carrying out this part, there are authorized to be appropriated $50,000,000 for fiscal year 1994, such sums as may be necessary for each of the fiscal years 1995 through 1998, and such sums as may be necessary for each of the fiscal years 2001 through 2005.

(b) Traumatic brain injury

To carry out sections 280b–1c and 280b–1d of this title, there are authorized to be appropriated $6,564,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title III, § 394A, formerly § 394, as added Pub. L. 99–649, § 3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, § 2(d), Nov. 15, 1990, 104 Stat. 2773; renumbered § 394A and amended Pub. L. 103–183, title II, §§ 201(1), 204, Dec. 14, 1993, 107 Stat. 2231, 2233; Pub. L. 106–310, div. A, title XIII, § 1306, Oct. 17, 2000, 114 Stat. 1143; Pub. L. 113–196, § 2(b), Nov. 26, 2014, 128 Stat. 2052.)

PRIOR PROVISIONS

A prior section 280b–3, act July 1, 1944, ch. 373, title III, § 393, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(a), 3, 10(d)(2), 84 Stat. 63, 64, 67, related to grants for construction of medical library facilities, prior to repeal by Pub. L. 93–353, title II, § 202(d), July 23, 1974, 88 Stat. 372.

AMENDMENTS

2014—Pub. L. 113–196 substituted ''Authorization of appropriations'' for ''Authorizations of appropriations'' in section catchline; designated existing provisions as subsec. (a), inserted heading, and struck out second period at end; and added subsec. (b).

2000—Pub. L. 106–310, which directed the amendment of this section by striking out ''and'' after ''1994'', was executed by striking ''and'' after ''1994,'' to reflect the probable intent of Congress.

Pub. L. 106–310 inserted before period at end '', and such sums as may be necessary for each of the fiscal years 2001 through 2005.''

1993—Pub. L. 103–183, § 204, amended section generally. Prior to amendment, section read as follows: ''To carry out sections 280b and 280b–1 of this title, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1988, 1989, and 1990, $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.''

1990—Pub. L. 101–558 struck out subsec. (a) designation, inserted before period at end of first sentence '', $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993'', and struck out at end ''Of the amounts appropriated under this section for any fiscal year, not more than 20 percent may be used for Federal administrative expenses to carry out such section for such fiscal year.''

§ 280b–4. Study conducted by the Centers for Disease Control and Prevention

(a) Purposes

The Secretary of Health and Human Services acting through the National Center for Injury Prevention and Control at the Centers for Disease Control[1] Prevention shall make grants to entities, including domestic and sexual assault coalitions and programs, research organizations, tribal organizations, and academic institutions to support research to examine prevention and intervention programs to further the understanding of sexual and domestic violence by and against adults, youth, and children.

(b) Use of funds

The research conducted under this section shall include evaluation and study of best practices for reducing and preventing violence against women and children addressed by the strategies included in Department of Health and Human Services-related provisions[2] this title,[3] including strategies addressing underserved communities.

(c) Authorization of appropriations

There shall be authorized to be appropriated to carry out this title $1,000,000 for each of the fiscal years 2014 through 2018.

(Pub. L. 109–162, title IV, § 402, Jan. 5, 2006, 119 Stat. 3023; Pub. L. 113–4, title IV, § 401, Mar. 7, 2013, 127 Stat. 92.)

REFERENCES IN TEXT

This title, referred to in subsecs. (b) and (c), is title IV of Pub. L. 109–162, Jan. 5, 2006, 119 Stat. 3017, which enacted this section and part L (§ 14043d et seq.) of subchapter III of chapter 136 and section 14045c of this title. For complete classification of title IV to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Violence Against Women and Department of Justice Reauthorization Act of 2005, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Prior sections 280b–4 to 280b–11 were repealed by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

Section 280b–4, act July 1, 1944, ch. 373, title III, § 393, formerly § 394, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1062; amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(b), 10(d)(2)(A), 84 Stat. 63, 67; June 18, 1973, Pub. L. 93–45, title I, § 107(a), 87 Stat. 92; renumbered § 393 and amended July 23, 1974, Pub. L. 93–353, title II, §§ 203(a), 204, 88 Stat. 372, 373, related to grants for training in medical library sciences.

Section 280b–5, act July 1, 1944, ch. 373, title III, § 394, formerly § 395, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1062; amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(c), (d), 4(a), 5(a), 10(c)(1)(A), (B), (2)(A)–(C), (d)(2)(A), 84 Stat. 63, 64, 66, 67; June 18, 1973, Pub. L. 93–45, title I, § 107(b), (c), 87 Stat. 92; renumbered § 394 and amended July 23, 1974, Pub. L. 93–353, title II, §§ 203(b), 204, 88 Stat. 372, 373, related to assistance for special scientific projects; research and development in medical library science and related fields.

Section 280b–6, act July 1, 1944, ch. 373, title III, § 396, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1063, was redesignated as subsecs. (b) and (c) of section 280b–5 of this title by Pub. L. 91–212, § 10(c)(2), Mar. 13, 1970, 84 Stat. 66.

Section 280b–7, act July 1, 1944, ch. 373, title III, § 395, formerly § 397, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1063; renumbered § 396 and amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(e), 6(a)(1), (2), 10(c)(3), (d)(2)(A),

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

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

[3] See References in Text note below.

84 Stat. 63, 64, 67; June 18, 1973, Pub. L. 93–45, title I, §107(d), 87 Stat. 92; renumbered §395 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(c), 204, 88 Stat. 372, 373, related to grants for establishing, expanding, and improving basic medical library or related resources.

Section 280b–8, act July 1, 1944, ch. 373, title III, §396, formerly §398, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1065; renumbered §397 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(f), 7, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(e), 87 Stat. 92; renumbered §396 and amended July 23, 1974, Pub. L. 93–353, title II, §§202(e), (f), 203(d), 204, 88 Stat. 372, 373, related to grants for establishment of regional medical libraries.

Section 280b–9, act July 1, 1944, ch. 373, title III, §397, formerly §399, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §398 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(g), 8, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(f), 87 Stat. 92; renumbered §397 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(e), 204, 88 Stat. 372, 373, related to grants to provide support for biomedical scientific publications.

Section 280b–10, act July 1, 1944, ch. 373, title III, §398, formerly §399a, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399, Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), 84 Stat. 67; renumbered §398, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373, related to the continuing availability of appropriated funds.

Section 280b–11, act July 1, 1944, ch. 373, title III, §399, formerly §399b, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399a and amended Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), (d)(2)(A), 84 Stat. 67; renumbered §399, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, related to the maintenance of records by recipients of grants and audits thereof by the Secretary of Health and Human Services and the Comptroller General of the United States.

A prior section 280b–12, act July 1, 1944, ch. 373, title III, §399b, as added Mar. 13, 1970, Pub. L. 91–212, §9, 84 Stat. 65, related to transfer of funds, prior to repeal by Pub. L. 93–353, title II, §204, July 23, 1974, 88 Stat. 373, applicable with respect to fiscal years beginning after June 30, 1974.

AMENDMENTS

2013—Subsec. (c). Pub. L. 113–4 substituted ''$1,000,000 for each of the fiscal years 2014 through 2018'' for ''$2,000,000 for each of the fiscal years 2007 through 2011''.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–4 not effective until the beginning of the fiscal year following Mar. 7, 2013, see section 4 of Pub. L. 113–4, set out as a note under section 2261 of Title 18, Crimes and Criminal Procedure.

PART K—HEALTH CARE SERVICES IN THE HOME

CODIFICATION

Pub. L. 103–43, title XX, §2008(i)(2)(B)(i), June 10, 1993, 107 Stat. 213, redesignated part L ''Health Care Services in the Home'' as K. Former part K ''Injury Control'' redesignated J.

Pub. L. 101–616, title I, §101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part J ''Injury Control'' as K. Former part K ''Health Care Services in the Home'' redesignated L.

PRIOR PROVISIONS

A prior part K, added Pub. L. 93–222, §3, Dec. 29, 1973, 87 Stat. 934, related to quality assurance, prior to repeal by Pub. L. 95–623, §11(b), Nov. 9, 1978, 92 Stat. 3455.

SUBPART I—GRANTS FOR DEMONSTRATION PROJECTS

§ 280c. Establishment of program

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make not less than 5, and not more than 20, grants to States for the purpose of assisting grantees in carrying out demonstration projects—

(1) to identify low-income individuals who can avoid institutionalization or prolonged hospitalization if skilled medical services, skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals;

(2) to pay the costs of the provision of such services in the homes of such individuals; and

(3) to coordinate the provision by public and private entities of such services, and other long-term care services, in the homes of such individuals.

(b) Requirement with respect to age of recipients of services

The Secretary may not make a grant under subsection (a) to a State unless the State agrees to ensure that—

(1) not less than 25 percent of the grant is expended to provide services under such subsection to individuals who are not less than 65 years of age; and

(2) of the portion of the grant reserved by the State for purposes of complying with paragraph (1), not less than 10 percent is expended to provide such services to individuals who are not less than 85 years of age.

(c) Relationship to items and services under other programs

A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

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

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

(July 1, 1944, ch. 373, title III, §395, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 979; amended Pub. L. 101–557, title I, §101(a)–(c), Nov. 15, 1990, 104 Stat. 2766; Pub. L. 102–108, §2(f), Aug. 17, 1991, 105 Stat. 550.)

PRIOR PROVISIONS

A prior section 280C, act July 1, 1944, ch. 373, title III, §399A, formerly §399c, as added Dec. 29, 1973, Pub. L. 93–222, §3, 87 Stat. 934; renumbered §399A, July 29, 1975, Pub. L. 94–63, title VI, §607(a), (c), 89 Stat. 351, provided for programs designed to assure the quality of health care, prior to repeal by Pub. L. 95–623, §11(b), Nov. 9, 1978, 92 Stat. 3455.

A prior section 395 of act July 1, 1944, ch. 373, title III, formerly §397, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1063; renumbered §396 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(e), 6(a)(1), (2), 10(c)(3), (d)(2)(A), 84 Stat. 63, 64, 67; June 18, 1973, Pub. L. 93–45, title I, §107(d), 87 Stat. 92; renumbered §395 and amended July

23, 1974, Pub. L. 93–353, title II, §§ 203(c), 204, 88 Stat. 372, 373, which related to grants for establishing, expanding, and improving basic medical library or related resources, was classified to section 280b–7 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1991—Subsec. (a)(1). Pub. L. 102–108 inserted ''skilled medical services,'' after ''if''.

1990—Subsec. (a). Pub. L. 101–557, § 101(a), substituted ''shall make not less than 5, and not more than 20, grants'' for ''shall make not less than 3, and not more than 5, grants''.

Subsec. (a)(1). Pub. L. 101–557, § 101(b), substituted ''skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals'' for ''skilled medical services or related health services (or both) are provided in the homes of the individuals''.

Subsec. (b). Pub. L. 101–557, § 101(c), substituted ''to ensure that—'' and pars. (1) and (2) for ''to ensure that not less than 25 percent of individuals receiving services pursuant to subsection (a) of this section are individuals who are not less than 65 years of age''.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

SHORT TITLE

For short title of title VI of Pub. L. 100–175, which enacted this part as the ''Health Care Services in the Home Act of 1987'', see section 601 of Pub. L. 100–175, set out as a Short Title of 1987 Amendments note under section 201 of this title.

§ 280c–1. Limitation on duration of grant and requirement of matching funds

(a) Limitation on duration of grant

The period during which payments are made to a State from a grant under section 280c(a) of this title may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.

(b) Requirement of matching funds

(1)(A) For the first year of payments to a State from a grant under section 280c(a) of this title, the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 280c(a) of this title to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than $25 (in cash or in kind under subsection (c)) for each $75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than $35 (in cash or in kind under subsection (c)) for each $65 of such Federal funds; and

(C) for the third year of such payments to the State, not less than $45 (in cash or in kind under subsection (c)) for each $55 of such Federal funds.

(c) Determination of amount of non-Federal contribution

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

(July 1, 1944, ch. 373, title III, § 396, as added Pub. L. 100–175, title VI, § 602, Nov. 29, 1987, 101 Stat. 979.)

PRIOR PROVISIONS

A prior section 396 of act July 1, 1944, ch. 373, title III, formerly § 398, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1065; renumbered § 397 and amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(f), 7, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, § 107(e), 87 Stat. 92; renumbered § 396 and amended July 23, 1974, Pub. L. 93–353, title II, §§ 202(e), (f), 203(d), 204, 88 Stat. 372, 373, which related to grants for establishment of regional medical libraries, was classified to section 280b–8 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

§ 280c–2. General provisions

(a) Limitation on administrative expenses

The Secretary may not make a grant under section 280c(a) of this title to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) Description of intended use of grant

The Secretary may not make a grant under section 280c(a) of this title to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 280c(a) of this title and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) Requirement of application

The Secretary may not make a grant under section 280c(a) of this title to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) Evaluations and report by Secretary

The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 280c(a) of this title; and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) Authorizations of appropriations

For the purpose of carrying out this subpart, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990, $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(July 1, 1944, ch. 373, title III, § 397, as added Pub. L. 100–175, title VI, § 602, Nov. 29, 1987, 101 Stat. 980; amended Pub. L. 101–557, title I, § 101(d), Nov. 15, 1990, 104 Stat. 2766.)

PRIOR PROVISIONS

A prior section 397 of act July 1, 1944, ch. 373, title III, formerly § 399, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1066; renumbered § 398 and amended Mar. 13, 1970, Pub. L. 91–212, §§ 2(g), 8, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, § 107(f), 87 Stat. 92; renumbered § 397 and amended July 23, 1974, Pub. L. 93–353, title II, §§ 203(e), 204, 88 Stat. 372, 373, which related to grants to provide support for biomedical scientific publications, was classified to section 280b–9 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Subsec. (e). Pub. L. 101–557 substituted ''there are'' for ''there is'' and inserted before period at end '', $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993''.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

SUBPART II—GRANTS FOR DEMONSTRATION PROJECTS WITH RESPECT TO ALZHEIMER'S DISEASE

§ 280c–3. Establishment of program

(a) In general

The Secretary shall make grants to States for the purpose of assisting grantees in carrying out demonstration projects for planning, establishing, and operating programs—

(1) to coordinate the development and operation with public and private organizations of diagnostic, treatment, care management, respite care, legal counseling, and education services provided within the State to individuals with Alzheimer's disease or related disorders and to the families and care providers of such individuals;

(2) to provide home health care, personal care, day care, companion services, short-term care in health facilities, and other respite care to individuals with Alzheimer's disease or related disorders who are living in single family homes or in congregate settings;

(3) to improve the access of such individuals to home-based or community-based long-term care services (subject to the services being provided by entities that were providing such services in the State involved as of October 1, 1995), particularly such individuals who are members of racial or ethnic minority groups, who have limited proficiency in speaking the English language, or who live in rural areas; and

(4) to provide to health care providers, to individuals with Alzheimer's disease or related disorders, to the families of such individuals, to organizations established for such individuals and such families, and to the general public, information with respect to—

(A) diagnostic services, treatment services, and related services available to such individuals and to the families of such individuals;

(B) sources of assistance in obtaining such services, including assistance under entitlement programs; and

(C) the legal rights of such individuals and such families.

(b) Requirement with respect to certain expenditures

The Secretary may not make a grant under subsection (a) to a State unless the State agrees to expend not less than 50 percent of the grant for the provision of services described in subsection (a)(2).

(c) Relationship to items and services under other programs

A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

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

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

(July 1, 1944, ch. 373, title III, § 398, as added Pub. L. 100–175, title VI, § 602, Nov. 29, 1987, 101 Stat. 981; amended Pub. L. 101–557, title I, § 102(a), (b), Nov. 15, 1990, 104 Stat. 2767; Pub. L. 105–392, title III, § 302(a), Nov. 13, 1998, 112 Stat. 3586.)

PRIOR PROVISIONS

A prior section 398 of act July 1, 1944, ch. 373, title III, formerly § 399a, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1066; renumbered § 399, Mar. 13, 1970, Pub. L. 91–212, § 10(c)(3), 84 Stat. 67; renumbered § 398, July 23, 1974, Pub. L. 93–353, title II, § 204, 88 Stat. 373, which related to the continuing availability of appropriated funds, was classified to section 280b–10 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1998—Subsec. (a). Pub. L. 105–392, § 302(a)(1), struck out ''not less than 5, and not more than 15,'' after ''shall make'' in introductory provisions.

Subsec. (a)(2). Pub. L. 105–392, § 302(a)(2), inserted ''who are living in single family homes or in congregate

settings'' after ''disorders'' and struck out ''and'' at end.

Subsec. (a)(3), (4). Pub. L. 105–392, § 302(a)(3), (4), added par. (3) and redesignated former par. (3) as (4).

1990—Subsec. (a). Pub. L. 101–557, § 102(a), substituted ''shall make not less than 5, and not more than 15, grants'' for ''shall make not less than 3, and not more than 5, grants''.

Subsec. (a)(1). Pub. L. 101–557, § 102(b), substituted ''with public and private organizations'' for ''by public and private organizations''.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

§ 280c–4. Requirement of matching funds

(a) Requirement of matching funds

(1)(A) For the first year of payments to a State from a grant under section 280c–3(a) of this title, the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third or subsequent year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 280c–3(a) of this title to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than $25 (in cash or in kind under subsection (c)[1]) for each $75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than $35 (in cash or in kind under subsection (c)[1]) for each $65 of such Federal funds; and

(C) for the third or subsequent year of such payments to the State, not less than $45 (in cash or in kind under subsection (c)[1]) for each $55 of such Federal funds.

(b) Determination of amount of non-Federal contribution

Non-Federal contributions required in subsection (b)[2] 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.

(July 1, 1944, ch. 373, title III, § 398A, formerly § 399, as added Pub. L. 100–175, title VI, § 602, Nov. 29, 1987, 101 Stat. 982; renumbered § 398A, Pub. L. 102–321, title V, § 502(1), July 10, 1992, 106 Stat. 427; amended Pub. L. 105–392, title III, § 302(b), Nov. 13, 1998, 112 Stat. 3586.)

[1] Probably should be ''subsection (b)''.

[2] Probably should be ''subsection (a)''.

AMENDMENTS

1998—Pub. L. 105–392, § 302(b)(1), substituted ''Requirement of matching funds'' for ''Limitation on duration of grant and requirement of matching funds'' in section catchline.

Subsec. (a). Pub. L. 105–392, § 302(b)(2)–(4), redesignated subsec. (b) as (a), substituted ''third or subsequent year'' for ''third year'' in pars. (1)(C) and (2)(C), and struck out heading and text of former subsec. (a). Text read as follows: ''The period during which payments are made to a State from a grant under section 280c–3(a) of this title may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.''

Subsecs. (b), (c). Pub. L. 105–392, § 302(b)(3), redesignated subsecs. (b) and (c) as (a) and (b), respectively.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

§ 280c–5. General provisions

(a) Limitation on administrative expenses

The Secretary may not make a grant under section 280c–3(a) of this title to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) Description of intended use of grant

The Secretary may not make a grant under section 280c–3(a) of this title to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 280c–3(a) of this title and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities.

(c) Requirement of application

The Secretary may not make a grant under section 280c–3(a) of this title to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) Evaluations and report by Secretary

The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 280c–3(a) of this title; and

(2) not later than 6 months after the completion of such evaluations, submit to the Con-

gress a report describing the findings made as a result of the evaluations.

(e) Authorizations of appropriations

For the purpose of carrying out this subpart, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990, $7,500,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $8,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(July 1, 1944, ch. 373, title III, § 398B, formerly § 399A, as added Pub. L. 100–175, title VI, § 602, Nov. 29, 1987, 101 Stat. 982; amended Pub. L. 101–557, title I, § 102(c), Nov. 15, 1990, 104 Stat. 2767; renumbered § 398B, Pub. L. 102–321, title V, § 502(1), July 10, 1992, 106 Stat. 427; Pub. L. 105–392, title III, § 302(c), Nov. 13, 1998, 112 Stat. 3586.)

AMENDMENTS

1998—Subsec. (e). Pub. L. 105–392 substituted ''1991, such sums'' for ''1991, and such sums'' and inserted before period at end '', $8,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002''.

1990—Subsec. (e). Pub. L. 101–557 substituted ''there are'' for ''there is'' and inserted before period at end '', $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993''.

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

SUBPART III—GRANTS FOR HOME VISITING SERVICES FOR AT-RISK FAMILIES

§ 280c–6. Projects to improve maternal, infant, and child health

(a) In general

(1) Establishment of program

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to pay the Federal share of the cost of providing the services specified in subsection (b) to families in which a member is—

(A) a pregnant woman at risk of delivering an infant with a health or developmental complication; or

(B) a child less than 3 years of age—

(i) who is experiencing or is at risk of a health or developmental complication, or of child abuse or neglect; or

(ii) who has been prenatally exposed to maternal substance abuse.

(2) Minimum period of awards; administrative consultations

(A) The Secretary shall award grants under paragraph (1) for periods of at least three years.

(B) The Administrator of the Administration for Children, Youth, and Families and the Director of the National Commission to Prevent Infant Mortality shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) Requirement of status as medicaid provider

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) Home visiting services for eligible families

With respect to an eligible family, each of the following services shall, directly or through arrangement with other public or nonprofit private entities, be available (as applicable to the family member involved) in each project operated with a grant under subsection (a):

(1) Prenatal and postnatal health care.

(2) Primary health care for the children, including developmental assessments.

(3) Education for the parents concerning infant care and child development, including the development and utilization of parent and teacher resource networks and other family resource and support networks where such networks are available.

(4) Upon the request of a parent, providing the education described in paragraph (3) to other individuals who have responsibility for caring for the children.

(5) Education for the parents concerning behaviors that adversely affect health.

(6) Assistance in obtaining necessary health, mental health, developmental, social, housing, and nutrition services and other assistance, including services and other assistance under maternal and child health programs; the special supplemental nutrition program for women, infants, and children; section 1786 of this title; title V of the Social Security Act [42 U.S.C. 701 et seq.]; title XIX of such Act [42 U.S.C. 1396 et seq.] (including the program for early and periodic screening, diagnostic, and treatment services described in section 1905(r) of such Act [42 U.S.C. 1396d(r)]); titles IV and

XIX of the Social Security Act [42 U.S.C. 601 et seq., 1396 et seq.]; housing programs; other food assistance programs; and appropriate alcohol and drug dependency treatment programs, according to need.

(c) Considerations in making grants

In awarding grants under subsection (a), the Secretary shall take into consideration—

(1) the ability of the entity involved to provide, either directly or through linkages, a broad range of preventive and primary health care services and related social, family support, and developmental services;

(2) different combinations of professional and lay home visitors utilized within programs that are reflective of the identified service needs and characteristics of target populations;

(3) the extent to which the population to be targeted has limited access to health care, and related social, family support, and developmental services; and

(4) whether such grants are equitably distributed among urban and rural settings and whether entities serving Native American communities are represented among the grantees.

(d) Federal share

With respect to the costs of carrying out a project under subsection (a), a grant under such subsection for the project may not exceed 90 percent of such costs. To be eligible to receive such a grant, an applicant must provide assurances that the applicant will obtain at least 10 percent of such costs from non-Federal funds (and such contributions to such costs may be in cash or in-kind, including facilities and personnel).

(e) Rule of construction regarding at-risk births

For purposes of subsection (a)(1), a pregnant woman shall be considered to be at risk of delivering an infant with a health or developmental complication if during the pregnancy the woman—

(1) lacks appropriate access to, or information concerning, early and routine prenatal care;

(2) lacks the transportation necessary to gain access to the services described in subsection (b);

(3) lacks appropriate child care assistance, which results in impeding the ability of such woman to utilize health and related social services;

(4) is fearful of accessing substance abuse services or child and family support services; or

(5) is a minor with a low income.

(f) Delivery of services and case management

(1) Case management model

Home visiting services provided under this section shall be delivered according to a case management model, and a registered nurse, licensed social worker, or other licensed health care professional with experience and expertise in providing health and related social services in home and community settings shall be assigned as the case manager for individual cases under such model.

(2) Case manager

A case manager assigned under paragraph (1) shall have primary responsibility for coordinating and overseeing the development of a plan for each family that is to receive home visiting services under this section, and for coordinating the delivery of such services provided through appropriate personnel.

(3) Appropriate personnel

In determining which personnel shall be utilized in the delivery of services, the case manager shall consider—

(A) the stated objective of the project to be operated with the grant, as determined after considering identified gaps in the current service delivery system; and

(B) the nature of the needs of the family to be served, as determined at the initial assessment of the family that is conducted by the case manager, and through follow-up contacts by other providers of home visiting services.

(4) Family service plan

A case manager, in consultation with a team established in accordance with paragraph (5) for the family involved, shall develop a plan for the family following the initial visit to the home of the family. Such plan shall reflect—

(A) an assessment of the health and related social service needs of the family;

(B) a structured plan for the delivery of home visiting services to meet the identified needs of the family;

(C) the frequency with which such services are to be provided to the family;

(D) ongoing revisions made as the needs of family members change; and

(E) the continuing voluntary participation of the family in the plan.

(5) Home visiting services team

The team to be consulted under paragraph (4) on behalf of a family shall include, as appropriate, other nursing professionals, physician assistants, social workers, child welfare professionals, infant and early childhood specialists, nutritionists, and laypersons trained as home visitors. The case manager shall ensure that the plan is coordinated with those physician services that may be required by the mother or child.

(g) Outreach

Each grantee under subsection (a) shall provide outreach and casefinding services to inform eligible families of the availability of home visiting services from the project.

(h) Confidentiality

In accordance with applicable State law, an entity receiving a grant under subsection (a) shall maintain confidentiality with respect to services provided to families under this section.

(i) Certain assurances

The Secretary may award a grant under subsection (a) only if the entity involved provides assurances satisfactory to the Secretary that—

(1) the entity will provide home visiting services with reasonable frequency—

(A) to families with pregnant women, as early in the pregnancy as is practicable, and

until the infant reaches at least 2 years of age; and

(B) to other eligible families, for at least 2 years; and

(2) the entity will coordinate with public health and related social service agencies to prevent duplication of effort and improve the delivery of comprehensive health and related social services.

(j) Submission to Secretary of certain information

The Secretary may award a grant under subsection (a) only if the entity involved submits to the Secretary—

(1) a description of the population to be targeted for home visiting services and methods of outreach and casefinding for identifying eligible families, including the use of lay home visitors where appropriate;

(2) a description of the types and qualifications of home visitors used by the entity and the process by which the entity will provide continuing training and sufficient support to the home visitors; and

(3) such other information as the Secretary determines to be appropriate.

(k) Limitation regarding administrative expenses

Not more than 10 percent of a grant under subsection (a) may be expended for administrative expenses with respect to the grant. The costs of training individuals to serve in the project involved are not subject to the preceding sentence.

(*l*) Restrictions on use of grant

To be eligible to receive a grant under this section, an entity must agree that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(m) Reports to Secretary

To be eligible to receive a grant under this section, an entity must agree to submit an annual report on the services provided under this section to the Secretary in such manner and containing such information as the Secretary by regulation requires. At a minimum, the entity shall report information concerning eligible families, including—

(1) the characteristics of the families and children receiving services under this section;

(2) the usage, nature, and location of the provider, of preventive health services, including prenatal, primary infant, and child health care;

(3) the incidence of low birthweight and premature infants;

(4) the length of hospital stays for pre- and post-partum women and their children;

(5) the incidence of substantiated child abuse and neglect for all children within participating families;

(6) the number of emergency room visits for routine health care;

(7) the source of payment for health care services and the extent to which the utilization of health care services, other than routine screening and medical care, available to the individuals under the program established under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], and under other Federal, State, and local programs, is reduced;

(8) the number and type of referrals made for health and related social services, including alcohol and drug treatment services, and the utilization of such services provided by the grantee; and

(9) the incidence of developmental disabilities.

(n) Requirement of application

The Secretary may make a grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements and assurances required in this section, and the information required in subsection (j);

(3) the application contains evidence that the preparation of the application has been coordinated with the State agencies responsible for maternal and child health and child welfare, and coordinated with services provided under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; and

(4) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(*o*) Peer review

(1) Requirement

In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) Composition

The Secretary shall establish a review panel to make recommendations under paragraph (1) that shall be composed of—

(A) national experts in the fields of maternal and child health, child abuse and neglect, and the provision of community-based primary health services; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Administration for Children, Youth, and Families, the U.S. Advisory Board on Child Abuse and Neglect, and the National Commission to Prevent Infant Mortality.

(p) Evaluations

(1) In general

The Secretary shall, directly or through contracts with public or private entities—

(A) conduct evaluations to determine the effectiveness of projects under subsection (a) in reducing the incidence of children born with health or developmental complications, the incidence among children less than 3 years of age of such complications, and the incidence of child abuse and neglect; and

(B) not less than once during each 3-year period, prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluations.

(2) Contents

The evaluations conducted under paragraph (1) shall—

(A) include a summary of the data contained in the annual reports submitted under subsection (m);

(B) assess the relative effectiveness of projects under subsection (a) in urban and rural areas, and among programs utilizing differing combinations of professionals and trained home visitors recruited from the community to meet the needs of defined target service populations; and

(C) make further recommendations necessary or desirable to increase the effectiveness of such projects.

(q) Definitions

For purposes of this section:

(1) The term ''eligible entity'' includes public and nonprofit private entities that provide health or related social services, including community-based organizations, visiting nurse organizations, hospitals, local health departments, community health centers, Native Hawaiian health centers, nurse managed clinics, family service agencies, child welfare agencies, developmental service providers, family resource and support programs, and resource mothers projects.

(2) The term ''eligible family'' means a family described in subsection (a).

(3) The term ''health or developmental complication'', with respect to a child, means—

(A) being born in an unhealthy or potentially unhealthy condition, including premature birth, low birthweight, and prenatal exposure to maternal substance abuse;

(B) a condition arising from a condition described in subparagraph (A);

(C) a physical disability or delay; and

(D) a developmental disability or delay.

(4) The term ''home visiting services'' means the services specified in subsection (b), provided at the residence of the eligible family involved or provided pursuant to arrangements made for the family (including arrangements for services in community settings).

(5) The term ''home visitors'' means providers of home visiting services.

(r) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $30,000,000 for each of the fiscal years 1993 and 1994.

(July 1, 1944, ch. 373, title III, § 399, as added Pub. L. 102–321, title V, § 502(2), July 10, 1992, 106 Stat. 427; amended Pub. L. 103–448, title II, § 204(w)(2)(D), Nov. 2, 1994, 108 Stat. 4746; Pub. L. 108–446, title III, § 305(i)(2), Dec. 3, 2004, 118 Stat. 2806.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(3)(A), (b)(6), and (m)(7), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles IV, V, and XIX of the Act are classified generally to subchapters IV (§ 601 et seq.), 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.

The Individuals with Disabilities Education Act, referred to in subsec. (n)(3), 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.

PRIOR PROVISIONS

A prior section 399 of act July 1, 1944, was renumbered section 398A by section 502(1) of Pub. L. 102–321 and is classified to section 280c–4 of this title.

Another prior section 399 of act July 1, 1944, ch. 373, title III, formerly § 399b, as added Oct. 22, 1965, Pub. L. 89–291, § 2, 79 Stat. 1066; renumbered § 399a and amended Mar. 13, 1970, Pub. L. 91–212, § 10(c)(3), (d)(2)(A), 84 Stat. 67; renumbered § 399, July 23, 1974, Pub. L. 93–353, title II, § 204, 88 Stat. 373; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695, which related to the maintenance of records by recipients of grants and audits thereof by the Secretary of Health and Human Services and the Comptroller General of the United States, was classified to section 280b–11 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2004—Subsec. (n)(3). Pub. L. 108–446 substituted ''part C'' for ''part H''.

1994—Subsec. (b)(6). Pub. L. 103–448 substituted ''special supplemental nutrition program'' for ''special supplemental food program''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–448 effective Oct. 1, 1994, see section 401 of Pub. L. 103–448, set out as a note under section 1755 of this title.

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

PURPOSE

Pub. L. 102–321, title V, § 501, July 10, 1992, 106 Stat. 426, provided that: ''The purpose of this title [enacting this section] is—

''(1) to increase the use of, and to provide information on the availability of early, continuous and comprehensive prenatal care;

''(2) to reduce the incidence of infant mortality and of infants born prematurely, with low birthweight, or with other impairments including those associated with maternal substance abuse;

''(3) for pregnant women and mothers of children below the age of 3 whose children have experienced or

are at risk of experiencing a health or developmental complication, to provide assistance in obtaining health and related social services necessary to meet the special needs of the women and their children;

''(4) to assist, when requested, women who are pregnant and at-risk for poor birth outcomes, or who have young children and are abusing alcohol or other drugs, in obtaining appropriate treatment; and

''(5) to reduce the incidence of child abuse and neglect.''

PART L—[REPEALED]

CODIFICATION

Pub. L. 106–310, div. B, title XXXI, § 3106(n), Oct. 17, 2000, 114 Stat. 1179, struck out heading for part L ''Services for Children of Substance Abusers''.

Pub. L. 103–43, title XX, § 2008(i)(2)(B)(ii), June 10, 1993, 107 Stat. 213, redesignated part M ''Services for Children of Substance Abusers'' as L. Former part L ''Health Care Services in the Home'' redesignated K.

Pub. L. 101–616, title I, § 101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part K ''Health Care Services in the Home'' as L.

§ 280d. Transferred

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, § 399D, as added Pub. L. 102–321, title IV, § 401(a), July 10, 1992, 106 Stat. 419, and amended, which related to grants for services for children of substance abusers, was renumbered section 399A of title III of act July 1, 1944 by Pub. L. 106–310, div. A, title V, § 502(1), Oct. 17, 2000, 114 Stat. 1115. Subsequently, section 399D was renumbered section 519 of title V of act July 1, 1944, without reference to its prior renumbering as 399A, by Pub. L. 106–310, div. B, title XXXI, § 3106(m), Oct. 17, 2000, 114 Stat. 1179. Section was transferred to section 290bb–25 of this title.

§ 280d–11. Transferred

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, § 399F, as added Pub. L. 102–531, title II, § 201, Oct. 27, 1992, 106 Stat. 3474, which comprised part N in its entirety and which related to establishment and duties of National Foundation for the Centers for Disease Control and Prevention, was renumbered section 399G of act July 1, 1944, by Pub. L. 106–310, div. A, title V, § 502(3), Oct. 17, 2000, 114 Stat. 1115, and transferred to section 280e–11 of this title.

PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

§ 280e. National program of cancer registries

(a) In general

(1) Statewide cancer registries

The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to the State, to support the operation of population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data concerning—

(A) demographic information about each case of cancer;

(B) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

(C) administrative information, including date of diagnosis and source of information;

(D) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

(E) other elements determined appropriate by the Secretary.

(2) Cancer; benign brain-related tumors

(A) In general

For purposes of paragraph (1), the conditions referred to in this paragraph are the following:

(i) Each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), including malignant brain-related tumors.

(ii) Benign brain-related tumors.

(B) Brain-related tumor

For purposes of subparagraph (A):

(i) The term ''brain-related tumor'' means a listed primary tumor (whether malignant or benign) occurring in any of the following sites:

(I) The brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any other part of the central nervous system.

(II) The pituitary gland, pineal gland, or craniopharyngeal duct.

(ii) The term ''listed'', with respect to a primary tumor, means a primary tumor that is listed in the International Classification of Diseases for Oncology (commonly referred to as the ICD–O).

(iii) The term ''International Classification of Diseases for Oncology'' means a classification system that includes topography (site) information and histology (cell type information) developed by the World Health Organization, in collaboration with international centers, to promote international comparability in the collection, classification, processing, and presentation of cancer statistics. The ICD–O system is a supplement to the International Statistical Classification of Diseases and Related Health Problems (commonly known as the ICD) and is the standard coding system used by cancer registries worldwide. Such term includes any modification made to such system for purposes of the United States. Such term further includes any published classification system that is internationally recognized as a successor to the classification system referred to in the first sentence of this clause.

(C) Statewide cancer registry

References in this section to cancer registries shall be considered to be references to registries described in this subsection.

(b) Matching funds

(1) In general

The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated

by the State to operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or $1 for every $3 of Federal funds provided in the grant.

(2) Determination of amount of non-Federal contribution; maintenance of effort

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) With respect to a State in which the purpose described in subsection (a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

(c) Eligibility for grants

(1) In general

No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a), and that the applicant will comply with the peer review requirements under sections 289 and 289a of this title.

(2) Assurances

Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will—

(A) provide for the establishment of a registry in accordance with subsection (a);

(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

(C) provide for the annual publication of reports of cancer data under subsection (a); and

(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing—

(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) Relationship to certain programs

(1) In general

This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) Supplanting of activities

In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2)(C) and (D) and are appropriately coordinated with the existing SEER program.

(3) Transfer of responsibility

The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) Coordination

To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

(e) Requirement regarding certain study on breast cancer

In the case of a grant under subsection (a) to any State specified in subsection (b) of section 280e–3 of this title, the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under such section.

(July 1, 1944, ch. 373, title III, § 399B, formerly § 399H, as added Pub. L. 102–515, § 3, Oct. 24, 1992, 106 Stat. 3372; renumbered § 399B and amended Pub. L. 106–310, div. A, title V, § 502(2)(A), (B), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 107–260, § 2(a), Oct. 29, 2002, 116 Stat. 1743.)

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–260 designated existing provisions as par. (1), inserted par. (1) heading, substituted ''population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data'' for ''population-based, statewide cancer registries in order to collect, for each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), data'', redesignated former pars. (1) to (5) as subpars. (A) to (E) of par. (1), respectively, and added par. (2).

2000—Subsec. (e). Pub. L. 106–310, § 502(2)(B), substituted ''subsection (b) of section 280e–3 of this title'' for ''section 280e–3(b) of this title'' and ''such section'' for ''section 399C''.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–260, § 2(b), Oct. 29, 2002, 116 Stat. 1744, provided that: ''The amendments made by subsection (a) [amending this section] apply to grants under section 399B of the Public Health Service Act [42 U.S.C. 280e] for fiscal year 2002 and subsequent fiscal years, except that, in the case of a State that received such a grant for fiscal year 2000, the Secretary of Health and Human Services may delay the applicability of such amendments to the State for not more than 12 months if the Secretary determines that compliance with such amendments requires the enactment of a statute by the State or the issuance of State regulations.''

CONGRESSIONAL FINDINGS AND PURPOSE

Pub. L. 102–515, § 2, Oct. 24, 1992, 106 Stat. 3372, provided that:

''(a) FINDINGS.—Congress finds that—

''(1) cancer control efforts, including prevention and early detection, are best addressed locally by State health departments that can identify unique needs;

''(2) cancer control programs and existing statewide population-based cancer registries have identified cancer incidence and cancer mortality rates that indicate the burden of cancer for Americans is substantial and varies widely by geographic location and by ethnicity;

''(3) statewide cancer incidence and cancer mortality data, can be used to identify cancer trends, patterns, and variation for directing cancer control intervention;

''(4) the American Association of Central Cancer Registries (AACCR) cites that of the 50 States, approximately 38 have established cancer registries, many are not statewide and 10 have no cancer registry; and

''(5) AACCR also cites that of the 50 States, 39 collect data on less than 100 percent of their population, and less than half have adequate resources for insuring minimum standards for quality and for completeness of case information.

''(b) PURPOSE.—It is the purpose of this Act [enacting this part and provisions set out as a note under section 201 of this title] to establish a national program of cancer registries.''

§ 280e–1. Planning grants regarding registries

(a) In general

(1) States

The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 280e(c)(2) of this title.

(2) Other entities

For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) Application

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(July 1, 1944, ch. 373, title III, § 399C, formerly § 399I, as added Pub. L. 102–515, § 3, Oct. 24, 1992,

106 Stat. 3375; renumbered § 399C, Pub. L. 106–310, div. A, title V, § 502(2)(A), Oct. 17, 2000, 114 Stat. 1115.)

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

§ 280e–2. Technical assistance in operations of statewide cancer registries

The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

(July 1, 1944, ch. 373, title III, § 399D, formerly § 399J, as added Pub. L. 102–515, § 3, Oct. 24, 1992, 106 Stat. 3376; renumbered § 399D, Pub. L. 106–310, div. A, title V, § 502(2)(A), Oct. 17, 2000, 114 Stat. 1115.)

PRIOR PROVISIONS

A prior section 399D of act July 1, 1944, was renumbered section 519, and is classified to section 290bb–25 of this title.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

§ 280e–3. Study in certain States to determine factors contributing to elevated breast cancer mortality rates

(a) In general

Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) Relevant States

The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) Cooperation of State

The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 280e(a) of this title.

(d) Planning, commencement, and duration

The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

(July 1, 1944, ch. 373, title III, § 399E, formerly § 399K, as added Pub. L. 102–515, § 3, Oct. 24, 1992, 106 Stat. 3376; renumbered § 399E and amended Pub. L. 106–310, div. A, title V, § 502(2)(A), (C), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 109–482, title I, § 104(b)(2)(A), Jan. 15, 2007, 120 Stat. 3693.)

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: ''Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) of this section and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and recommendations made as a result of the study.''

2000—Subsec. (c). Pub. L. 106–310, § 502(2)(C), made technical amendment to reference in original act which appears in text as reference to section 280e(a) of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment 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 a note under section 281 of this title.

POTENTIAL ENVIRONMENTAL AND OTHER RISKS CONTRIBUTING TO INCIDENCE OF BREAST CANCER

Pub. L. 103–43, title XIX, § 1911, June 10, 1993, 107 Stat. 205, provided that Director of the National Cancer Institute, in collaboration with Director of the National Institute of Environmental Health Sciences, was to conduct case-control study to assess biological markers of environmental and other potential risk factors contributing to incidence of breast cancer in specified counties in State of New York and northeastern United States that had highest age-adjusted mortality rate of such cancer, and to report results of such study to Congress not later than 30 months after June 10, 1993.

§ 280e–3a. National childhood cancer registry

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award a grant to enhance and expand infrastructure to track the epidemiology of pediatric cancer into a comprehensive nationwide registry of actual occurrences of pediatric cancer. Such registry shall be updated to include an actual occurrence within weeks of the date of such occurrence.

(b) Informed consent and privacy requirements and coordination with existing programs

The registry established pursuant to subsection (a) shall be subject to section 552a of title 5, the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, applicable Federal and State informed consent regulations, any other applicable Federal and State laws relating to the privacy of patient information, and section 280e(d)(4) of this title.

(July 1, 1944, ch. 373, title III, § 399E–1, as added Pub. L. 110–285, § 4(b)(1), July 29, 2008, 122 Stat. 2630.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

FINDINGS AND PURPOSES

Pub. L. 110–285, §§ 2, 3, July 29, 2008, 122 Stat. 2628, provided that:

''SEC. 2. FINDINGS

''Congress makes the following findings:

''(1) Cancer kills more children than any other disease.

''(2) Each year cancer kills more children between 1 and 20 years of age than asthma, diabetes, cystic fibrosis, and AIDS, combined.

''(3) Every year, over 12,500 young people are diagnosed with cancer.

''(4) Each year about 2,300 children and teenagers die from cancer.

''(5) One in every 330 Americans develops cancer before age 20.

''(6) Some forms of childhood cancer have proven to be so resistant that even in spite of the great research strides made, most of those children die. Up to 75 percent of the children with cancer can now be cured.

''(7) The causes of most childhood cancers are not yet known.

''(8) Childhood cancers are mostly those of the white blood cells (leukemias), brain, bone, the lymphatic system, and tumors of the muscles, kidneys, and nervous system. Each of these behaves differently, but all are characterized by an uncontrolled proliferation of abnormal cells.

''(9) Eighty percent of the children who are diagnosed with cancer have disease which has already spread to distant sites in the body.

''(10) Ninety percent of children with a form of pediatric cancer are treated at one of the more than 200 Children's Oncology Group member institutions throughout the United States.

''SEC. 3. PURPOSES

''It is the purpose of this Act [see Short Title of 2008 Amendment note set out under section 201 of this title] to authorize appropriations to—

''(1) encourage the support for pediatric cancer research and other activities related to pediatric cancer;

''(2) establish a comprehensive national childhood cancer registry; and

''(3) provide informational services to patients and families affected by childhood cancer.''

§ 280e–4. Authorization of appropriations

(a) Registries

For the purpose of carrying out this part (other than section 280e–3a of this title), there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 280e–1 of this title, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under section 280e–2 of this title.

(b) Breast cancer study

Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of subchapter III for any fiscal year in which the study required in section 280e–3 of this title is being carried out, the Secretary shall expend not less than $1,000,000 for the study.

(July 1, 1944, ch. 373, title III, § 399F, formerly § 399L, as added Pub. L. 102–515, § 3, Oct. 24, 1992, 106 Stat. 3376; amended Pub. L. 103–43, title XX, § 2003, June 10, 1993, 107 Stat. 208; Pub. L. 103–183, title VII, § 705(c), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–340, title II, § 202, Oct. 31, 1998, 112 Stat. 3194; renumbered § 399F and amended Pub. L. 106–310, div. A, title V, § 502(2)(A), (D), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 110–285, § 4(b)(2), July 29, 2008, 122 Stat. 2631.)

PRIOR PROVISIONS

A prior section 399F of act July 1, 1944, was renumbered section 399G and is classified to section 280e–11 of this title.

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–285 inserted ''(other than section 280e–3a of this title)'' after ''this part''.

2000—Subsec. (a). Pub. L. 106–310, § 502(2)(D)(ii), substituted ''section 280e–2 of this title'' for ''subsection 280e–2 of this title''.

Pub. L. 106–310, § 502(2)(D)(i), made technical amendment to reference in original act which appears in text as reference to section 280e–1 of this title.

Subsec. (b). Pub. L. 106–310, § 502(2)(D)(iii), made technical amendment to reference in original act which appears in text as reference to section 280e–3 of this title.

1998—Subsec. (a). Pub. L. 105–340 substituted ''2003'' for ''1998''.

1993—Subsec. (a). Pub. L. 103–183 substituted ''through 1998'' for ''through 1996''.

Pub. L. 103–43 substituted ''there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996'' for ''the Secretary may use $30,000,000 for each of the fiscal years 1993 through 1997'' in first sentence and ''Of the amounts appropriated under the preceding sentence'' for ''Out of any amounts used'' in second sentence.

PART N—NATIONAL FOUNDATION FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

CODIFICATION

This part was formerly set out preceding part M of this subchapter.

§ 280e–11. Establishment and duties of Foundation

(a) In general

There shall be established in accordance with this section a nonprofit private corporation to be known as the National Foundation for the Centers for Disease Control and Prevention (in this part referred to as the ''Foundation''). The Foundation shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Foundation shall not be officers or employees of the Federal Government.

(b) Purpose of Foundation

The purpose of the Foundation shall be to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health.

(c) Endowment fund

(1) In general

In carrying out subsection (b), the Foundation shall establish a fund for providing endowments for positions that are associated with the Centers for Disease Control and Prevention and dedicated to the purpose described in such subsection. Subject to subsection (f)(1)(B), the fund shall consist of such donations as may be provided by non-Federal entities and such non-Federal assets of the Foun-

dation (including earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund.

(2) Authorized expenditures of fund

The provision of endowments under paragraph (1) shall be the exclusive function of the fund established under such paragraph. Such endowments may be expended only for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the positions, and for recruiting individuals to hold the positions endowed by the fund.

(d) Certain activities of Foundation

In carrying out subsection (b), the Foundation may provide for the following with respect to the purpose described in such subsection:

(1) Programs of fellowships for State and local public health officials to work and study in association with the Centers for Disease Control and Prevention.

(2) Programs of international arrangements to provide opportunities for public health officials of other countries to serve in public health capacities in the United States in association with the Centers for Disease Control and Prevention or elsewhere, or opportunities for employees of such Centers (or other public health officials in the United States) to serve in such capacities in other countries, or both.

(3) Studies, projects, and research (which may include applied research on the effectiveness of prevention activities, demonstration projects, and programs and projects involving international, Federal, State, and local governments).

(4) Forums for government officials and appropriate private entities to exchange information. Participants in such forums may include institutions of higher education and appropriate international organizations.

(5) Meetings, conferences, courses, and training workshops.

(6) Programs to improve the collection and analysis of data on the health status of various populations.

(7) Programs for writing, editing, printing, and publishing of books and other materials.

(8) Other activities to carry out the purpose described in subsection (b).

(e) General structure of Foundation; nonprofit status

(1) Board of directors

The Foundation shall have a board of directors (in this part referred to as the ''Board''), which shall be established and conducted in accordance with subsection (f). The Board shall establish the general policies of the Foundation for carrying out subsection (b), including the establishment of the bylaws of the Foundation.

(2) Executive director

The Foundation shall have an executive director (in this part referred to as the ''Director''), who shall be appointed by the Board, who shall serve at the pleasure of the Board, and for whom the Board shall establish the rate of compensation. Subject to compliance with the policies and bylaws established by the Board pursuant to paragraph (1), the Director shall be responsible for the daily operations of the Foundation in carrying out subsection (b).

(3) Nonprofit status

In carrying out subsection (b), the Board shall establish such policies and bylaws under paragraph (1), and the Director shall carry out such activities under paragraph (2), as may be necessary to ensure that the Foundation maintains status as an organization that—

(A) is described in subsection (c)(3) of section 501 of title 26; and

(B) is, under subsection (a) of such section, exempt from taxation.

(f) Board of directors

(1) Certain bylaws

(A) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation include bylaws for the following:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance and disposition of donations to the Foundation and for the disposition of the assets of the Foundation.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, and publishing of books and other materials, and the acquisition of patents and licenses for devices and procedures developed by the Foundation.

(B) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation, or the Centers for Disease Control and Prevention, to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.

(2) Composition

(A) Subject to subparagraph (B), the Board shall be composed of 7 individuals, appointed in accordance with paragraph (4), who collectively possess education or experience appropriate for representing the general field of public health, the general field of international health, and the general public. Each such individual shall be a voting member of the Board.

(B) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be a greater number than the number specified in subparagraph (A).

(3) Chair

The Board shall, from among the members of the Board, designate an individual to serve

as the chair of the Board (in this subsection referred to as the ''Chair'').

(4) Appointments, vacancies, and terms

Subject to subsection (j) (regarding the initial membership of the Board), the following shall apply to the Board:

(A) Any vacancy in the membership of the Board shall be filled by appointment by the Board, after consideration of suggestions made by the Chair and the Director regarding the appointments. Any such vacancy shall be filled not later than the expiration of the 180-day period beginning on the date on which the vacancy occurs.

(B) The term of office of each member of the Board appointed under subparagraph (A) shall be 5 years. A member of the Board may continue to serve after the expiration of the term of the member until the expiration of the 180-day period beginning on the date on which the term of the member expires.

(C) A vacancy in the membership of the Board shall not affect the power of the Board to carry out the duties of the Board. If a member of the Board does not serve the full term applicable under subparagraph (B), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(5) Compensation

Members of the Board may not receive compensation for service on the Board. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board.

(g) Certain responsibilities of executive director

In carrying out subsection (e)(2), the Director shall carry out the following functions:

(1) Hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees.

(2) Accept and administer donations to the Foundation, and administer the assets of the Foundation.

(3) Establish a process for the selection of candidates for holding endowed positions under subsection (c).

(4) Enter into such financial agreements as are appropriate in carrying out the activities of the Foundation.

(5) Take such action as may be necessary to acquire patents and licenses for devices and procedures developed by the Foundation and the employees of the Foundation.

(6) Adopt, alter, and use a corporate seal, which shall be judicially noticed.

(7) Commence and respond to judicial proceedings in the name of the Foundation.

(8) Other functions that are appropriate in the determination of the Director.

(h) General provisions

(1) Authority for accepting funds

The Director of the Centers for Disease Control and Prevention may accept and utilize, on behalf of the Federal Government, any gift, donation, bequest, or devise of real or personal property from the Foundation for the purpose of aiding or facilitating the work of such Centers. Funds may be accepted and utilized by such Director under the preceding sentence without regard to whether the funds are designated as general-purpose funds or special-purpose funds.

(2) Authority for acceptance of voluntary services

(A) The Director of the Centers for Disease Control and Prevention may accept, on behalf of the Federal Government, any voluntary services provided to such Centers by the Foundation for the purpose of aiding or facilitating the work of such Centers. In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual until such time as the private funding for such individual ends.

(B) The limitation established in subparagraph (A) regarding the period of time in which services may be accepted applies to each individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation.

(3) Administrative control

No officer, employee, or member of the Board of the Foundation may exercise any administrative or managerial control over any Federal employee.

(4) Applicability of certain standards to non-Federal employees

In the case of any individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation, the Foundation shall negotiate a memorandum of understanding with the individual and the Director of the Centers for Disease Control and Prevention specifying that the individual—

(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Centers for Disease Control and Prevention, including standards under this chapter, the Ethics in Government Act, and the Technology Transfer Act;[1] and

(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18 (relating to conflicts of interest), as the Director of such Centers determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of title 18.

(5) Financial conflicts of interest

Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or determination by the Foundation of any question affecting—

(A) any direct or indirect financial interest of the individual; or

[1] See References in Text note below.

(B) any direct or indirect financial interest of any business organization or other entity of which the individual is an officer or employee or in which the individual has a direct or indirect financial interest.

(6) Audits; availability of records

The Foundation shall—

(A) provide for biennial audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(7) Reports

(A) Not later than February 1 of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts provided for under subsection (i).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts to the Foundation of real or personal property, and the source and amount of all gifts to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge not to exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(8) Liaison from Centers for Disease Control and Prevention

The Director of the Centers for Disease Control and Prevention shall serve as the liaison representative of such Centers to the Board and the Foundation.

(i) Federal funding

(1) Authority for annual grants

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(i) for fiscal year 1993, make a grant to an entity described in subsection (j)(9) (relating to the establishment of a committee to establish the Foundation);

(ii) for fiscal year 1994, make a grant to the committee established under such subsection, or if the Foundation has been established, to the Foundation; and

(iii) for fiscal year 1995 and each subsequent fiscal year, make a grant to the Foundation.

(B) A grant under subparagraph (A) may be expended—

(i) in the case of an entity receiving the grant under subparagraph (A)(i), only for the purpose of carrying out the duties established in subsection (j)(9) for the entity;

(ii) in the case of the committee established under such subsection, only for the purpose of carrying out the duties established in subsection (j) for the committee; and

(iii) in the case of the Foundation, only for the purpose of the administrative expenses of the Foundation.

(C) A grant under subparagraph (A) may not be expended to provide amounts for the fund established under subsection (c).

(D) For the purposes described in subparagraph (B)—

(i) any portion of the grant made under subparagraph (A)(i) for fiscal year 1993 that remains unobligated after the entity receiving the grant completes the duties established in subsection (j)(9) for the entity shall be available to the committee established under such subsection; and

(ii) any portion of a grant under subparagraph (A) made for fiscal year 1993 or 1994 that remains unobligated after such committee completes the duties established in such subsection for the committee shall be available to the Foundation.

(2) Funding for grants

(A) For the purpose of grants under paragraph (1), there is authorized to be appropriated $1,250,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not less than $500,000, and not more than $1,250,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

(3) Certain restriction

If the Foundation receives Federal funds for the purpose of serving as a fiscal intermediary between Federal agencies, the Foundation may not receive such funds for the indirect costs of carrying out such purpose in an amount exceeding 10 percent of the direct costs of carrying out such purpose. The preceding sentence may not be construed as authorizing the expenditure of any grant under paragraph (1) for such purpose.

(4) Support services

The Director of the Centers for Disease Control and Prevention may provide facilities, utilities, and support services to the Foundation if it is determined by the Director to be advantageous to the programs of such Centers.

(j) Committee for establishment of Foundation

(1) In general

There shall be established in accordance with this subsection a committee to carry out the functions described in paragraph (2) (which committee is referred to in this subsection as the ''Committee'').

(2) Functions

The functions referred to in paragraph (1) for the Committee are as follows:

(A) To carry out such activities as may be necessary to incorporate the Foundation under the laws of the State involved, including serving as incorporators for the Foundation. Such activities shall include ensuring that the articles of incorporation for the Foundation require that the Foundation be established and operated in accordance with the applicable provisions of this part (or any successor to this part), including such provisions as may be in effect pursuant to amendments enacted after October 27, 1992.

(B) To ensure that the Foundation qualifies for and maintains the status described in subsection (e)(3) (regarding taxation).

(C) To establish the general policies and initial bylaws of the Foundation, which bylaws shall include the bylaws described in subsections (e)(3) and (f)(1).

(D) To provide for the initial operation of the Foundation, including providing for quarters, equipment, and staff.

(E) To appoint the initial members of the Board in accordance with the requirements established in subsection (f)(2)(A) for the composition of the Board, and in accordance with such other qualifications as the Committee may determine to be appropriate regarding such composition. Of the members so appointed—

(i) 2 shall be appointed to serve for a term of 3 years;

(ii) 2 shall be appointed to serve for a term of 4 years; and

(iii) 3 shall be appointed to serve for a term of 5 years.

(3) Completion of functions of Committee; initial meeting of Board

(A) The Committee shall complete the functions required in paragraph (1) not later than September 30, 1994. The Committee shall terminate upon the expiration of the 30-day period beginning on the date on which the Secretary determines that the functions have been completed.

(B) The initial meeting of the Board shall be held not later than November 1, 1994.

(4) Composition

The Committee shall be composed of 5 members, each of whom shall be a voting member. Of the members of the Committee—

(A) no fewer than 2 shall have broad, general experience in public health; and

(B) no fewer than 2 shall have broad, general experience in nonprofit private organizations (without regard to whether the individuals have experience in public health).

(5) Chair

The Committee shall, from among the members of the Committee, designate an individual to serve as the chair of the Committee.

(6) Terms; vacancies

The term of members of the Committee shall be for the duration of the Committee. A vacancy in the membership of the Committee shall not affect the power of the Committee to carry out the duties of the Committee. If a member of the Committee does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(7) Compensation

Members of the Committee may not receive compensation for service on the Committee. Members of the Committee may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Committee.

(8) Committee support

The Director of the Centers for Disease Control and Prevention may, from amounts available to the Director for the general administration of such Centers, provide staff and financial support to assist the Committee with carrying out the functions described in paragraph (2). In providing such staff and support, the Director may both detail employees and contract for assistance.

(9) Grant for establishment of Committee

(A) With respect to a grant under paragraph (1)(A)(i) of subsection (i) for fiscal year 1993, an entity described in this paragraph is a private nonprofit entity with significant experience in domestic and international issues of public health. Not later than 180 days after October 27, 1992, the Secretary shall make the grant to such an entity (subject to the availability of funds under paragraph (2) of such subsection).

(B) The grant referred to in subparagraph (A) may be made to an entity only if the entity agrees that—

(i) the entity will establish a committee that is composed in accordance with paragraph (4); and

(ii) the entity will not select an individual for membership on the Committee unless the individual agrees that the Committee will operate in accordance with each of the provisions of this subsection that relate to the operation of the Committee.

(C) The Secretary may make a grant referred to in subparagraph (A) only if the applicant for the grant makes an agreement that the grant will not be expended for any purpose other than carrying out subparagraph (B). Such a grant may be made only if an application for the grant is submitted to the Secretary containing such agreement, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

(July 1, 1944, ch. 373, title III, § 399G, formerly § 399F, as added Pub. L. 102–531, title II, § 201, Oct. 27, 1992, 106 Stat. 3474; renumbered § 399G, Pub. L. 106–310, div. A, title V, § 502(3), Oct. 17, 2000, 114 Stat. 1115; amended Pub. L. 109–245, § 1, July 26, 2006, 120 Stat. 575.)

REFERENCES IN TEXT

The Ethics in Government Act, referred to in subsec. (h)(4)(A), probably means the Ethics in Government Act of 1978, Pub. L. 95–521, Oct. 26, 1978, 92 Stat. 1824, as amended. For complete classification of this Act to the Code, see Short Title note set out under section 101 of

Pub. L. 95–521 in the Appendix to Title 5, Government Organization and Employees, and Tables.

The Technology Transfer Act, referred to in subsec. (h)(4)(A), may mean the Federal Technology Transfer Act of 1986, Pub. L. 99–502, Oct. 20, 1986, 100 Stat. 1785, as amended, or the National Competitiveness Technology Transfer Act of 1989, part C (§§ 3131–3133) of title XXXI of div. C of Pub. L. 101–189, Nov. 29, 1989, 103 Stat. 1674. For complete classification of these Acts to the Code, see Short Title of 1986 Amendment note and Short Title of 1989 Amendment note both set out under section 3701 of Title 15, Commerce and Trade, and Tables.

CODIFICATION

Section was formerly classified to section 280d–11 of this title prior to renumbering by Pub. L. 106–310.

PRIOR PROVISIONS

A prior section 399G of act July 1, 1944, was renumbered section 399H and was classified to section 280f of this title, prior to being omitted from the Code.

AMENDMENTS

2006—Subsec. (h)(2)(A). Pub. L. 109–245, §1(a), substituted ''In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual until such time as the private funding for such individual ends.'' for ''In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual for not more than 2 years.''

Subsec. (h)(7)(A). Pub. L. 109–245, §1(b)(1), inserted '', including an accounting of the use of amounts provided for under subsection (i)'' before period at end of second sentence.

Subsec. (h)(7)(C). Pub. L. 109–245, §1(b)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: ''The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.''

Subsec. (i)(2)(A). Pub. L. 109–245, §1(c)(1)(A), substituted ''$1,250,000'' for ''$500,000''.

Subsec. (i)(2)(B). Pub. L. 109–245, §1(c)(1)(B), substituted ''not less than $500,000, and not more than $1,250,000'' for ''not more than $500,000''.

Subsec. (i)(4). Pub. L. 109–245, §1(c)(2), added par. (4).

PART O—FETAL ALCOHOL SYNDROME PREVENTION AND SERVICES PROGRAM

§§ 280f to 280f–3. Omitted

CODIFICATION

Sections 280f to 280f–3, which provided for the establishment of a Fetal Alcohol Syndrome prevention and services program, were omitted pursuant to section 280f–3 which provided that this part would no longer apply on the date that was 7 years after the date on which all members of the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect established under section 280f(d)(1) were appointed, which occurred May 17, 2000.

Section 280f, act July 1, 1944, ch. 373, title III, §399H, formerly §399G, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3593; renumbered §399H and amended Pub. L. 106–310, div. A, title V, §502(4)(A), (B), Oct. 17, 2000, 114 Stat. 1115, required the Secretary of Health and Human Services to establish a comprehensive Fetal Alcohol Syndrome and Fetal Alcohol Effect prevention, intervention and services delivery program and to establish the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect.

Section 280f–1, act July 1, 1944, ch. 373, title III, §399I, formerly §399H, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3594; renumbered §399I, Pub. L. 106–310, div. A, title V, §502(4)(A), Oct. 17, 2000, 114 Stat. 1115, provided eligibility criteria for receiving a grant or entering into a cooperative agreement or contract under this part.

Section 280f–2, act July 1, 1944, ch. 373, title III, §399J, formerly §399I, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3595; renumbered §399J and amended Pub. L. 106–310, div. A, title V, §502(4)(A), (C), Oct. 17, 2000, 114 Stat. 1115, authorized appropriations to carry out this part.

Section 280f–3, act July 1, 1944, ch. 373, title III, §399K, formerly §399J, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3595; renumbered §399K and amended Pub. L. 106–310, div. A, title V, §502(4)(A), (D), Oct. 17, 2000, 114 Stat. 1115, provided for the expiration of this part 7 years after the date on which all members of the National Task Force had been appointed.

CONGRESSIONAL FINDINGS AND PURPOSE

Pub. L. 105–392, title IV, §419(b), (c), Nov. 13, 1998, 112 Stat. 3591, 3592, as amended by Pub. L. 111–256, §2(g), Oct. 5, 2010, 124 Stat. 2644, provided findings and purpose related to prevention of Fetal Alcohol Syndrome and Fetal Alcohol Effect.

PART P—ADDITIONAL PROGRAMS

§280g. Children's asthma treatment grants program

(a) Authority to make grants

(1) In general

In addition to any other payments made under this chapter or title V of the Social Security Act [42 U.S.C. 701 et seq.], the Secretary shall award grants to eligible entities to carry out the following purposes:

(A) To provide access to quality medical care for children who live in areas that have a high prevalence of asthma and who lack access to medical care.

(B) To provide on-site education to parents, children, health care providers, and medical teams to recognize the signs and symptoms of asthma, and to train them in the use of medications to treat asthma and prevent its exacerbations.

(C) To decrease preventable trips to the emergency room by making medication available to individuals who have not previously had access to treatment or education in the management of asthma.

(D) To provide other services, such as smoking cessation programs, home modification, and other direct and support services that ameliorate conditions that exacerbate or induce asthma.

(2) [1] Certain projects

In making grants under paragraph (1), the Secretary may make grants designed to develop and expand the following projects:

(A) Projects to provide comprehensive asthma services to children in accordance with the guidelines of the National Asthma Education and Prevention Program (through the National Heart, Lung and Blood Institute), including access to care and treatment for asthma in a community-based setting.

(B) Projects to fully equip mobile health care clinics that provide preventive asthma

[1] So in original. Two pars. (2) have been enacted.

care including diagnosis, physical examinations, pharmacological therapy, skin testing, peak flow meter testing, and other asthma-related health care services.

(C) Projects to conduct validated asthma management education programs for patients with asthma and their families, including patient education regarding asthma management, family education on asthma management, and the distribution of materials, including displays and videos, to reinforce concepts presented by medical teams.

(2)[1] Award of grants

(A) Application

(i) In general

An eligible entity shall submit an application to the Secretary for a grant under this section in such form and manner as the Secretary may require.

(ii) Required information

An application submitted under this subparagraph shall include a plan for the use of funds awarded under the grant and such other information as the Secretary may require.

(B) Requirement

In awarding grants under this section, the Secretary shall give preference to eligible entities that demonstrate that the activities to be carried out under this section shall be in localities within areas of known or suspected high prevalence of childhood asthma or high asthma-related mortality or high rate of hospitalization or emergency room visits for asthma (relative to the average asthma prevalence rates and associated mortality rates in the United States). Acceptable data sets to demonstrate a high prevalence of childhood asthma or high asthma-related mortality may include data from Federal, State, or local vital statistics, claims data under title XIX or XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], other public health statistics or surveys, or other data that the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, deems appropriate.

(3) Definition of eligible entity

For purposes of this section, the term ''eligible entity'' means a public or nonprofit private entity (including a State or political subdivision of a State), or a consortium of any of such entities.

(b) Coordination with other children's programs

An eligible entity shall identify in the plan submitted as part of an application for a grant under this section how the entity will coordinate operations and activities under the grant with—

(1) other programs operated in the State that serve children with asthma, including any such programs operated under title V, XIX, or XXI of the Social Security Act [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) Evaluation

An eligible entity that receives a grant under this section shall submit to the Secretary an evaluation of the operations and activities carried out under the grant that includes—

(1) a description of the health status outcomes of children assisted under the grant;

(2) an assessment of the utilization of asthma-related health care services as a result of activities carried out under the grant;

(3) the collection, analysis, and reporting of asthma data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention; and

(4) such other information as the Secretary may require.

(d) Preference for States that allow students to self-administer medication to treat asthma and anaphylaxis

(1) Preference

The Secretary, in making any grant under this section or any other grant that is asthma-related (as determined by the Secretary) to a State, shall give preference to any State that satisfies the following:

(A) In general

The State must require that each public elementary school and secondary school in that State will grant to any student in the school an authorization for the self-administration of medication to treat that student's asthma or anaphylaxis, if—

(i) a health care practitioner prescribed the medication for use by the student during school hours and instructed the student in the correct and responsible use of the medication;

(ii) the student has demonstrated to the health care practitioner (or such practitioner's designee) and the school nurse (if available) the skill level necessary to use the medication and any device that is necessary to administer such medication as prescribed;

(iii) the health care practitioner formulates a written treatment plan for managing asthma or anaphylaxis episodes of the student and for medication use by the student during school hours; and

(iv) the student's parent or guardian has completed and submitted to the school any written documentation required by the school, including the treatment plan formulated under clause (iii) and other documents related to liability.

(B) Scope

An authorization granted under subparagraph (A) must allow the student involved to possess and use his or her medication—

(i) while in school;

(ii) while at a school-sponsored activity, such as a sporting event; and

(iii) in transit to or from school or school-sponsored activities.

(C) Duration of authorization

An authorization granted under subparagraph (A)—

(i) must be effective only for the same school and school year for which it is granted; and

(ii) must be renewed by the parent or guardian each subsequent school year in accordance with this subsection.

(D) Backup medication

The State must require that backup medication, if provided by a student's parent or guardian, be kept at a student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(E) Maintenance of information

The State must require that information described in subparagraphs (A)(iii) and (A)(iv) be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(F) School personnel administration of epinephrine

In determining the preference (if any) to be given to a State under this subsection, the Secretary shall give additional preference to a State that provides to the Secretary the certification described in subparagraph (G) and that requires that each public elementary school and secondary school in the State—

(i) permits trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;

(ii) maintains a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and

(iii) has in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

(G) Civil liability protection law

The certification required in subparagraph (F) shall be a certification made by the State attorney general that the State has reviewed any applicable civil liability protection law to determine the application of such law with regard to elementary and secondary school trained personnel who may administer epinephrine to a student reasonably believed to be having an anaphylactic reaction and has concluded that such law provides adequate civil liability protection applicable to such trained personnel. For purposes of the previous sentence, the term ''civil liability protection law'' means a State law offering legal protection to individuals who give aid on a voluntary basis in an emergency to an individual who is ill, in peril, or otherwise incapacitated.

(2) Rule of construction

Nothing in this subsection creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(3) Definitions

For purposes of this subsection:

(A) The terms ''elementary school'' and ''secondary school'' have the meaning given to those terms in section 7801 of title 20.

(B) The term ''health care practitioner'' means a person authorized under law to prescribe drugs subject to section 353(b) of title 21.

(C) The term ''medication'' means a drug as that term is defined in section 321 of title 21 and includes inhaled bronchodilators and auto-injectable epinephrine.

(D) The term ''self-administration'' means a student's discretionary use of his or her prescribed asthma or anaphylaxis medication, pursuant to a prescription or written direction from a health care practitioner.

(E) The term ''trained personnel'' means, with respect to an elementary or secondary school, an individual—

(i) who has been designated by the principal (or other appropriate administrative staff) of the school to administer epinephrine on a voluntary basis outside their scope of employment;

(ii) who has received training in the administration of epinephrine; and

(iii) whose training in the administration of epinephrine meets appropriate medical standards and has been documented by appropriate administrative staff of the school.

(e) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399L, as added Pub. L. 106–310, div. A, title V, § 501, Oct. 17, 2000, 114 Stat. 1113; amended Pub. L. 108–377, § 3(a), Oct. 30, 2004, 118 Stat. 2203; Pub. L. 113–48, § 2, Nov. 13, 2013, 127 Stat. 575; Pub. L. 114–95, title IX, § 9215(kkk)(2), Dec. 10, 2015, 129 Stat. 2187.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(1), (2)(B) and (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.

PRIOR PROVISIONS

A prior section 399L of act July 1, 1944, was renumbered section 399F and is classified to section 280e–4 of this title.

AMENDMENTS

2015—Subsec. (d)(3)(A). Pub. L. 114–95 made technical amendment to reference in original act which appears in text as reference to section 7801 of title 20.

2013—Subsec. (d)(1)(F), (G). Pub. L. 113–48, § 2(1), added subpars. (F) and (G).

Subsec. (d)(3)(E). Pub. L. 113–48, § 2(2), added subpar. (E).

2004—Subsecs. (d), (e). Pub. L. 108–377 added subsec. (d) and redesignated former subsec. (d) as (e).

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–377, § 3(b), Oct. 30, 2004, 118 Stat. 2204, provided that: ''The amendments made by this section [amending this section] shall apply only with respect to grants made on or after the date that is 9 months after the date of the enactment of this Act [Oct. 30, 2004].''

FINDINGS OF 2004 AMENDMENT

Pub. L. 108–377, § 2, Oct. 30, 2004, 118 Stat. 2202, provided that: ''The Congress finds the following:

''(1) Asthma is a chronic condition requiring lifetime, ongoing medical intervention.

''(2) In 1980, 6,700,000 Americans had asthma.

''(3) In 2001, 20,300,000 Americans had asthma; 6,300,000 children under age 18 had asthma.

''(4) The prevalence of asthma among African-American children was 40 percent greater than among Caucasian children, and more than 26 percent of all asthma deaths are in the African-American population.

''(5) In 2000, there were 1,800,000 asthma-related visits to emergency departments (more than 728,000 of these involved children under 18 years of age).

''(6) In 2000, there were 465,000 asthma-related hospitalizations (214,000 of these involved children under 18 years of age).

''(7) In 2000, 4,487 people died from asthma, and of these 223 were children.

''(8) According to the Centers for Disease Control and Prevention, asthma is a common cause of missed school days, accounting for approximately 14,000,000 missed school days annually.

''(9) According to the New England Journal of Medicine, working parents of children with asthma lose an estimated $1,000,000,000 a year in productivity.

''(10) At least 30 States have legislation protecting the rights of children to carry and self-administer asthma metered-dose inhalers, and at least 18 States expand this protection to epinephrine auto-injectors.

''(11) Tragic refusals of schools to permit students to carry their inhalers and auto-injectable epinephrine have occurred, some resulting in death and spawning litigation.

''(12) School district medication policies must be developed with the safety of all students in mind. The immediate and correct use of asthma inhalers and auto-injectable epinephrine are necessary to avoid serious respiratory complications and improve health care outcomes.

''(13) No school should interfere with the patient-physician relationship.

''(14) Anaphylaxis, or anaphylactic shock, is a systemic allergic reaction that can kill within minutes. Anaphylaxis occurs in some asthma patients. According to the American Academy of Allergy, Asthma, and Immunology, people who have experienced symptoms of anaphylaxis previously are at risk for subsequent reactions and should carry an epinephrine auto-injector with them at all times, if prescribed.

''(15) An increasing number of students and school staff have life-threatening allergies. Exposure to the affecting allergen can trigger anaphylaxis. Anaphylaxis requires prompt medical intervention with an injection of epinephrine.''

§ 280g–1. Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children

(a) Statewide newborn, infant, and young child hearing screening, evaluation and intervention programs and systems

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers (including, as appropriate, education and training of family members), for the following purposes:

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns, infants, and young children (referred to in this section as ''children''); prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:

(A) Early intervention includes referral to, and delivery of, information and services by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated by part C of the Individuals with Disabilities Education Act [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 children.

(B) Information provided to families should be accurate, comprehensive, up-to-date, and evidence-based, as appropriate, to allow families to make important decisions for their children in a timely manner, including decisions with respect to the full range of assistive hearing technologies and communications modalities, as appropriate.

(C) Programs and systems under this paragraph shall offer mechanisms that foster family-to-family and deaf and hard-of-hearing consumer-to-family supports.

(2) To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing

and enhancing State early hearing detection and intervention programs.

(3) To identify or develop efficient models (educational and medical) to ensure that children who are identified as deaf or hard-of-hearing through screening receive follow-up by qualified early intervention providers or qualified health care providers (including those at medical homes for children), and referrals, as appropriate, including to early intervention services under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]. State agencies shall be encouraged to effectively increase the rate of such follow-up and referral.

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

(1) Centers for Disease Control and Prevention

(A) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies or designated entities of States—

(i) to develop, maintain, and improve data collection systems related to newborn, infant, and young child hearing screening, evaluation (including audiologic, medical, and language acquisition evaluations), diagnosis, and intervention services;

(ii) to conduct applied research related to newborn, infant, and young child hearing screening, evaluation, and intervention programs and outcomes;

(iii) to ensure quality monitoring of hearing screening, evaluation, and intervention programs and systems for newborns, infants, and young children; and

(iv) to support newborn, infant, and young child hearing screening, evaluation, and intervention programs, and information systems.

(B) Use of awards

The awards made under subparagraph (A) may be used—

(i) to provide technical assistance on data collection and management, including to coordinate and develop standardized procedures for data management;

(ii) to assess and report on the cost and program effectiveness of newborn, infant, and young child hearing screening, evaluation, and intervention programs and systems;

(iii) to collect data and report on newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems for applied research, program evaluation, and policy improvement;

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

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

(vi) to promote the integration and interoperability of data regarding early hearing loss across multiple sources to increase the flow of information between clinical care and public health settings, including the ability of States and territories to exchange and share data.

(2) National Institutes of Health

The Director of the National Institutes of Health, acting through the Director of the National Institute on Deafness and Other Communication Disorders, shall for purposes of this section, continue a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, studies on efficacy of intervention, and related research.

(c) Coordination and collaboration

(1) In general

In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with—

(A) other Federal agencies;

(B) State and local agencies, including agencies responsible for early intervention services pursuant to title XIX of the Social Security Act [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.];

(C) consumer groups of, and that serve, individuals who are deaf and hard-of-hearing and their families;

(D) appropriate national medical and other health and education specialty organizations;

(E) individuals who are deaf or hard-of-hearing and their families;

(F) other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing children, and their families;

(G) third-party payers and managed care organizations; and

(H) related commercial industries.

(2) Policy development

The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education profes-

sional-based organizations, with respect to newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems.

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

The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States—

(A) to establish newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems under subsection (a); and

(B) to develop a data collection system under subsection (b).

(d) Rule of construction; religious accommodation

Nothing in this section shall be construed to preempt or prohibit any State law, including State laws that do not require the screening for hearing loss of children of parents who object to the screening on the grounds that such screening conflicts with the parent's religious beliefs.

(e) Definitions

For purposes of this section:

(1) The term ''audiologic'', when used in connection with evaluation, means procedures—

(A) to assess the status of the auditory system;

(B) to establish the site of the auditory disorder, the type and degree of hearing loss, and the potential effects of hearing loss on communication; and

(C) to identify appropriate treatment and referral options, including—

(i) linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.] or other appropriate agencies;

(ii) medical evaluation;

(iii) assessment for the full range of assistive hearing technologies appropriate for newborns, infants, and young children;

(iv) audiologic rehabilitation treatment; and

(v) referral to national and local consumer, self-help, parent, family, and education organizations, and other family-centered services.

(2) The term ''early intervention'' means—

(A) providing appropriate services for the child who is deaf or hard-of-hearing, including nonmedical services; and

(B) ensuring that the family of the child is—

(i) provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language acquisition in oral and visual modalities; and

(ii) given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for the child from highly qualified providers.

The[1] term ''medical evaluation'' means key components performed by a physician including history, examination, and medical decisionmaking focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(4) The term ''medical intervention'' means the process by which a physician provides medical diagnosis and direction for medical or surgical treatment options for hearing loss or other medical disorders associated with hearing loss.

(5) The term ''newborn, infant, and young child hearing screening'' means objective physiologic procedures to detect possible hearing loss and to identify newborns, infants, and young children under 3 years of age who require further audiologic and medical evaluations.

(f) Authorization of appropriations

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

For the purpose of carrying out subsection (a), there are authorized to be appropriated to the Health Resources and Services Administration $17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022.

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

For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated to the Centers for Disease Control and Prevention $10,800,000 for fiscal year 2018, $11,026,800 for fiscal year 2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022.

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

For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated to the National Institute on Deafness and Other Communication Disorders such sums as may be necessary for fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, § 399M, as added Pub. L. 106–310, div. A, title VII, § 702, Oct. 17, 2000, 114 Stat. 1121; amended Pub. L. 111–337, § 2, Dec. 22, 2010, 124 Stat. 3588; Pub. L. 115–71, § 2, Oct. 18, 2017, 131 Stat. 1218.)

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsecs. (a)(1)(A), (3), (c)(1)(B), and (e)(1)(C)(i), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. 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. (c)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles

[1] So in original. Probably should be preceded by ''(3)''.

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.

AMENDMENTS

2017—Pub. L. 115–71, § 2(a), substituted ''Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children'' for ''Early detection, diagnosis, and treatment regarding hearing loss in newborns and infants'' in section catchline.

Subsec. (a). Pub. L. 115–71, § 2(b)(2), substituted ''newborn, infant, and young child'' for ''newborn and infant'' and ''providers (including, as appropriate, education and training of family members),'' for ''providers,'' in introductory provisions.

Pub. L. 115–71, § 2(b)(1), substituted ''newborn, infant, and young child'' for ''newborn and infant'' in heading.

Subsec. (a)(1). Pub. L. 115–71, § 2(b)(3), in first sentence, substituted ''newborns, infants, and young children (referred to in this section as 'children')'' for ''newborns and infants'' and ''medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:'' for ''and medical interventions for children identified with hearing loss.''; designated second sentence as subpar. (A) and substituted '', and delivery of,'' for ''and delivery of'', ''by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated'' for ''by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated'', and ''hard-of-hearing children.'' for ''hard of hearing newborns, infants, toddlers, and children.''; struck out third sentence which read ''Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss.''; and added subpars. (B) and (C).

Subsec. (a)(2). Pub. L. 115–71, § 2(b)(4), substituted ''To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs.'' for ''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.''

Subsec. (a)(3). Pub. L. 115–71, § 2(b)(5), added par. (3) and struck out former par. (3) which read as follows: ''Other activities may include developing efficient models to ensure that newborns and infants who are identified with a hearing loss through screening receive follow-up by a qualified health care provider, and State agencies shall be encouraged to adopt models that effectively increase the rate of occurrence of such follow-up.''

Subsec. (b)(1). Pub. L. 115–71, § 2(c), made extensive amendments to text and structure of par. (1). Prior to amendments, text of par. (1) read as follows: ''The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

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

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

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

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

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

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

Subsec. (c)(1). Pub. L. 115–71, § 2(d)(1), substituted ''consult with—'' for ''consult with'', ''(A) other Federal'' for ''other Federal'', ''(B) State and local agencies, including agencies'' for ''State and local agencies, including those'', ''(C) consumer groups of, and that serve,'' for ''consumer groups of and that serve'', ''(D) appropriate national'' for ''appropriate national'', ''(E) individuals who are deaf or'' for ''persons who are deaf and'', ''(F) other qualified'' for ''other qualified'', ''children,'' for ''newborns, infants, toddlers, children,'', ''(G) third-party'' for ''third-party'', and ''(H) related commercial'' for ''related commercial''.

Subsec. (c)(3). Pub. L. 115–71, § 2(d)(2), substituted ''States—'' for ''States'', ''(A) to establish newborn, infant, and young child'' for ''to establish newborn and infant'', ''subsection (a); and'' for ''subsection (a) and'', and ''(B) to develop'' for ''to develop''.

Subsec. (d). Pub. L. 115–71, § 2(e), substituted ''that do not'' for ''which do not'' and ''parent's'' for ''parents' '' and struck out ''newborn infants or young'' after ''hearing loss of''.

Subsec. (e)(1). Pub. L. 115–71, § 2(f)(1), made extensive amendments to text and structure of par. (1). Prior to amendments, par. (1) read as follows: ''The term 'audiologic evaluation' refers to procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.''

Subsec. (e)(2). Pub. L. 115–71, § 2(f)(4), made extensive amendments to text and structure of par. (2). Prior to amendments, par. (2) read as follows: ''The term 'early intervention' refers to providing appropriate services for the child with hearing loss, including nonmedical services, and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.''

Pub. L. 115–71, § 2(f)(2), (3), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: ''The terms 'audiologic rehabilitation' and 'audiologic intervention' refer to procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.''

Subsec. (e)(3). Pub. L. 115–71, § 2(f)(5), substituted ''The term 'medical evaluation' means key components performed by a physician including history, examination, and medical decisionmaking'' for ''(3) The term 'medical evaluation by a physician' refers to key components including history, examination, and medical decision making''.

Pub. L. 115–71, § 2(f)(3), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (e)(4). Pub. L. 115–71, §2(f)(6), substituted ''means'' for ''refers to'', ''or surgical'' for ''and/or surgical'', and ''for hearing loss or other medical disorders'' for ''of hearing loss and/or related medical disorder''.

Pub. L. 115–71, §2(f)(3), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (e)(5). Pub. L. 115–71, §2(f)(7), substituted ''The term 'newborn, infant, and young child hearing screening' means'' for ''The term 'newborn and infant hearing screening' refers to'' and '', infants, and young children under 3 years of age'' for ''and infants''.

Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5). Former par. (5) redesignated (4).

Subsec. (e)(6). Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5).

Subsec. (f)(1). Pub. L. 115–71, §2(g)(1), substituted ''$17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022.'' for ''such sums as may be necessary for fiscal years 2011 through 2015.''

Subsec. (f)(2). Pub. L. 115–71, §2(g)(2), substituted ''$10,800,000 for fiscal year 2018, $11,026,800 for fiscal year 2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022.'' for ''such sums as may be necessary for fiscal years 2011 through 2015.''

2010—Pub. L. 111–337, §2(1), substituted ''newborns and infants'' for ''infants'' in section catchline.

Subsec. (a). Pub. L. 111–337, §2(2)(A), substituted ''screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers,'' for ''screening, evaluation and intervention programs and systems'' in introductory provisions.

Subsec. (a)(1). Pub. L. 111–337, §2(2)(B), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''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, which offer programs specifically designed to meet the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children.''

Subsec. (a)(3). Pub. L. 111–337, §2(2)(C), added par. (3).

Subsec. (b)(1)(A). Pub. L. 111–337, §2(3), substituted ''hearing loss screening, evaluation, diagnosis, and intervention programs'' for ''hearing loss screening, evaluation, and intervention programs''.

Subsec. (c)(2), (3). Pub. L. 111–337, §2(4), substituted ''hearing screening, evaluation, diagnosis, and intervention programs'' for ''hearing screening, evaluation and intervention programs''.

Subsec. (e)(3). Pub. L. 111–337, §2(5)(A), substituted ''ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.'' for ''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.''

Subsec. (e)(6). Pub. L. 111–337, §2(5)(B), struck out '', after rescreening,'' after ''infants who''.

Subsec. (f). Pub. L. 111–337, §2(6), substituted ''fiscal years 2011 through 2015'' for ''fiscal year 2002'' in pars. (1) to (3).

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

Pub. L. 111–8, div. F, title II, §224, Mar. 11, 2009, 123 Stat. 784, provided that: ''Hereafter, the activities authorized under section 399M of the Public Health Service Act [42 U.S.C. 280g–1] shall be known as the 'James T. Walsh Universal Newborn Hearing Screening Program.'''

PURPOSES

Pub. L. 106–310, div. A, title VII, §701, Oct. 17, 2000, 114 Stat. 1120, provided that: ''The purposes of this title [enacting 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 state-wide 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.''

§ 280g–2. Childhood malignancies

(a) In general

The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hos-

pitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) Coordination of activities

The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) Definition

For purposes of this section, the term ''childhood cancer'' refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

(e) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399N, as added Pub. L. 106–310, div. A, title XI, § 1101, Oct. 17, 2000, 114 Stat. 1131.)

§ 280g–3. Controlled substance monitoring program

(a) Grants

(1) In general

Each fiscal year, the Secretary, in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention, shall award a grant to each State with an application approved under this section to enable the State—

(A) to establish and implement a State controlled substance monitoring program;

(B) to make improvements to an existing State controlled substance monitoring program; or

(C) to maintain an existing State-controlled substance monitoring program.

(2) Determination of amount

(A) Minimum amount

In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

(B) Additional amounts

In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

(3) Term of grants

Grants awarded under this section shall be obligated in the year in which funds are allotted.

(b) Minimum requirements

The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

(c) Application approval process

(1) In general

To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

(iv) criteria for meeting the uniform electronic format requirement of subsection (i);

(v) criteria for availability of information and limitation on access to program personnel;

(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

(x) assurances of compliance with all other requirements of this section; or

(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B) or (a)(1)(C)—

(i) a budget cost estimate for the controlled substance monitoring program to be improved or maintained under the grant;

(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

(iii) a plan to apply the latest advances in health information technology, to the extent practicable, in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients' controlled prescription drug history;

(iv) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;

(v) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health or safety in such State; and

(vi) information, where applicable, on how the controlled substance monitoring program jointly works with the applicant's respective State substance abuse agency to ensure information collected and maintained by the controlled substance monitoring program is used to inform the provision of clinically appropriate substance use disorder services to individuals in need.

(2) State legislation

As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

(3) Interoperability

(A) In general

If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability.

(B) Monitoring of efforts

The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).

(4) Approval

If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

(5) Return of funds

If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to establish, improve, or maintain a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant). The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).

(d) Reporting requirements

In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health or safety in such State, with the following:

(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

(2) The State may exclude from the reporting requirement of this subsection—

(A) the direct administration of a controlled substance to the body of an ultimate user;

(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

(C) the administration or dispensing of a controlled substance in accordance with any

other exclusion identified by the Secretary for purposes of this paragraph.

(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

(D) Identification of the drug by a national drug code number.

(E) Quantity dispensed.

(F) Number of refills ordered.

(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(H) Date of the dispensing.

(I) Date of origin of the prescription.

(J) Such other information as may be required by State law to be reported under this subsection.

(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (i), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

(5) The State shall report on interoperability with the controlled substance monitoring program of Federal agencies, where appropriate, interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) Database

In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply with the following:

(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

(2) The database must be searchable by any field or combination of fields.

(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

(f) Use and disclosure of information

(1) In general

Subject to subsection (g), in establishing, improving, or maintaining a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a controlled substance included in schedule II, III, or IV of section 812(c) of title 21, and such information will further the purpose of the investigation or assist in the proceeding;

(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, a State substance abuse agency, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, agency, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, agency, or administration by law that is not investigative in nature; or

(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

(i) the State has an application approved under this section; and

(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

(2) Drug diversion

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion

investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

(3) Evaluation and reporting

Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data to enable the Secretary—

(A) to evaluate the success of the State's program in achieving its purposes; or

(B) to prepare and submit the report to Congress required by subsection (k)(2).

(4) Research by other entities

A department, program, agency, or administration receiving nonidentifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.

(g) Limitations

In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State—

(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

(h) Education and access to the monitoring system

A State receiving a grant under subsection (a) shall take steps to—

(1) facilitate prescriber and dispenser use of the State's controlled substance monitoring system, to the extent practicable; and

(2) educate prescribers and dispensers on the benefits of the system.

(i) Electronic format

The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

(j) Rules of construction

(1) Functions otherwise authorized by law

Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) No preemption

Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this chapter.

(3) Additional privacy protections

Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(4) Federal privacy requirements

Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 290dd–2 of this title.

(5) No Federal private cause of action

Nothing in this section shall be construed to create a Federal private cause of action.

(k) Studies and reports

(1) Implementation report

(A) In general

Not later than 180 days after August 11, 2005, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

(i) patient access to treatment, including therapy for pain or controlled substance abuse;

(ii) pediatric patient access to treatment; or

(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

(B) Additional categories of exclusion

If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

(2) Progress report

Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

(A) complete a study that—

(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances, established or strengthened initiatives to ensure linkages to substance use disorder services, or affected patient access to appropriate pain care in States operating such programs;

(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, and between controlled substance monitoring programs and health information technology systems, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

(iv) determines the feasibility of implementing a real-time electronic controlled

substance monitoring program, including the costs associated with establishing such a program;

(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

(B) submit a report to the Congress on the results of the study.

(*l*) Advisory council

(1) Establishment

A State may establish an advisory council to assist in the establishment, improvement, or maintenance of a controlled substance monitoring program under this section.

(2) Limitation

A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

(3) Sense of Congress

It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

(m) Definitions

For purposes of this section:

(1) The term ''bona fide patient'' means an individual who is a patient of the practitioner involved.

(2) The term ''controlled substance'' means a drug that is included in schedule II, III, or IV of section 812(c) of title 21.

(3) The term ''dispense'' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(4) The term ''dispenser'' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(5) The term ''interoperability'' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The term ''nonidentifiable information'' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term ''practitioner'' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(8) The term ''State'' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(9) The term ''ultimate user'' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

(n) Authorization of appropriations

To carry out this section, there are authorized to be appropriated, $10,000,000 for each of fiscal years 2017 through 2021.

(July 1, 1944, ch. 373, title III, § 399O, as added Pub. L. 109–60, § 3, Aug. 11, 2005, 119 Stat. 1979; amended Pub. L. 114–198, title I, § 109(b), July 22, 2016, 130 Stat. 706.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (j)(4), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

Another section 399O of act July 1, 1944, was renumbered section 399P and is classified to section 280g–4 of this title.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–198, § 109(b)(1)(A), inserted '', in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention,'' after ''the Secretary'' in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 114–198, § 109(b)(1)(B)–(D), added subpar. (C).

Subsec. (b). Pub. L. 114–198, § 109(b)(2), amended subsec. (b) generally. Prior to amendment, text read as follows: ''Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for pur-

poses of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A) of this section.''

Subsec. (c)(1)(A)(iv). Pub. L. 114–198, §109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (c)(1)(B). Pub. L. 114–198, §109(b)(3)(A)(i), substituted ''(a)(1)(B) or (a)(1)(C)'' for ''(a)(1)(B)'' in introductory provisions.

Subsec. (c)(1)(B)(i). Pub. L. 114–198, §109(b)(3)(A)(ii), substituted ''program to be improved or maintained'' for ''program to be improved''.

Subsec. (c)(1)(B)(iii). Pub. L. 114–198, §109(b)(3)(A)(iv), added cl. (iii). Former cl. (iii) redesignated (iv).

Subsec. (c)(1)(B)(iv). Pub. L. 114–198, §109(b)(3)(A)(iii), (v), redesignated cl. (iii) as (iv) and substituted ''and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;'' for ''; and''. Former cl. (iv) redesignated (v).

Subsec. (c)(1)(B)(v). Pub. L. 114–198, §109(b)(3)(A)(iii), (vi), redesignated cl. (iv) as (v) and substituted ''public health or safety in such State; and'' for ''public health in such State.''

Subsec. (c)(1)(B)(vi). Pub. L. 114–198, §109(b)(3)(A)(vii), added cl. (vi).

Subsec. (c)(3). Pub. L. 114–198, §109(b)(3)(B), designated existing provisions as subpar. (A) and inserted heading, inserted before period at end ''and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability'', and added subpar. (B).

Subsec. (c)(5). Pub. L. 114–198, §109(b)(3)(C), substituted ''establish, improve, or maintain'' for ''implement or improve'' and inserted at end ''The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).''

Subsec. (d). Pub. L. 114–198, §109(b)(4)(A), in introductory provisions, substituted ''In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)'' for ''In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B)'' and ''public health or safety'' for ''public health''.

Subsec. (d)(4). Pub. L. 114–198, §109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (d)(5). Pub. L. 114–198, §109(b)(4)(B), added par. (5).

Subsecs. (e), (f)(1). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsec. (f)(1)(B). Pub. L. 114–198, §109(b)(6)(A)(i), substituted ''misuse of a controlled substance included in schedule II, III, or IV of section 812(c) of title 21'' for ''misuse of a schedule II, III, or IV substance''.

Subsec. (f)(1)(D). Pub. L. 114–198, §109(b)(6)(A)(ii), inserted ''a State substance abuse agency,'' after ''State health department,'' and substituted ''such department, program, agency, or administration'' for ''such department, program, or administration'' in two places.

Subsec. (f)(3), (4). Pub. L. 114–198, §109(b)(6)(B), added pars. (3) and (4).

Subsec. (g). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsecs. (h) to (j). Pub. L. 114–198, §109(b)(8), (10), added subsec. (h) and redesignated former subsecs. (h) and (i) as (i) and (j), respectively. Former subsec. (j) redesignated (k).

Subsec. (k). Pub. L. 114–198, §109(b)(7), (8), redesignated subsec. (j) as (k) and struck out former subsec. (k). Prior to amendment, text of subsec. (k) read as follows: ''Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).''

Subsec. (k)(2)(A)(ii). Pub. L. 114–198, §109(b)(11)(A), substituted '', established or strengthened initiatives to ensure linkages to substance use disorder services, or affected'' for ''or affected''.

Subsec. (k)(2)(A)(iii). Pub. L. 114–198, §109(b)(11)(B), substituted ''and between controlled substance monitoring programs and health information technology systems, including an assessment'' for ''including an assessment''.

Subsec. (*l*)(1). Pub. L. 114–198, §109(b)(12), substituted ''establishment, improvement, or maintenance'' for ''establishment, implementation, or improvement''.

Subsec. (m)(8). Pub. L. 114–198, §109(b)(13), substituted '', the District of Columbia, and any commonwealth or territory of the United States'' for ''and the District of Columbia''.

Subsec. (n). Pub. L. 114–198, §109(b)(14), amended subsec. (n) generally. Prior to amendment, subsec. (n) authorized appropriations for fiscal years 2006 to 2010.

PURPOSE

Pub. L. 109–60, §2, Aug. 11, 2005, 119 Stat. 1979, as amended by Pub. L. 114–198, title I, §109(a), July 22, 2016, 130 Stat. 706, provided that: ''It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

''(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

''(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.''

§ 280g–4. Grants to strengthen the healthcare system's response to domestic violence, dating violence, sexual assault, and stalking

(a) In general

The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, nursing, dental, and other health profession students and residents to prevent and respond to domestic violence, dating violence, sexual assault, and stalking; and

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the response of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to domestic violence, dating violence, sexual assault, and stalking.

(b) Use of funds

(1) Required uses

Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to identify and provide health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking; and

(ii) plan and develop culturally competent clinical training components for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse, focus on reducing health disparities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(B) design and implement comprehensive strategies to improve the response of the health care system to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—

(i) the implementation, dissemination, and evaluation of policies and procedures to guide health professionals and public health staff in identifying and responding to domestic violence, dating violence, sexual assault, and stalking, including strategies to ensure that health information is maintained in a manner that protects the patient's privacy and safety, and safely uses health information technology to improve documentation, identification, assessment, treatment, and follow-up care;

(ii) the development of on-site access to services to address the safety, medical, and mental health needs of patients by increasing the capacity of existing health care professionals and public health staff to address domestic violence, dating violence, sexual assault, and stalking, or by contracting with or hiring domestic or sexual assault advocates to provide such services or to model other services appropriate to the geographic and cultural needs of a site;

(iii) the development of measures and methods for the evaluation of the practice of identification, intervention, and documentation regarding victims of domestic violence, dating violence, sexual assault, and stalking, including the development and testing of quality improvement measurements, in accordance with the multistakeholder and quality measurement processes established under paragraphs (7) and (8) of section 1395aaa(b) of this title and section 1395aaa–1 of this title; and

(iv) the provision of training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking, including using tools and training materials already developed.

(2) Permissible uses

(A) Child and elder abuse

To the extent consistent with the purpose of this section, a grantee may use amounts received under this section to address, as part of a comprehensive programmatic approach implemented under the grant, issues relating to child or elder abuse.

(B) Rural areas

Grants funded under paragraphs (1) and (2) of subsection (a) may be used to offer to rural areas community-based training opportunities, which may include the use of distance learning networks and other available technologies needed to reach isolated rural areas, for medical, nursing, and other health profession students and residents on domestic violence, dating violence, sexual assault, stalking, and, as appropriate, other forms of violence and abuse.

(C) Other uses

Grants funded under subsection (a)(3) may be used for—

(i) the development of training modules and policies that address the overlap of child abuse, domestic violence, dating violence, sexual assault, and stalking and elder abuse, as well as childhood exposure to domestic and sexual violence;

(ii) the development, expansion, and implementation of sexual assault forensic medical examination or sexual assault nurse examiner programs;

(iii) the inclusion of the health effects of lifetime exposure to violence and abuse as well as related protective factors and behavioral risk factors in health professional training schools including medical, dental, nursing, social work, and mental and behavioral health curricula, and allied health service training courses; or

(iv) the integration of knowledge of domestic violence, dating violence, sexual assault, and stalking into health care accreditation and professional licensing examinations, such as medical, dental, social work, and nursing boards, and where appropriate, other allied health exams.

(c) Requirements for grantees

(1) Confidentiality and safety

(A) In general

Grantees under this section shall ensure that all programs developed with grant

funds address issues of confidentiality and patient safety and comply with applicable confidentiality and nondisclosure requirements under section 12291(b)(2) of title 34 and the Family Violence Prevention and Services Act [42 U.S.C. 10401 et seq.], and that faculty and staff associated with delivering educational components are fully trained in procedures that will protect the immediate and ongoing security and confidentiality of the patients, patient records, and staff. Such grantees shall consult entities with demonstrated expertise in the confidentiality and safety needs of victims of domestic violence, dating violence, sexual assault, and stalking on the development and adequacy of confidentially and security procedures, and provide documentation of such consultation.

(B) Advance notice of information disclosure

Grantees under this section shall provide to patients advance notice about any circumstances under which information may be disclosed, such as mandatory reporting laws, and shall give patients the option to receive information and referrals without affirmatively disclosing abuse.

(2) Limitation on administrative expenses

A grantee shall use not more than 10 percent of the amounts received under a grant under this section for administrative expenses.

(3) Application

(A) Preference

In selecting grant recipients under this section, the Secretary shall give preference to applicants based on the strength of their evaluation strategies, with priority given to outcome based evaluations.

(B) Subsection (a)(1) and (2) grantees

Applications for grants under paragraphs (1) and (2) of subsection (a) shall include—

(i) documentation that the applicant represents a team of entities working collaboratively to strengthen the response of the health care system to domestic violence, dating violence, sexual assault, or stalking, and which includes at least one of each of—

(I) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or other health field;

(II) a health care facility or system; or

(III) a government or nonprofit entity with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking; and

(ii) strategies for the dissemination and sharing of curricula and other educational materials developed under the grant, if any, with other interested health professions schools and national resource repositories for materials on domestic violence, dating violence, sexual assault, and stalking.

(C) Subsection (a)(3) grantees

An entity desiring a grant under subsection (a)(3) shall submit an application to the Secretary at such time, in such a manner, and containing such information and assurances as the Secretary may require, including—

(i) documentation that all training, education, screening, assessment, services, treatment, and any other approach to patient care will be informed by an understanding of violence and abuse victimization and trauma-specific approaches that will be integrated into prevention, intervention, and treatment activities;

(ii) strategies for the development and implementation of policies to prevent and address domestic violence, dating violence, sexual assault, and stalking over the lifespan in health care settings;

(iii) a plan for consulting with State and tribal domestic violence or sexual assault coalitions, national nonprofit victim advocacy organizations, State or tribal law enforcement task forces (where appropriate), and population specific organizations with demonstrated expertise in domestic violence, dating violence, sexual assault, or stalking;

(iv) with respect to an application for a grant under which the grantee will have contact with patients, a plan, developed in collaboration with local victim service providers, to respond appropriately to and make correct referrals for individuals who disclose that they are victims of domestic violence, dating violence, sexual assault, stalking, or other types of violence, and documentation provided by the grantee of an ongoing collaborative relationship with a local victim service provider; and

(v) with respect to an application for a grant proposing to fund a program described in subsection (b)(2)(C)(ii), a certification that any sexual assault forensic medical examination and sexual assault nurse examiner programs supported with such grant funds will adhere to the guidelines set forth by the Attorney General.

(d) Eligible entities

(1) In general

To be eligible to receive funding under paragraph (1) or (2) of subsection (a), an entity shall be—

(A) a nonprofit organization with a history of effective work in the field of training health professionals with an understanding of, and clinical skills pertinent to, domestic violence, dating violence, sexual assault, or stalking, and lifetime exposure to violence and abuse;

(B) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or allied health;

(C) a health care provider membership or professional organization, or a health care system; or

(D) a State, tribal, territorial, or local entity.

(2) Subsection (a)(3) grantees

To be eligible to receive funding under subsection (a)(3), an entity shall be—

(A) a State department (or other division) of health, a State, tribal, or territorial domestic violence or sexual assault coalition or victim service provider, or any other nonprofit, nongovernmental organization with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking, and health care, including physical or mental health care; or

(B) a local victim service provider, a local department (or other division) of health, a local health clinic, hospital, or health system, or any other community-based organization with a history of effective work in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care.

(e) Technical assistance

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may make grants or enter into contracts to provide technical assistance with respect to the planning, development, and operation of any program, activity or service carried out pursuant to this section. Not more than 8 percent of the funds appropriated under this section in each fiscal year may be used to fund technical assistance under this subsection.

(2) Availability of materials

The Secretary shall make publicly available materials developed by grantees under this section, including materials on training, best practices, and research and evaluation.

(3) Reporting

The Secretary shall publish a biennial report on—

(A) the distribution of funds under this section; and

(B) the programs and activities supported by such funds.

(f) Research and evaluation

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may use not more than 20 percent to make a grant or enter into a contract for research and evaluation of—

(A) grants awarded under this section; and

(B) other training for health professionals and effective interventions in the health care setting that prevent domestic violence, dating violence, and sexual assault across the lifespan, prevent the health effects of such violence, and improve the safety and health of individuals who are currently being victimized.

(2) Research

Research authorized in paragraph (1) may include—

(A) research on the effects of domestic violence, dating violence, sexual assault, and childhood exposure to domestic, dating or sexual violence on health behaviors, health conditions, and health status of individuals, families, and populations, including underserved populations;

(B) research to determine effective health care interventions to respond to and prevent domestic violence, dating violence, sexual assault, and stalking;

(C) research on the impact of domestic, dating and sexual violence, childhood exposure to such violence, and stalking on the health care system, health care utilization, health care costs, and health status; and

(D) research on the impact of adverse childhood experiences on adult experience with domestic violence, dating violence, sexual assault, stalking, and adult health outcomes, including how to reduce or prevent the impact of adverse childhood experiences through the health care setting.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2014 through 2018.

(h) Definitions

Except as otherwise provided herein, the definitions provided for in section 12291 of title 34 shall apply to this section.

(July 1, 1944, ch. 373, title III, § 399P, formerly § 399O, as added Pub. L. 109–162, title V, § 504, Jan. 5, 2006, 119 Stat. 3026; renumbered § 399P, Pub. L. 109–450, § 4(1), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–4, title V, § 501(a), Mar. 7, 2013, 127 Stat. 96.)

REFERENCES IN TEXT

The Family Violence Prevention and Services Act, referred to in subsec. (c)(1)(A), is title III of Pub. L. 98–457, Oct. 9, 1984, 98 Stat. 1757, which is classified generally to chapter 110 (§ 10401 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10401 of this title and Tables.

AMENDMENTS

2013—Pub. L. 113–4 amended section generally. Prior to amendment, section related to grants to foster public health responses to domestic violence, dating violence, sexual assault, and stalking.

FINDINGS

Pub. L. 109–162, title V, § 501, Jan. 5, 2006, 119 Stat. 3023, provided that: ''Congress makes the following findings:

''(1) The health-related costs of intimate partner violence in the United States exceed $5,800,000,000 annually.

''(2) Thirty-seven percent of all women who sought care in hospital emergency rooms for violence-related injuries were injured by a current or former spouse, boyfriend, or girlfriend.

''(3) In addition to injuries sustained during violent episodes, physical and psychological abuse is linked to a number of adverse physical and mental health effects. Women who have been abused are much more likely to suffer from chronic pain, diabetes, depression, unintended pregnancies, substance abuse and sexually transmitted infections, including HIV/AIDS.

''(4) Health plans spend an average of $1,775 more a year on abused women than on general enrollees.

''(5) Each year about 324,000 pregnant women in the United States are battered by the men in their lives. This battering leads to complications of pregnancy, including low weight gain, anemia, infections, and first and second trimester bleeding.

''(6) Pregnant and recently pregnant women are more likely to be victims of homicide than to die of

any other pregnancy-related cause, and evidence exists that a significant proportion of all female homicide victims are killed by their intimate partners.

''(7) Children who witness domestic violence are more likely to exhibit behavioral and physical health problems including depression, anxiety, and violence towards peers. They are also more likely to attempt suicide, abuse drugs and alcohol, run away from home, engage in teenage prostitution, and commit sexual assault crimes.

''(8) Recent research suggests that women experiencing domestic violence significantly increase their safety-promoting behaviors over the short- and long-term when health care providers screen for, identify, and provide followup care and information to address the violence.

''(9) Currently, only about 10 percent of primary care physicians routinely screen for intimate partner abuse during new patient visits and 9 percent routinely screen for intimate partner abuse during periodic checkups.

''(10) Recent clinical studies have proven the effectiveness of a 2-minute screening for early detection of abuse of pregnant women. Additional longitudinal studies have tested a 10-minute intervention that was proven highly effective in increasing the safety of pregnant abused women. Comparable research does not yet exist to support the effectiveness of screening men.

''(11) Seventy to 81 percent of the patients studied reported that they would like their healthcare providers to ask them privately about intimate partner violence.''

PURPOSE

Pub. L. 109–162, title V, § 502, Jan. 5, 2006, 119 Stat. 3024, provided that: ''It is the purpose of this title [enacting this section, sections 294h and 13973 of this title, and provisions set out as a note above] to improve the health care system's response to domestic violence, dating violence, sexual assault, and stalking through the training and education of health care providers, developing comprehensive public health responses to violence against women and children, increasing the number of women properly screened, identified, and treated for lifetime exposure to violence, and expanding research on effective interventions in the health care setting.''

§ 280g–5. Public and health care provider education and support services

(a) In general

The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct demonstration projects for the purpose of improving the provision of information on prematurity to health professionals and other health care providers and the public and improving the treatment and outcomes for babies born preterm.

(b) Activities

Activities to be carried out under the demonstration project under subsection (a) may include the establishment of—

(1) programs to test and evaluate various strategies to provide information and education to health professionals, other health care providers, and the public concerning—

(A) the core risk factors for preterm labor and delivery;

(B) medically indicated deliveries before full term;

(C) the importance of preconception and prenatal care, including—

(i) smoking cessation;

(ii) weight maintenance and good nutrition, including folic acid;

(iii) the screening for and the treatment of infections; and

(iv) stress management;

(D) treatments and outcomes for premature infants, including late preterm infants;

(E) the informational needs of families during the stay of an infant in a neonatal intensive care unit; and

(F) utilization of evidence-based strategies to prevent birth injuries;

(2) programs to increase the availability, awareness, and use of pregnancy and post-term information services that provide evidence-based, clinical information through counselors, community outreach efforts, electronic or telephonic communication, or other appropriate means regarding causes associated with prematurity, birth defects, or health risks to a post-term infant;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section $1,900,000 for each of fiscal years 2014 through 2018.

(July 1, 1944, ch. 373, title III, § 399Q, as added Pub. L. 109–450, § 4(2), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–55, title I, § 103(b), Nov. 27, 2013, 127 Stat. 642.)

AMENDMENTS

2013—Subsec. (b)(1). Pub. L. 113–55, § 103(b)(1)(A), added subpars. (A) to (F) and struck out former subpars. (A) to (F) which read as follows:

''(A) the signs of preterm labor, updated as new research results become available;

''(B) the screening for and the treating of infections;

''(c) counseling on optimal weight and good nutrition, including folic acid;

''(D) smoking cessation education and counseling;

''(E) stress management; and

''(F) appropriate prenatal care;''.

Subsec. (b)(2). Pub. L. 113–55, § 103(b)(1)(B), added par. (2) and struck out former par. (2) which read as follows: ''programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;''.

Subsec. (c). Pub. L. 113–55, § 103(b)(2), substituted ''$1,900,000 for each of fiscal years 2014 through 2018.'' for ''$5,000,000 for each of fiscal years 2007 through 2011.''

§ 280g–6. Chronic kidney disease initiatives

(a) In general

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regard-

ing chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) Scope and duration

(1) Scope

The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) Duration

The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) Evaluation and report

The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

(July 1, 1944, ch. 373, title III, § 399R, as added Pub. L. 110–275, title I, § 152(a), July 15, 2008, 122 Stat. 2551.)

CODIFICATION

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110–373, § 2, Oct. 8, 2008, 122 Stat. 4047, was renumbered section 399S and is classified to section 280g–7 of this title.

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110–374, § 3, Oct. 8, 2008, 122 Stat. 4051, was renumbered section 399T and is classified to section 280g–8 of this title.

§ 280g–7. Amyotrophic lateral sclerosis registry

(a) Establishment

(1) In general

Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as ''ALS'') and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) Purpose

It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) Advisory Committee

(1) Establishment

Not later than 180 days after October 8, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ''Advisory Committee''). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations;[1]

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

[1] So in original. Probably should be ''national voluntary health associations;''.

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases[2] and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

(2) Duties

The Advisory Committee may review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) Report

Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) Grants

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

(d) Coordination with State, local, and Federal registries

(1)[3] In general

In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries;

(vi) the National Vital Statistics System; and

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) Definition

For the purposes of this section, the term ''national voluntary health association'' means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

(July 1, 1944, ch. 373, title III, § 399S, formerly § 399R, as added Pub. L. 110–373, § 2, Oct. 8, 2008, 122 Stat. 4047; renumbered § 399S, Pub. L. 111–148, title IV, § 4003(b)(2)(A), Mar. 23, 2010, 124 Stat. 544.)

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(1)(A)(ii), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

§ 280g–7a. Surveillance of neurological diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

(b) Research

The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) Content

In carrying out subsection (a), the Secretary—

[2] So in original. Probably should be followed by a semicolon.

[3] So in original. No par. (2) has been enacted.

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the natural history of the diseases;

(B) the prevention of the diseases;

(C) the detection, management, and treatment approaches for the diseases; and

(D) the development of outcomes measures;

(4) may address issues identified during the consultation process under subsection (d); and

(5) initially may address a limited number of neurological diseases.

(d) Consultation

In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases; and

(B) have demonstrated experience in research, care, or patient services;

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

(4) clinicians with expertise in neurological diseases; and

(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) Grants

The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) Coordination with other Federal, State, and local agencies

Subject to subsection (h), the Secretary shall—

(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

(B) to State and local agencies; and

(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(g) Public access

Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

(h) Privacy

The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(i) Reports

(1) Report on information and analyses

Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

(2) Implementation report

Not later than 4 years after December 13, 2016, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

(A) the development and maintenance of the National Neurological Conditions Surveillance System;

(B) the type of information collected and stored in the surveillance system;

(C) the use and availability of such information, including guidelines for such use; and

(D) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) Definition

In this section, the term ''national voluntary health association'' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

(k) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 399S–1, as added Pub. L. 114–255, div. A, title II, § 2061, Dec. 13, 2016, 130 Stat. 1076.)

§ 280g–8. Support for patients receiving a positive diagnosis of Down syndrome or other prenatally or postnatally diagnosed conditions

(a) Definitions

In this section:

(1) Down syndrome

The term ''Down syndrome'' refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) Health care provider

The term ''health care provider'' means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) Postnatally diagnosed condition

The term ''postnatally diagnosed condition'' means any health condition identified during the 12-month period beginning at birth.

(4) Prenatally diagnosed condition

The term ''prenatally diagnosed condition'' means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) Prenatal test

The term ''prenatal test'' means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) Information and support services

(1) In general

The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1)[1] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) Eligible entity

In this subsection, the term ''eligible entity'' means—

(A) a State or a political subdivision of a State;

(B) a consortium of 2 or more States or political subdivisions of States;

(C) a territory;

(D) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(E) any other entity with appropriate expertise in prenatally and postnatally diagnosed conditions (including nationally recognized disability groups), as determined by the Secretary.

(3) Distribution

In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care professional groups and disability advocacy organizations.

(c) Provision of information to providers

(1) In general

A grantee under this section shall make available to health care providers of parents who receive a prenatal or postnatal diagnosis the following:

(A) Up-to-date, evidence-based, written information concerning the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes.

(B) Contact information regarding support services, including information hotlines spe-

[1] See References in Text note below.

cific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, national and local peer support groups, and other education and support programs as described in subsection (b)(2).

(2) Informational requirements

Information provided under this subsection shall be—

(A) culturally and linguistically appropriate as needed by women receiving a positive prenatal diagnosis or the family of infants receiving a postnatal diagnosis; and

(B) approved by the Secretary.

(d) Report

Not later than 2 years after October 8, 2008, the Government Accountability Office shall submit a report to Congress concerning the effectiveness of current healthcare and family support programs serving as resources for the families of children with disabilities.

(July 1, 1944, ch. 373, title III, § 399T, formerly § 399R, as added Pub. L. 110–374, § 3, Oct. 8, 2008, 122 Stat. 4051; renumbered § 399T, Pub. L. 111–148, title IV, § 4003(b)(2)(B), Mar. 23, 2010, 124 Stat. 544.)

REFERENCES IN TEXT

Section 2(b)(1) of the Prenatally and Postnatally Diagnosed Conditions Awareness Act, referred to in subsec. (b)(1)(B)(v), probably means section 2(1) of that Act, Pub. L. 110–374, which is set out as a note under this section.

PURPOSES

Pub. L. 110–374, § 2, Oct. 8, 2008, 122 Stat. 4051, provided that: ''It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

''(1) increase patient referrals to providers of key support services for women who have received a positive diagnosis for Down syndrome, or other prenatally or postnatally diagnosed conditions, as well as to provide up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

''(2) strengthen existing networks of support through the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and other patient and provider outreach programs; and

''(3) ensure that patients receive up-to-date, evidence-based information about the accuracy of the test.''

§ 280g–9. Programs to improve quality of life for persons with paralysis and other physical disabilities

(a) In general

The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') may study the unique health challenges associated with paralysis and other physical disabilities and carry out projects and interventions to improve the quality of life and long-term health status of persons with paralysis and other physical disabilities. The Secretary may carry out such projects directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) may include—

(1) the development of a national paralysis and physical disability quality of life action plan, to promote health and wellness in order to enhance full participation, independent living, self-sufficiency, and equality of opportunity in partnership with voluntary health agencies focused on paralysis and other physical disabilities, to be carried out in coordination with the State-based Disability and Health Program of the Centers for Disease Control and Prevention;

(2) support for programs to disseminate information involving care and rehabilitation options and quality of life grant programs supportive of community-based programs and support systems for persons with paralysis and other physical disabilities;

(3) in collaboration with other centers and national voluntary health agencies, the establishment of a population-based database that may be used for longitudinal and other research on paralysis and other disabling conditions; and

(4) the replication and translation of best practices and the sharing of information across States, as well as the development of comprehensive, unique, and innovative programs, services, and demonstrations within existing State-based disability and health programs of the Centers for Disease Control and Prevention which are designed to support and advance quality of life programs for persons living with paralysis and other physical disabilities focusing on—

(A) caregiver education;

(B) promoting proper nutrition, increasing physical activity, and reducing tobacco use;

(C) education and awareness programs for health care providers;

(D) prevention of secondary complications;

(E) home- and community-based interventions;

(F) coordinating services and removing barriers that prevent full participation and integration into the community; and

(G) recognizing the unique needs of underserved populations.

(c) Grants

The Secretary may award grants in accordance with the following:

(1) To State and local health and disability agencies for the purpose of—

(A) establishing a population-based database that may be used for longitudinal and other research on paralysis and other disabling conditions;

(B) developing comprehensive paralysis and other physical disability action plans and activities focused on the items listed in subsection (b)(4);

(C) assisting State-based programs in establishing and implementing partnerships and collaborations that maximize the input and support of people with paralysis and other physical disabilities and their constituent organizations;

(D) coordinating paralysis and physical disability activities with existing State-based disability and health programs;

(E) providing education and training opportunities and programs for health professionals and allied caregivers; and

(F) developing, testing, evaluating, and replicating effective intervention programs to maintain or improve health and quality of life.

(2) To private health and disability organizations for the purpose of—

(A) disseminating information to the public;

(B) improving access to services for persons living with paralysis and other physical disabilities and their caregivers;

(C) testing model intervention programs to improve health and quality of life; and

(D) coordinating existing services with State-based disability and health programs.

(d) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate by the agencies of the Department of Health and Human Services.

(e) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $25,000,000 for each of fiscal years 2008 through 2011.

(Pub. L. 111–11, title XIV, § 14301, Mar. 30, 2009, 123 Stat. 1454.)

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

§ 280g–10. Community Preventive Services Task Force

(a) Establishment and purpose

The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the ''Task Force'') to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the ''Guide''), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

(b) Duties

The duties of the Task Force shall include—

(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

(2) at least once during every 5-year period, review[1] interventions and update[1] recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

(3) improved integration with Federal Government health objectives and related target setting for health improvement;

(4) the enhanced dissemination of recommendations;

(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(c) Role of agency

The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

(d) Coordination with Preventive Services Task Force

The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(e) Operation

In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of Appendix 2 of title 5.

(f) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(July 1, 1944, ch. 373, title III, § 399U, as added Pub. L. 111–148, title IV, § 4003(b)(1), Mar. 23, 2010, 124 Stat. 543.)

REFERENCES IN TEXT

Appendix 2 of title 5, referred to in subsec. (e), probably means the Federal Advisory Committee Act, Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

§ 280g–11. Grants to promote positive health behaviors and outcomes

(a) Grants authorized

The Director of the Centers for Disease Control and Prevention, in collaboration with the

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

Secretary, shall award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(b) Use of funds

Grants awarded under subsection (a) shall be used to support community health workers—

(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, particularly racial and ethnic minority populations;

(2) to educate and provide guidance regarding effective strategies to promote positive health behaviors and discourage risky health behaviors;

(3) to educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], Medicare under title XVIII of such Act [42 U.S.C. 1395 et seq.] and Medicaid under title XIX of such Act [42 U.S.C. 1396 et seq.];

(4) to identify and refer underserved populations to appropriate healthcare agencies and community-based programs and organizations in order to increase access to quality healthcare services and to eliminate duplicative care; or

(5) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

(c) Application

Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

(d) Priority

In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to target geographic areas—

(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

(B) with a high percentage of residents who suffer from chronic diseases; or

(C) with a high infant mortality rate;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

(3) have documented community activity and experience with community health workers.

(e) Collaboration with academic institutions and the one-stop delivery system

The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions and one-stop delivery systems under section 3151(e) of title 29. Nothing in this section shall be construed to require such collaboration.

(f) Evidence-based interventions

The Secretary shall encourage community health worker programs receiving funding under this section to implement a process or an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such a payment.

(g) Quality assurance and cost effectiveness

The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

(h) Monitoring

The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

(i) Technical assistance

The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

(j) Authorization of appropriations

There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2010 through 2014.

(k) Definitions

In this section:

(1) Community health worker

The term ''community health worker'' means an individual who promotes health or nutrition within the community in which the individual resides—

(A) by serving as a liaison between communities and healthcare agencies;

(B) by providing guidance and social assistance to community residents;

(C) by enhancing community residents' ability to effectively communicate with healthcare providers;

(D) by providing culturally and linguistically appropriate health or nutrition education;

(E) by advocating for individual and community health;

(F) by providing referral and follow-up services or otherwise coordinating care; and

(G) by proactively identifying and enrolling eligible individuals in Federal, State, local, private or nonprofit health and human services programs.

(2) Community setting

The term ''community setting'' means a home or a community organization located in the neighborhood in which a participant in the program under this section resides.

(3) Eligible entity

The term ''eligible entity'' means a public or nonprofit private entity (including a State or public subdivision of a State, a public health department, a free health clinic, a hospital, or a Federally-qualified health center (as defined

in section 1861(aa) of the Social Security Act [42 U.S.C. 1395x(aa)])), or a consortium of any such entities.

(4) Medically underserved community

The term ''medically underserved community'' means a community identified by a State—

(A) that has a substantial number of individuals who are members of a medically underserved population, as defined by section 254b(b)(3) of this title; and

(B) a significant portion of which is a health professional shortage area as designated under section 254e of this title.

(July 1, 1944, ch. 373, title III, § 399V, as added and amended Pub. L. 111–148, title V, § 5313(a), title X, § 10501(c), Mar. 23, 2010, 124 Stat. 633, 994; Pub. L. 113–128, title V, § 512(z)(1), July 22, 2014, 128 Stat. 1716.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 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.

AMENDMENTS

2014—Subsec. (e). Pub. L. 113–128 substituted ''one-stop delivery systems under section 3151(e) of title 29'' for ''one-stop delivery systems under section 2864(c) of title 29''.

2010—Subsec. (b)(4). Pub. L. 111–148, § 10501(c)(1), substituted ''identify and refer'' for ''identify, educate, refer, and enroll''.

Subsec. (k)(1). Pub. L. 111–148, § 10501(c)(2), struck out '', as defined by the Department of Labor as Standard Occupational Classification [21–1094]'' before ''means'' in introductory provisions.

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

§ 280g–12. Primary Care Extension Program

(a) Establishment, purpose and definition

(1) In general

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

(2) Purpose

The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as ''Health Extension Agents'').

(3) Definitions

In this section:

(A) Health Extension Agent

The term ''Health Extension Agent'' means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

(B) Primary care provider

The term ''primary care provider'' means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

(b) Grants to establish State Hubs and local Primary Care Extension Agencies

(1) Grants

The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as ''Hubs'').

(2) Composition of Hubs

A Hub established by a State pursuant to paragraph (1)—

(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments that train providers in primary care in 1 or more health professions schools in the State; and

(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1320c–2 of this title, consumer groups, and other appropriate entities.

(c) State and local activities

(1) Hub activities

Hubs established under a grant under subsection (b) shall—

(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

(B) contract with a county- or local-level entity that shall serve as the Primary Care

Extension Agency to administer the services described in paragraph (2);

(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

(2) Local Primary Care Extension Agency activities

(A) Required activities

Primary Care Extension Agencies established by a Hub under paragraph (1) shall—

(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

(B) Discretionary activities

Primary Care Extension Agencies established by a Hub under paragraph (1) may—

(i) provide technical assistance, training, and organizational support for community health teams established under section 256a–1[1] of this title;

(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

(v) participate in other activities, as determined appropriate by the Secretary.

(d) Federal program administration

(1) Grants; types

Grants awarded under subsection (b) shall be—

(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

(2) Applications

To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(3) Evaluation

A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

(4) Continuing support

After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

(5) Limitation

A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

(e) Requirements on the Secretary

In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

(f) Authorization of appropriations

To awards grants as provided in subsection (d), there are authorized to be appropriated $120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.

(July 1, 1944, ch. 373, title III, § 399V–1, formerly § 399W, as added, amended, and renumbered § 399V–1, Pub. L. 111–148, title V, § 5405, title X, § 10501(f)(1), (2), Mar. 23, 2010, 124 Stat. 649, 996.)

[1] See References in Text note below.

REFERENCES IN TEXT

Section 256a–1 of this title, referred to in subsec. (c)(2)(B)(i), was in the original ''section 3602 of the Patient Protection and Affordable Care Act'', and was translated as meaning section 3502 of the Patient Protection and Affordable Care Act, Pub. L. 111–148, to reflect the probable intent of Congress.

AMENDMENTS

2010—Subsec. (b)(2)(A). Pub. L. 111–148, § 10501(f)(2), substituted ''and the departments that train providers in primary care in 1 or more health professions schools in the State'' for ''and the departments of 1 or more health professions schools in the State that train providers in primary care''.

§ 280g–13. National Congenital Heart Disease Surveillance System

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into a nationally-representative, population-based surveillance system that compiles data concerning actual occurrences of congenital heart disease, to be known as the ''National Congenital Heart Disease Surveillance System''; or

(2) award a grant to one eligible entity to undertake the activities described in paragraph (1).

(b) Purpose

The purpose of the Congenital Heart Disease Surveillance System shall be to facilitate further research into the types of health services patients use and to identify possible areas for educational outreach and prevention in accordance with standard practices of the Centers for Disease Control and Prevention.

(c) Content

The Congenital Heart Disease Surveillance System—

(1) may include information concerning the incidence and prevalence of congenital heart disease in the United States;

(2) may be used to collect and store data on congenital heart disease, including data concerning—

(A) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease;

(B) risk factors associated with the disease;

(C) causation of the disease;

(D) treatment approaches; and

(E) outcome measures, such that analysis of the outcome measures will allow derivation of evidence-based best practices and guidelines for congenital heart disease patients; and

(3) may ensure the collection and analysis of longitudinal data related to individuals of all ages with congenital heart disease, including infants, young children, adolescents, and adults of all ages.

(d) Public access

The Congenital Heart Disease Surveillance System shall be made available to the public, as appropriate, including congenital heart disease researchers.

(e) Patient privacy

The Secretary shall ensure that the Congenital Heart Disease Surveillance System is maintained in a manner that complies with the regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996.

(f) Eligibility for grant

To be eligible to receive a grant under subsection (a)(2), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

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

(July 1, 1944, ch. 373, title III, § 399V–2, as added Pub. L. 111–148, title X, § 10411(b)(1), Mar. 23, 2010, 124 Stat. 988.)

REFERENCES IN TEXT

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (e), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

§ 280g–14. National diabetes prevention program

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the ''program'') targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) Program activities

The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) Eligible entities

To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based non-profits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such

sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, § 399V–3, as added Pub. L. 111–148, title X, § 10501(g), Mar. 23, 2010, 124 Stat. 996.)

§ 280g–15. State demonstration programs to evaluate alternatives to current medical tort litigation

(a) In general

The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) Duration

The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) Conditions for demonstration grants

(1) Requirements

Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) Alternative to current tort litigation

Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) Sources of compensation

Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) Scope

(A) In general

Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) Notification of patients

A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) Preference in awarding demonstration grants

In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) Application

(1) In general

Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) Review panel

(A) In general

In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) Composition

(i) Nominations

The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) Appointment

The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) Chairperson

The Comptroller General shall designate a member of the review panel to be the chairperson of the review panel.

(D) Availability of information

The Secretary shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) Information from agencies

The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) Reports

(1) By State

Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) By Secretary

The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) Technical assistance

(1) In general

The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) Requirements

Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) Use of common definitions, formats, and data collection infrastructure

States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) Evaluation

(1) In general

The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) Contents

The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to March 23, 2010, any cap on non-economic damages; and

(iii) States that have enacted, prior to March 23, 2010, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bear-

ing on whether the complainant may proceed with a case.

(3) Measures

The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) Funding

The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MedPAC and MACPAC reports

(1) MedPAC

The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and its beneficiaries.

(2) MACPAC

The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], and their beneficiaries.

(3) Reports

Not later than December 31, 2016, the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommendations of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

(i) Option to provide for initial planning grants

Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed $500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

(j) Definitions

In this section:

(1) Health care services

The term ''health care services'' means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment of the health of human beings.

(2) Health care organization

The term ''health care organization'' means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

(3) Health care provider

The term ''health care provider'' means any individual or entity—

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

***(l)* Current State efforts to establish alternative to tort litigation**

Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

(m) Rule of construction

Nothing in this section shall be construed as limiting states'[1] authority over or responsibility for their state[1] justice systems.

(July 1, 1944, ch. 373, title III, § 399V–4, as added Pub. L. 111–148, title X, § 10607, Mar. 23, 2010, 124 Stat. 1009; amended Pub. L. 114–301, § 3(d), Dec. 16, 2016, 130 Stat. 1515.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (h)(1), (2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 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.

AMENDMENTS

2016—Subsec. (d)(2)(C). Pub. L. 114–301, § 3(d)(1), substituted ''shall designate a member of the review panel

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

to'' for '', or an individual within the Government Accountability Office designated by the Comptroller General, shall''.

Subsec. (d)(2)(D). Pub. L. 114–301, § 3(d)(2), substituted ''Secretary'' for ''Comptroller General''.

§ 280g–16. Food Safety Integrated Centers of Excellence

(a) In general

Not later than 1 year after January 4, 2011, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the ''Centers of Excellence'') to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

(b) Selection of Centers of Excellence

(1) Eligible entities

To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) Working group

Not later than 180 days after January 4, 2011, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) Additional Centers of Excellence

The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) Activities

Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

(5) training and coordinating State and local personnel;

(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

(d) Report to Congress

Not later than 2 years after January 4, 2011, the Secretary shall submit to Congress a report that—

(1) describes the effectiveness of the Centers of Excellence; and

(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

(e) Authorization of appropriations

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

(f) No duplication of effort

In carrying out activities of the Centers of Excellence or other programs under this section, the Secretary shall not duplicate other Federal foodborne illness response efforts.

(July 1, 1944, ch. 373, title III, § 399V–5, as added Pub. L. 111–353, title II, § 210(b), Jan. 4, 2011, 124 Stat. 3950.)

§ 280g–17. Designation and investigation of potential cancer clusters

(a) Definitions

In this section:

(1) Cancer cluster

The term ''cancer cluster'' means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

(2) Particular cancer

The term ''particular cancer'' means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

(3) Population group

The term ''population group'' means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

(b) Criteria for designation of potential cancer clusters

(1) Development of criteria

The Secretary shall develop criteria for the designation of potential cancer clusters.

(2) Requirements

The criteria developed under paragraph (1) shall consider, as appropriate—

(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

(c) Guidelines for investigation of potential cancer clusters

The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

(1) recommend that investigations of cancer clusters—

(A) use the criteria developed under subsection (b);

(B) use the best available science; and

(C) rely on a weight of the scientific evidence;

(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

(d) Investigation of cancer clusters

(1) Secretary discretion

The Secretary—

(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

(2) Coordination

In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

(3) Biomonitoring

In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

(e) Duties

The Secretary shall—

(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.

(July 1, 1944, ch. 373, title III, § 399V–6, as added Pub. L. 114–182, title I, § 21(b), June 22, 2016, 130 Stat. 510.)

PURPOSES OF TREVOR'S LAW

Pub. L. 114–182, title I, § 21(a), June 22, 2016, 130 Stat. 510, provided that: ''The purposes of this section [enacting this section] are—

''(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

''(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

''(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.''

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

§ 280h. Grants to promote childhood nutrition and physical activity

(a) In general

The Secretary, acting though the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote good nutrition and physical activity in children and adolescents.

(b) Eligibility

To be eligible to receive a grant under this section a State or political subdivision of a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Sec-

retary may require, including a plan that describes—

(1) how the applicant proposes to develop a comprehensive program of school- and community-based approaches to encourage and promote good nutrition and appropriate levels of physical activity with respect to children or adolescents in local communities;

(2) the manner in which the applicant shall coordinate with appropriate State and local authorities, such as State and local school departments, State departments of health, chronic disease directors, State directors of programs under section 1786 of this title, 5-a-day coordinators, governors councils for physical activity and good nutrition, and State and local parks and recreation departments; and

(3) the manner in which the applicant will evaluate the effectiveness of the program carried out under this section.

(c) Use of funds

A State or political subdivision of a State shall use amount received under a grant under this section to—

(1) develop, implement, disseminate, and evaluate school- and community-based strategies in States to reduce inactivity and improve dietary choices among children and adolescents;

(2) expand opportunities for physical activity programs in school- and community-based settings; and

(3) develop, implement, and evaluate programs that promote good eating habits and physical activity including opportunities for children with cognitive and physical disabilities.

(d) Technical assistance

The Secretary may set-aside an amount not to exceed 10 percent of the amount appropriated for a fiscal year under subsection (h) to permit the Director of the Centers for Disease Control and Prevention to—

(1) provide States and political subdivisions of States with technical support in the development and implementation of programs under this section; and

(2) disseminate information about effective strategies and interventions in preventing and treating obesity through the promotion of good nutrition and physical activity.

(e) Limitation on administrative costs

Not to exceed 10 percent of the amount of a grant awarded to the State or political subdivision under subsection (a) for a fiscal year may be used by the State or political subdivision for administrative expenses.

(f) Term

A grant awarded under subsection (a) shall be for a term of 3 years.

(g) Definition

In this section, the term ''children and adolescents'' means individuals who do not exceed 18 years of age.

(h) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399W, as added Pub. L. 106–310, div. A, title XXIV, § 2401, Oct. 17, 2000, 114 Stat. 1158.)

CODIFICATION

Another section 399W of act July 1, 1944, was renumbered section 399V–1 and is classified to section 280g–12 of this title.

§ 280h–1. Applied research program

(a) In general

The Secretary, acting through the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall—

(1) conduct research to better understand the relationship between physical activity, diet, and health and factors that influence health-related behaviors;

(2) develop and evaluate strategies for the prevention and treatment of obesity to be used in community-based interventions and by health professionals;

(3) develop and evaluate strategies for the prevention and treatment of eating disorders, such as anorexia and bulimia;

(4) conduct research to establish the prevalence, consequences, and costs of childhood obesity and its effects in adulthood;

(5) identify behaviors and risk factors that contribute to obesity;

(6) evaluate materials and programs to provide nutrition education to parents and teachers of children in child care or pre-school and the food service staff of such child care and pre-school entities; and

(7) evaluate materials and programs that are designed to educate and encourage physical activity in child care and pre-school facilities.

(b) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399X, as added Pub. L. 106–310, div. A, title XXIV, § 2401, Oct. 17, 2000, 114 Stat. 1159.)

§ 280h–2. Education campaign

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in collaboration with national, State, and local partners, physical activity organizations, nutrition experts, and health professional organizations, shall develop a national public campaign to promote and educate children and their parents concerning—

(1) the health risks associated with obesity, inactivity, and poor nutrition;

(2) ways in which to incorporate physical activity into daily living; and

(3) the benefits of good nutrition and strategies to improve eating habits.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be nec-

essary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, § 399Y, as added Pub. L. 106–310, div. A, title XXIV, § 2401, Oct. 17, 2000, 114 Stat. 1160.)

§ 280h–3. Health professional education and training

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Administrator of the Health Resources and Services Administration and the heads of other agencies, and in consultation with appropriate health professional associations, shall develop and carry out a program to educate and train health professionals in effective strategies to—

(1) better identify and assess patients with obesity or an eating disorder or patients at-risk of becoming obese or developing an eating disorder;

(2) counsel, refer, or treat patients with obesity or an eating disorder; and

(3) educate patients and their families about effective strategies to improve dietary habits and establish appropriate levels of physical activity.

(b) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399Z, as added Pub. L. 106–310, div. A, title XXIV, § 2401, Oct. 17, 2000, 114 Stat. 1160.)

EDUCATION AND TRAINING ON EATING DISORDERS

Pub. L. 114–255, div. B, title XIII, § 13006, Dec. 13, 2016, 130 Stat. 1287, provided that: ''The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

''(1) identify individuals with eating disorders;

''(2) provide early intervention services for individuals with eating disorders;

''(3) refer patients with eating disorders for appropriate treatment;

''(4) prevent the development of eating disorders; and

''(5) provide appropriate treatment services for individuals with eating disorders.''

§ 280h–4. Grants for the establishment of school-based health centers

(1) Program

The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a program to award grants to eligible entities to support the operation of school-based health centers.

(2) Eligibility

To be eligible for a grant under this section, an entity shall—

(A) be a school-based health center or a sponsoring facility of a school-based health center; and

(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including at a minimum an assurance that funds awarded under the grant shall not be used to provide any service that is not authorized or allowed by Federal, State, or local law.

(3) Preference

In awarding grants under this section,[1] the Secretary shall give preference to awarding grants for school-based health centers that serve a large population of children eligible for medical assistance under the State Medicaid plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] or under a waiver of such plan or children eligible for child health assistance under the State child health plan under title XXI of that Act (42 U.S.C. 1397aa et seq.).

(4) Limitation on use of funds

An eligible entity shall use funds provided under a grant awarded under this section only for expenditures for facilities (including the acquisition or improvement of land, or the acquisition, construction, expansion, replacement, or other improvement of any building or other facility), equipment, or similar expenditures, as specified by the Secretary. No funds provided under a grant awarded under this section[1] shall be used for expenditures for personnel or to provide health services.

(5) Appropriations

Out of any funds in the Treasury not otherwise appropriated, there is appropriated for each of fiscal years 2010 through 2013, $50,000,000 for the purpose of carrying out this section. Funds appropriated under this paragraph shall remain available until expended.

(6) Definitions

In this section, the terms ''school-based health center'' and ''sponsoring facility'' have the meanings given those terms in section 2110(c)(9) of the Social Security Act (42 U.S.C. 1397jj(c)(9)).

(Pub. L. 111–148, title IV, § 4101(a), Mar. 23, 2010, 124 Stat. 546.)

REFERENCES IN TEXT

This section, referred to in par. (3) and in par. (4) the second place it appears, was in the original ''this section'', meaning section 4101 of Pub. L. 111–148, which enacted this section and section 280h–5 of this title.

The Social Security Act, referred to in par. (3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters 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 Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 280h–5. School-based health centers

(a) Definitions; establishment of criteria

In this section:

(1) Comprehensive primary health services

The term ''comprehensive primary health services'' means the core services offered by

[1] See References in Text note below.

school-based health centers, which shall include the following:

(A) Physical

Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions, and referrals to, and follow-up for, specialty care and oral and vision health services.

(B) Mental health

Mental health and substance use disorder assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

(2) Medically underserved children and adolescents

(A) In general

The term ''medically underserved children and adolescents'' means a population of children and adolescents who are residents of an area designated as a medically underserved area or a health professional shortage area by the Secretary.

(B) Criteria

The Secretary shall prescribe criteria for determining the specific shortages of personal health services for medically underserved children and adolescents under subparagraph (A) that shall—

(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children and adolescents, and other factors as determined appropriate by the Secretary.

(3) School-based health center

The term ''school-based health center'' means a health clinic that—

(A) meets the definition of a school-based health center under section 1397jj(c)(9)(A) of this title and is administered by a sponsoring facility (as defined in section 1397jj(c)(9)(B) of this title);

(B) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law; and

(C) does not perform abortion services.

(b) Authority to award grants

The Secretary shall award grants for the costs of the operation of school-based health centers (referred to in this section as ''SBHCs'') that meet the requirements of this section.

(c) Applications

To be eligible to receive a grant under this section, an entity shall—

(1) be an SBHC (as defined in subsection (a)(3)); and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;

(B) evidence of local need for the services to be provided by the SBHC;

(C) an assurance that—

(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and adolescents;

(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;

(iii) the SBHC will provide on-site access during the academic day when school is in session and 24-hour coverage through an on-call system and through its backup health providers to ensure access to services on a year-round basis when the school or the SBHC is closed;

(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;

(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 1232g of title 20; and

(D) such other information as the Secretary may require.

(d) Preferences and consideration

In reviewing applications:

(1) The Secretary may give preference to applicants who demonstrate an ability to serve the following:

(A) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.

(B) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.

(C) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.

(2) The Secretary may give consideration to whether an applicant has received a grant under section 280h–4 of this title.

(e) Waiver of requirements

The Secretary may—

(1) under appropriate circumstances, waive the application of all or part of the require-

ments of this subsection with respect to an SBHC for not to exceed 2 years; and

(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.

(f) Use of funds

(1) Funds

Funds awarded under a grant under this section—

(A) may be used for—

(i) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);

(ii) providing training related to the provision of required comprehensive primary health services and additional health services;

(iii) the management and operation of health center programs;

(iv) the payment of salaries for physicians, nurses, and other personnel of the SBHC; and

(B) may not be used to provide abortions.

(2) Construction

The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.

(3) Limitations

(A) In general

Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(3)(B) with respect to activities carried out at a[1] SBHC shall not be eligible to receive additional funding under this section.

(B) No overlapping grant period

No entity that has received funding under section 254b of this title for a grant period shall be eligible for a grant under this section for with respect to[1] the same grant period.

(g) Matching requirement

(1) In general

Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.

(2) Waiver

The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.

[1] So in original.

(h) Supplement, not supplant

Grant funds provided under this section shall be used to supplement, not supplant, other Federal or State funds.

(i) Evaluation

The Secretary shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.

(j) Age appropriate services

An eligible entity receiving funds under this section shall only provide age appropriate services through a[1] SBHC funded under this section to an individual.

(k) Parental consent

An eligible entity receiving funds under this section shall not provide services through a[1] SBHC funded under this section to an individual without the consent of the parent or guardian of such individual if such individual is considered a minor under applicable State law.

***(l)* Authorization of appropriations**

For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, § 399Z–1, as added and amended Pub. L. 111–148, title IV, § 4101(b), title X, § 10402(a), Mar. 23, 2010, 124 Stat. 547, 975.)

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c)(2)(C)(vi), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

AMENDMENTS

2010—Subsec. (a)(1)(A). Pub. L. 111–148, § 10402(a), inserted ''and vision'' after ''oral''.

§ 280h–6. Infant and early childhood mental health promotion, intervention, and treatment

(a) Grants

The Secretary shall—

(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

(B) multigenerational therapy and other services that support the caregiving relationship; and

(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

(b) Eligible children and entities

In this section:

(1) Eligible child

The term ''eligible child'' means a child from birth to not more than 12 years of age who—

(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(2) Eligible entity

The term ''eligible entity'' means a human services agency or nonprofit institution that—

(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(c) Application

An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Use of funds for early intervention and treatment programs

An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

(e) Matching funds

The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

(f) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $20,000,000 for the period of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 399Z–2, as added Pub. L. 114–255, div. B, title X, § 10006, Dec. 13, 2016, 130 Stat. 1267.)

PART R—PROGRAMS RELATING TO AUTISM

§ 280i. Developmental disabilities surveillance and research program

(a) Autism spectrum disorder and other developmental disabilities

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data for children and adults on autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(2) Data standards

In submitting epidemiological data to the Secretary pursuant to paragraph (1), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder or other developmental disabilities.

(3) Eligibility

To be eligible to receive an award under paragraph (1), an entity shall be a public or

nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, or any other educational institution), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(b) Centers of excellence in autism spectrum disorder epidemiology

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, award grants or cooperative agreements for the establishment or support of regional centers of excellence in autism spectrum disorder and other developmental disabilities epidemiology for the purpose of collecting and analyzing information on the number, incidence, correlates, and causes of autism spectrum disorder and other developmental disabilities for children and adults.

(2) Requirements

To be eligible to receive a grant or cooperative agreement under paragraph (1), an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including an agreement that the center to be established or supported under the grant or cooperative agreement shall operate in accordance with the following:

(A) The center will collect, analyze, and report autism spectrum disorder and other developmental disability data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with developmental disabilities.

(B) The center will develop or extend an area of special research expertise (including genetics, epigenetics, and epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas.

(C) The center will identify eligible cases and controls through its surveillance system and conduct research into factors which may cause or increase the risk of autism spectrum disorder and other developmental disabilities.

(c) Federal response

The Secretary shall coordinate the Federal response to requests for assistance from State health, mental health, and education department officials regarding potential or alleged autism spectrum disorder or developmental disability clusters.

(d) Definitions

In this part:

(1) Other developmental disabilities

The term ''other developmental disabilities'' has the meaning given the term ''developmental disability'' in section 15002(8) of this title.

(2) State

The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(e) Sunset

This section shall not apply after September 30, 2019.

(July 1, 1944, ch. 373, title III, § 399AA, as added Pub. L. 109–416, § 3(a), Dec. 19, 2006, 120 Stat. 2822; amended Pub. L. 112–32, § 2(1), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, § 3, Aug. 8, 2014, 128 Stat. 1831.)

AMENDMENTS

2014—Subsec. (a)(1). Pub. L. 113–157, § 3(1), inserted ''for children and adults'' after ''reporting of State epidemiological data''.

Subsec. (b)(1). Pub. L. 113–157, § 3(2), substituted ''establishment or support of regional centers of excellence'' for ''establishment of regional centers of excellence'' and inserted ''for children and adults'' before period at end.

Subsec. (b)(2). Pub. L. 113–157, § 3(3), substituted ''center to be established or supported'' for ''center to be established'' in introductory provisions.

Subsec. (e). Pub. L. 113–157, § 3(4), substituted ''2019'' for ''2014''.

2011—Subsec. (e). Pub. L. 112–32 substituted ''2014'' for ''2011''.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

NATIONAL AUTISM SPECTRUM DISORDER INITIATIVE

Pub. L. 113–157, § 2, Aug. 8, 2014, 128 Stat. 1831, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall designate an existing official within the Department of Health and Human Services to oversee, in consultation with the Secretaries of Defense and Education, national autism spectrum disorder research, services, and support activities.

''(b) DUTIES.—The official designated under subsection (a) shall—

''(1) implement autism spectrum disorder activities, taking into account the strategic plan developed by the Interagency Autism Coordinating Committee under section 399CC(b) of the Public Health Service Act (42 U.S.C. 280i–2(b)); and

''(2) ensure that autism spectrum disorder activities of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative.''

§ 280i–1. Autism education, early detection, and intervention

(a) Purpose

It is the purpose of this section—

(1) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder or other developmental disabilities, and train professionals to utilize valid and reliable screening tools to diagnose or rule out and provide evidence-based interventions for children with autism spectrum disorder and other developmental disabilities; and

(2) to conduct activities under this section with a focus on an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)]) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

(b) In general

The Secretary shall, subject to the availability of appropriations, establish and evaluate activities to—

(1) provide culturally competent information and education on autism spectrum disorder and other developmental disabilities to increase public awareness of developmental milestones;

(2) promote research into the development and validation of reliable screening tools for autism spectrum disorder and other developmental disabilities and disseminate information regarding those screening tools;

(3) promote early screening of individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable, given evidence-based screening techniques and interventions;

(4) increase the number of individuals who are able to confirm or rule out a diagnosis of autism spectrum disorder and other developmental disabilities;

(5) increase the number of individuals able to provide evidence-based interventions for individuals diagnosed with autism spectrum disorder or other developmental disabilities; and

(6) promote the use of evidence-based interventions for individuals at higher risk for autism spectrum disorder and other developmental disabilities as early as practicable.

(c) Information and education

(1) In general

In carrying out subsection (b)(1), the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, shall, subject to the availability of appropriations, provide culturally competent information regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, and evidence-based interventions to meet the needs of individuals with autism spectrum disorder or other developmental disabilities and their families through—

(A) Federal programs, including—

(i) the Head Start program;

(ii) the Early Start program;

(iii) the Healthy Start program;

(iv) programs under the Child Care and Development Block Grant Act of 1990 [42 U.S.C. 9857 et seq.];

(v) programs under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (particularly the Medicaid Early and Periodic Screening, Diagnosis and Treatment Program);

(vi) the program under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.] (the State Children's Health Insurance Program);

(vii) the program under title V of the Social Security Act [42 U.S.C. 701 et seq.] (the Maternal and Child Health Block Grant Program);

(viii) the program under parts B and C of the Individuals with Disabilities Education Act [20 U.S.C. 1411 et seq., 1431 et seq.];

(ix) the special supplemental nutrition program for women, infants, and children established under section 1786 of this title; and

(x) the State grant program under the Rehabilitation Act of 1973 [29 U.S.C. 701 et seq.].

(B) State licensed child care facilities; and

(C) other community-based organizations or points of entry for individuals with autism spectrum disorder and other developmental disabilities to receive services.

(2) Lead agency

(A) Designation

As a condition on the provision of assistance or the conduct of activities under this section with respect to a State, the Secretary may require the Governor of the State—

(i) to designate a public agency as a lead agency to coordinate the activities provided for under paragraph (1) in the State at the State level; and

(ii) acting through such lead agency, to make available to individuals and their family members, guardians, advocates, or authorized representatives; providers; and other appropriate individuals in the State, comprehensive culturally competent information about State and local resources regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, available services and supports (which may include respite care for caregivers of individuals with an autism spectrum disorder), and evidence-based interventions.

(B) Requirements of agency

In designating the lead agency under subparagraph (A)(i), the Governor shall—

(i) select an agency that has demonstrated experience and expertise in—

(I) autism spectrum disorder and other developmental disability issues; and

(II) developing, implementing, conducting, and administering programs and delivering education, information, and referral services (including technology-based curriculum-development services) to individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals locally and across the State; and

(ii) consider input from individuals with developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals.

(C) Information

Information under subparagraph (A)(ii) shall be provided through—

(i) toll-free telephone numbers;

(ii) Internet websites;

(iii) mailings; or

(iv) such other means as the Governor may require.

(d) Tools

(1) In general

To promote the use of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities, the Secretary shall develop a curriculum for continuing education to assist individuals in recognizing the need for valid and reliable screening tools and the use of such tools.

(2) Collection, storage, coordination, and availability

The Secretary, in collaboration with the Secretary of Education, shall provide for the collection, storage, coordination, and public availability of tools described in paragraph (1), educational materials and other products that are used by the Federal programs referred to in subsection (c)(1)(A), as well as—

(A) programs authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 et seq.];

(B) early intervention programs or interagency coordinating councils authorized under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; and

(C) children with special health care needs programs authorized under title V of the Social Security Act [42 U.S.C. 701 et seq.].

(3) Required sharing

In establishing mechanisms and entities under this subsection, the Secretary, and the Secretary of Education, shall ensure the sharing of tools, materials, and products developed under this subsection among entities receiving funding under this section.

(e) Diagnosis

(1) Training

The Secretary, in coordination with activities conducted under title V of the Social Security Act [42 U.S.C. 701 et seq.], shall, subject to the availability of appropriations, expand existing interdisciplinary training opportunities or opportunities to increase the number of sites able to diagnose or rule out individuals with autism spectrum disorder or other developmental disabilities and ensure that—

(A) competitive grants or cooperative agreements are awarded to public or nonprofit agencies, including institutions of higher education, to expand existing or develop new maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs (similar to the programs developed under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)]) in States that do not have such a program;

(B) trainees under such training programs—

(i) receive an appropriate balance of academic, clinical, and community opportunities;

(ii) are culturally competent;

(iii) are ethnically diverse;

(iv) demonstrate a capacity to evaluate, diagnose or rule out, develop, and provide evidence-based interventions to individuals with autism spectrum disorder and other developmental disabilities; and

(v) demonstrate an ability to use a family-centered approach, which may include collaborating with research centers or networks to provide training for providers of respite care (as defined in section 300ii of this title); and

(C) program sites provide culturally competent services.

(2) Technical assistance

The Secretary may award one or more grants under this section to provide technical assistance to the network of interdisciplinary training programs.

(3) Best practices

The Secretary shall promote research into additional valid and reliable tools for shortening the time required to confirm or rule out a diagnosis of autism spectrum disorder or other developmental disabilities and detecting individuals with autism spectrum disorder or other developmental disabilities at an earlier age.

(f) Intervention

The Secretary shall promote research, through grants or contracts, which may include grants or contracts to research centers or networks, to determine the evidence-based practices for interventions to improve the physical and behavioral health of individuals with autism spectrum disorder or other developmental disabilities, develop guidelines for those interventions, and disseminate information related to such research and guidelines.

(g) Sunset

This section shall not apply after September 30, 2019.

(July 1, 1944, ch. 373, title III, § 399BB, as added Pub. L. 109–416, § 3(a), Dec. 19, 2006, 120 Stat. 2823; amended Pub. L. 112–32, § 2(2), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, § 4, Aug. 8, 2014, 128 Stat. 1831.)

REFERENCES IN TEXT

The Child Care and Development Block Grant Act of 1990, referred to in subsec. (c)(1)(A)(iv), is subchapter C (§ 658A et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, as added by Pub. L. 101–508, title V, § 5082(2), Nov. 5, 1990, 104 Stat. 1388–236, which is classified generally to subchapter II–B (§ 9857 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see section 9857(a) of this title and Tables.

The Social Security Act, referred to in subsecs. (c)(1)(A)(v)–(vii), (d)(2)(C), and (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.

The Individuals with Disabilities Education Act, referred to in subsecs. (c)(1)(A)(viii) and (d)(2)(B), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, as amended. Parts B and C of the Act are classified generally to subchapters II (§1411 et seq.) and III (§1431 et seq.), respectively, 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 Rehabilitation Act of 1973, referred to in subsec. (c)(1)(A)(x), is Pub. L. 93–112, Sept. 26, 1973, 87 Stat. 355, as amended, which is classified principally to chapter 16 (§701 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 701 of Title 29 and Tables.

The Developmental Disabilities Assistance and Bill of Rights Act of 2000, referred to in subsec. (d)(2)(A), is Pub. L. 106–402, Oct. 30, 2000, 114 Stat. 1677, which is classified principally to chapter 144 (§15001 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 15001 of this title and Tables.

AMENDMENTS

2014—Subsec. (b)(1). Pub. L. 113–157, §4(1), inserted ''culturally competent'' after ''provide''.

Subsec. (c)(2)(A)(ii). Pub. L. 113–157, §4(2), inserted ''(which may include respite care for caregivers of individuals with an autism spectrum disorder)'' after ''services and supports''.

Subsec. (e)(1)(B)(v). Pub. L. 113–157, §4(3), inserted before semicolon '', which may include collaborating with research centers or networks to provide training for providers of respite care (as defined in section 300ii of this title)''.

Subsec. (f). Pub. L. 113–157, §4(4), substituted ''grants or contracts, which may include grants or contracts to research centers or networks, to determine the evidence-based practices for interventions to improve the physical and behavioral health of individuals with'' for ''grants or contracts, to determine the evidence-based practices for interventions for individuals with''.

Subsec. (g). Pub. L. 113–157, §4(5), substituted ''2019'' for ''2014''.

2011—Subsec. (g). Pub. L. 112–32 substituted ''2014'' for ''2011''.

§ 280i–2. Interagency Autism Coordinating Committee

(a) Establishment

The Secretary shall establish a committee, to be known as the ''Interagency Autism Coordinating Committee'' (in this section referred to as the ''Committee''), to coordinate all efforts within the Department of Health and Human Services concerning autism spectrum disorder.

(b) Responsibilities

In carrying out its duties under this section, the Committee shall—

(1) monitor autism spectrum disorder research, and to the extent practicable services and support activities, across all relevant Federal departments and agencies, including coordination of Federal activities with respect to autism spectrum disorder;

(2) develop a summary of advances in autism spectrum disorder research related to causes, prevention, treatment, early screening, diagnosis or rule out, interventions, including school and community-based interventions, and access to services and supports for individuals with autism spectrum disorder;

(3) make recommendations to the Secretary regarding any appropriate changes to such activities, including with[1] respect to the strategic plan developed under paragraph (5);

(4) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder, and the process by which public feedback can be better integrated into such decisions;

(5) develop a strategic plan for the conduct of, and support for, autism spectrum disorder research, including as practicable for services and supports, for individuals with an autism spectrum disorder and the families of such individuals, which shall include—

(A) proposed budgetary requirements; and

(B) recommendations to ensure that autism spectrum disorder research, and services and support activities to the extent practicable, of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative; and

(6) submit to Congress and the President—

(A) an annual update on the summary of advances described in paragraph (2); and

(B) an annual update to the strategic plan described in paragraph (5), including any progress made in achieving the goals outlined in such strategic plan.

(c) Membership

(1) Federal membership

The Committee shall be composed of the following Federal members—

(A) the Director of the Centers for Disease Control and Prevention;

(B) the Director of the National Institutes of Health, and the Directors of such national research institutes of the National Institutes of Health as the Secretary determines appropriate;

(C) the heads of such other agencies as the Secretary determines appropriate, such as the Administration for Community Living, Administration for Children and Families, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and the Health Resources and Services Administration; and

(D) representatives of other Federal Governmental agencies that serve individuals with autism spectrum disorder such as the Department of Education and the Department of Defense.

(2) Non-Federal members

Not more than ½, but not fewer than ⅓, of the total membership of the Committee,[2] shall be composed of non-Federal public members to be appointed by the Secretary, of which—

(A) at least two such members shall be individuals with a diagnosis of autism spectrum disorder;

(B) at least two such members shall be parents or legal guardians of an individual with an autism spectrum disorder; and

(C) at least two such members shall be representatives of leading research, advocacy,

[1] So in original. Probably should be preceded by ''recommendations''.

[2] So in original. The comma probably should not appear.

and service organizations for individuals with autism spectrum disorder.

(3) Period of appointment; vacancies

(A) Period of appointment for non-Federal members

Non-Federal members shall serve for a term of 4 years, and may be reappointed for one or more additional 4-year terms.

(B) Vacancies

A vacancy on the Committee shall be filled in the manner in which the original appointment was made and shall not affect the powers or duties of the Committee. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(d) Administrative support; terms of service; other provisions

The following provisions shall apply with respect to the Committee:

(1) The Committee shall receive necessary and appropriate administrative support from the Secretary.

(2) The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

(3) All meetings of the Committee shall be public and shall include appropriate time periods for questions and presentations by the public.

(e) Subcommittees; establishment and membership

In carrying out its functions, the Committee may establish subcommittees and convene workshops and conferences. Such subcommittees shall be composed of Committee members and may hold such meetings as are necessary to enable the subcommittees to carry out their duties.

(f) Sunset

This section shall not apply after September 30, 2019, and the Committee shall be terminated on such date.

(July 1, 1944, ch. 373, title III, §399CC, as added Pub. L. 109–416, §3(a), Dec. 19, 2006, 120 Stat. 2827; amended Pub. L. 112–32, §2(3), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §5, Aug. 8, 2014, 128 Stat. 1832.)

AMENDMENTS

2014—Subsec. (b)(1). Pub. L. 113–157, §5(1)(C), added par. (1). Former par. (1) redesignated (2).

Pub. L. 113–157, §5(1)(A), struck out ''and annually update'' after ''develop'' and substituted ''interventions, including school and community-based interventions'' for ''intervention''.

Subsec. (b)(2). Pub. L. 113–157, §5(1)(B), (C), redesignated par. (1) as (2) and struck out former par. (2) which read as follows: ''monitor Federal activities with respect to autism spectrum disorder;''.

Subsec. (b)(3). Pub. L. 113–157, §5(1)(D), struck out ''recommendations to the Director of NIH'' after ''including''.

Subsec. (b)(4). Pub. L. 113–157, §5(1)(E), inserted before semicolon '', and the process by which public feedback can be better integrated into such decisions''.

Subsec. (b)(5), (6). Pub. L. 113–157, §5(1)(F), added pars. (5) and (6) and struck out former pars. (5) and (6) which read as follows:

''(5) develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements; and

''(6) submit to the Congress such strategic plan and any updates to such plan.''

Subsec. (c)(1). Pub. L. 113–157, §5(2)(A)(i), substituted ''Federal membership'' for ''In general'' in heading and ''The Committee shall be composed of the following Federal members—'' for ''The Committee shall be composed of—'' in introductory provisions.

Subsec. (c)(1)(C). Pub. L. 113–157, §5(2)(A)(ii), inserted '', such as the Administration for Community Living, Administration for Children and Families, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and the Health Resources and Services Administration'' before semicolon and inserted ''and'' at end.

Subsec. (c)(1)(D). Pub. L. 113–157, §5(2)(A)(iii), inserted ''and the Department of Defense'' after ''Department of Education'' and substituted period at end for ''; and''.

Subsec. (c)(1)(E). Pub. L. 113–157, §5(2)(A)(iv), struck out subpar. (E) which read as follows: ''the additional members appointed under paragraph (2).''

Subsec. (c)(2). Pub. L. 113–157, §5(2)(B)(i), (ii), substituted ''Non-Federal'' for ''Additional'' in heading and ''Not more than ½, but not fewer than ⅓, of the total membership of the Committee'' for ''Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater'' in introductory provisions. Substitution in text was executed as the probable intent of Congress, notwithstanding directory language that struck out ''⅓'' instead of ''1/3'' as it appeared in the original.

Subsec. (c)(2)(A). Pub. L. 113–157, §5(2)(B)(iii), substituted ''two such members shall be individuals'' for ''one such member shall be an individual''.

Subsec. (c)(2)(B). Pub. L. 113–157, §5(2)(B)(iv), substituted ''two such members shall be parents or legal guardians'' for ''one such member shall be a parent or legal guardian''.

Subsec. (c)(2)(C). Pub. L. 113–157, §5(2)(B)(v), substituted ''two such members shall be representatives'' for ''one such member shall be a representative''.

Subsec. (c)(3). Pub. L. 113–157, §5(2)(C), added par. (3).

Subsec. (d)(2) to (4). Pub. L. 113–157, §5(3), redesignated pars. (3) and (4) as (2) and (3), respectively, and struck out former par. (2) which read as follows: ''Members of the Committee appointed under subsection (c)(2) shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year term. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office.''

Subsec. (f). Pub. L. 113–157, §5(4), substituted ''2019'' for ''2014''.

2011—Subsec. (f). Pub. L. 112–32 substituted ''2014'' for ''2011''.

§ 280i–3. Reports to Congress

(a) Progress report

(1) In general

Not later than 4 years after August 8, 2014, the Secretary, in coordination with the Secretary of Education and the Secretary of Defense, shall prepare and submit to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives, and make publicly available, including through posting on the Internet Web site of the Department of Health and Human Services, a progress report on activities related to

autism spectrum disorder and other developmental disabilities.

(2) Contents

The report submitted under subsection (a) shall contain—

(A) a description of the progress made in implementing the provisions of the Autism CARES Act of 2014;

(B) a description of the amounts expended on the implementation of the amendments made by the Autism CARES Act of 2014;

(C) information on the incidence and prevalence of autism spectrum disorder, including available information on the prevalence of autism spectrum disorder among children and adults, and identification of any changes over time with respect to the incidence and prevalence of autism spectrum disorder;

(D) information on the average age of diagnosis for children with autism spectrum disorder and other disabilities, including how that age may have changed over the 4-year period beginning on August 8, 2014, and, as appropriate, how this age varies across population subgroups;

(E) information on the average age for intervention for individuals diagnosed with autism spectrum disorder and other developmental disabilities, including how that age may have changed over the 4-year period beginning on August 8, 2014, and, as appropriate, how this age varies across population subgroups;

(F) information on the average time between initial screening and then diagnosis or rule out for individuals with autism spectrum disorder or other developmental disabilities, as well as information on the average time between diagnosis and evidence-based intervention for individuals with autism spectrum disorder or other developmental disabilities and, as appropriate, on how such average time varies across population subgroups;

(G) information on the effectiveness and outcomes of interventions for individuals diagnosed with autism spectrum disorder, including by severity level as practicable, and other developmental disabilities and how the age of the child or other factors, such as demographic characteristics, may affect such effectiveness;

(H) information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with autism spectrum disorder or other developmental disabilities; and

(I) a description of the actions taken to implement and the progress made on implementation of the strategic plan developed by the Interagency Autism Coordinating Committee under section 280i–2(b) of this title.

(b) Report on young adults and transitioning youth

(1) In general

Not later than 2 years after August 8, 2014, the Secretary of Health and Human Services, in coordination with the Secretary of Education and in collaboration with the Secretary of Transportation, the Secretary of Labor, the Secretary of Housing and Urban Development, and the Attorney General, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning young adults with autism spectrum disorder and the challenges related to the transition from existing school-based services to those services available during adulthood.

(2) Contents

The report submitted under paragraph (1) shall contain—

(A) demographic characteristics of youth transitioning from school-based to community-based supports;

(B) an overview of policies and programs relevant to young adults with autism spectrum disorder relating to post-secondary school transitional services, including an identification of existing Federal laws, regulations, policies, research, and programs;

(C) proposals on establishing best practices guidelines to ensure—

(i) interdisciplinary coordination between all relevant service providers receiving Federal funding;

(ii) coordination with transitioning youth and the family of such transitioning youth; and

(iii) inclusion of the individualized education program for the transitioning youth, as prescribed in section 1414 of title 20;

(D) comprehensive approaches to transitioning from existing school-based services to those services available during adulthood, including—

(i) services that increase access to, and improve integration and completion of, post-secondary education, peer support, vocational training (as defined in section 723 of title 29), rehabilitation, self-advocacy skills, and competitive, integrated employment;

(ii) community-based behavioral supports and interventions;

(iii) community-based integrated residential services, housing, and transportation;

(iv) nutrition, health and wellness, recreational, and social activities;

(v) personal safety services for individuals with autism spectrum disorder related to public safety agencies or the criminal justice system; and

(vi) evidence-based approaches for coordination of resources and services once individuals have aged out of post-secondary education; and

(E) proposals that seek to improve outcomes for adults with autism spectrum disorder making the transition from a school-based support system to adulthood by—

(i) increasing the effectiveness of programs that provide transition services;

(ii) increasing the ability of the relevant service providers described in subpara-

graph (C) to provide supports and services to underserved populations and regions;

(iii) increasing the efficiency of service delivery to maximize resources and outcomes, including with respect to the integration of and collaboration among services for transitioning youth;

(iv) ensuring access to all services necessary to transitioning youth of all capabilities; and

(v) encouraging transitioning youth to utilize all available transition services to maximize independence, equal opportunity, full participation, and self-sufficiency.

(July 1, 1944, ch. 373, title III, § 399DD, as added Pub. L. 109–416, § 3(a), Dec. 19, 2006, 120 Stat. 2828; amended Pub. L. 112–32, § 2(4), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, § 6, Aug. 8, 2014, 128 Stat. 1834.)

REFERENCES IN TEXT

The Autism CARES Act of 2014, referred to in subsec. (a)(2)(A), (B), is Pub. L. 113–157, Aug. 8, 2014, 128 Stat. 1831, also known as the Autism Collaboration, Accountability, Research, Education, and Support Act of 2014. For complete classification of this Act to the Code, see Short Title of 2014 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2014—Pub. L. 113–157, § 6(1), substituted ''Reports'' for ''Report'' in section catchline.

Subsec. (a). Pub. L. 113–157, § 6(2)–(4), designated existing provisions of entire section as subsec. (a), inserted heading, redesignated former subsecs. (a) and (b) as pars. (1) and (2), respectively, of subsec. (a), redesignated pars. (1) to (9) of former subsec. (b) as subpars. (A) to (I), respectively, of par. (2) of subsec. (a), and realigned margins.

Subsec. (a)(1). Pub. L. 113–157, § 6(5), substituted ''4 years after August 8, 2014'' for ''2 years after September 30, 2011'' and inserted ''and the Secretary of Defense'' after ''the Secretary of Education'' and '', and make publicly available, including through posting on the Internet Web site of the Department of Health and Human Services,'' after ''Representatives''.

Subsec. (a)(2)(A). Pub. L. 113–157, § 6(6)(A), substituted ''Autism CARES Act of 2014'' for ''Combating Autism Act of 2006''.

Subsec. (a)(2)(B). Pub. L. 113–157, § 6(6)(B), substituted ''amendments made by the Autism CARES Act of 2014'' for ''particular provisions of Combating Autism Act of 2006''.

Subsec. (a)(2)(C). Pub. L. 113–157, § 6(6)(C), added subpar. (C) and struck out former subpar. (C) which read as follows: ''information on the incidence of autism spectrum disorder and trend data of such incidence since December 19, 2006;''.

Subsec. (a)(2)(D), (E). Pub. L. 113–157, § 6(6)(D), (E), substituted ''4-year period beginning on August 8, 2014, and, as appropriate, how this age varies across population subgroups'' for ''6-year period beginning on December 19, 2006''.

Subsec. (a)(2)(F). Pub. L. 113–157, § 6(6)(F), inserted ''and, as appropriate, on how such average time varies across population subgroups'' before semicolon at end.

Subsec. (a)(2)(G). Pub. L. 113–157, § 6(6)(G), substituted ''including by severity level as practicable,'' for ''including by various subtypes,'' and ''child or other factors, such as demographic characteristics, may'' for ''child may''.

Subsec. (a)(2)(I). Pub. L. 113–157, § 6(6)(H), added subpar. (I) and struck out former subpar. (I) which read as follows: ''information on services and supports provided to individuals with autism spectrum disorder and other developmental disabilities who have reached the age of majority (as defined for purposes of section 1415(m) of title 20).''

Subsec. (b). Pub. L. 113–157, § 6(7), added subsec. (b). Former subsec. (b) redesignated par. (2) of subsec. (a).

2011—Subsec. (a). Pub. L. 112–32, § 2(4)(A), substituted ''Not later than 2 years after September 30, 2011'' for ''Not later than 4 years after December 19, 2006''.

Subsec. (b)(4), (5). Pub. L. 112–32, § 2(4)(B), substituted ''the 6-year period beginning on December 19, 2006'' for ''the 4-year period beginning on the date of enactment of this Act'', which for purposes of codification was translated as ''the 4-year period beginning on December 19, 2006''.

§ 280i–4. Authorization of appropriations

(a) Developmental disabilities surveillance and research program

To carry out section 280i of this title, there is authorized to be appropriated $22,000,000 for each of fiscal years 2015 through 2019.

(b) Autism education, early detection, and intervention

To carry out section 280i–1 of this title, there is authorized to be appropriated $48,000,000 for each of fiscal years 2015 through 2019.

(c) Interagency Autism Coordinating Committee; certain other programs

To carry out sections 280i–2 and 284g of this title, there is authorized to be appropriated $190,000,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title III, § 399EE, as added Pub. L. 109–416, § 4(a), Dec. 19, 2006, 120 Stat. 2829; amended Pub. L. 112–32, § 3, Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, § 7, Aug. 8, 2014, 128 Stat. 1836; Pub. L. 114–255, div. A, title II, § 2042(f)(2), Dec. 13, 2016, 130 Stat. 1073.)

AMENDMENTS

2016—Subsec. (c). Pub. L. 114–255 substituted ''280i–2'' for ''280i–2, 283j,''.

2014—Subsec. (a). Pub. L. 113–157, § 7(1), substituted ''fiscal years 2015 through 2019'' for ''fiscal years 2012 through 2014''.

Subsec. (b). Pub. L. 113–157, § 7(2), substituted ''fiscal years 2015 through 2019'' for ''fiscal years 2011 through 2014''.

Subsec. (c). Pub. L. 113–157, § 7(3), substituted ''$190,000,000 for each of fiscal years 2015 through 2019'' for ''$161,000,000 for each of fiscal years 2011 through 2014''.

2011—Pub. L. 112–32 amended section generally. Prior to amendment, section authorized appropriations for fiscal years 2007 to 2011.

PART S—HEALTH CARE QUALITY PROGRAMS

SUBPART I—NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE

CODIFICATION

Subpart is based on subpart I of part S of title III of act July 1, 1944, as added by Pub. L. 111–148, title III, § 3011, Mar. 23, 2010, 124 Stat. 378. No subpart II has been enacted.

§ 280j. National strategy for quality improvement in health care

(a) Establishment of national strategy and priorities

(1) National strategy

The Secretary, through a transparent collaborative process, shall establish a national

strategy to improve the delivery of health care services, patient health outcomes, and population health.

(2) Identification of priorities

(A) In general

The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).

(B) Requirements

The Secretary shall ensure that priorities identified under subparagraph (A) will—

(i) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;

(ii) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;

(iii) address gaps in quality, efficiency, comparative effectiveness information (taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social Security Act [42 U.S.C. 1320e–1(c), (d)]), and health outcomes measures and data aggregation techniques;

(iv) improve Federal payment policy to emphasize quality and efficiency;

(v) enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;

(vi) address the health care provided to patients with high-cost chronic diseases;

(vii) improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;

(viii) reduce health disparities across health disparity populations (as defined in section 285t[1] of this title) and geographic areas; and

(ix) address other areas as determined appropriate by the Secretary.

(C) Considerations

In identifying priorities under subparagraph (A), the Secretary shall take into consideration the recommendations submitted by the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] and other stakeholders.

(D) Coordination with State agencies

The Secretary shall collaborate, coordinate, and consult with State agencies responsible for administering the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] and the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.] with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under subparagraph (A).

(b) Strategic plan

(1) In general

The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).

(2) Requirements

The strategic plan shall include provisions for addressing, at a minimum, the following:

(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures identified by the Secretary under section 1139A or 1139B of the Social Security Act [42 U.S.C. 1320b–9a, 1320b–9b] or endorsed under section 1890 of such Act [42 U.S.C. 1395aaa].

(B) Agency-specific strategic plans to achieve national priorities.

(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.

(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.

(E) Strategies to align public and private payers with regard to quality and patient safety efforts.

(F) Incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).

(c) Periodic update of national strategy

The Secretary shall update the national strategy not less than annually. Any such update shall include a review of short- and long-term goals.

(d) Submission and availability of national strategy and updates

(1) Deadline for initial submission of national strategy

Not later than January 1, 2011, the Secretary shall submit to the relevant committees of Congress the national strategy described in subsection (a).

(2) Updates

(A) In general

The Secretary shall submit to the relevant committees of Congress an annual update to the strategy described in paragraph (1).

(B) Information submitted

Each update submitted under subparagraph (A) shall include—

(i) a review of the short- and long-term goals of the national strategy and any gaps in such strategy;

(ii) an analysis of the progress, or lack of progress, in meeting such goals and any barriers to such progress;

(iii) the information reported under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a], consistent with the reporting requirements of such section; and

(iv) in the case of an update required to be submitted on or after January 1, 2014,

[1] See References in Text note below.

the information reported under section 1139B(b)(4) of the Social Security Act [42 U.S.C. 1320b–9b(b)(4)], consistent with the reporting requirements of such section.

(C) Satisfaction of other reporting requirements

Compliance with the requirements of clauses (iii) and (iv) of subparagraph (B) shall satisfy the reporting requirements under sections 1139A(a)(6) and 1139B(b)(4), respectively, of the Social Security Act [42 U.S.C. 1320b–9a(a)(6), 1320b–9b(b)(4)].

(e) Health care quality Internet website

Not later than January 1, 2011, the Secretary shall create an Internet website to make public information regarding—

(1) the national priorities for health care quality improvement established under subsection (a)(2);

(2) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B); and

(3) other information, as the Secretary determines to be appropriate.

(July 1, 1944, ch. 373, title III, § 399HH, as added and amended Pub. L. 111–148, title III, § 3011, title X, § 10302, Mar. 23, 2010, 124 Stat. 378, 937.)

REFERENCES IN TEXT

Section 285t of this title, referred to in subsec. (a)(2)(B)(viii), was in the original ''section 485E'', meaning section 485E of act July 1, 1944, ch. 373, as added by section 101(a) of Pub. L. 106–525, which was classified to section 287c–31 of this title. Section 485E of act July 1, 1944, was renumbered section 464z–3 by Pub. L. 111–148, title X, § 10334(c)(1)(D)(i), Mar. 23, 2010, 124 Stat. 973, and transferred to section 285t of this title. The act July 1, 1944, no longer contains a section 485E.

The Social Security Act, referred to in subsec. (a)(2)(D), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters 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 American Recovery and Reinvestment Act of 2009, referred to in subsec. (b)(2)(F), is Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 115. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 1 of Title 26, Internal Revenue Code, and Tables.

AMENDMENTS

2010—Subsec. (a)(2)(B)(iii). Pub. L. 111–148, § 10302, inserted ''(taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social Security Act)'' after ''information''.

INTERAGENCY WORKING GROUP ON HEALTH CARE QUALITY

Pub. L. 111–148, title III, § 3012, Mar. 23, 2010, 124 Stat. 380, provided that:

''(a) IN GENERAL.—The President shall convene a working group to be known as the Interagency Working Group on Health Care Quality (referred to in this section as the 'Working Group').

''(b) GOALS.—The goals of the Working Group shall be to achieve the following:

''(1) Collaboration, cooperation, and consultation between Federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under section 399HH(a)(2) of the Public Health Service Act [42 U.S.C. 280j(a)(2)] (as added by section 3011 [of Pub. L. 111–148]).

''(2) Avoidance of inefficient duplication of quality improvement efforts and resources, where practicable, and a streamlined process for quality reporting and compliance requirements.

''(3) Assess alignment of quality efforts in the public sector with private sector initiatives.

''(c) COMPOSITION.—

''(1) IN GENERAL.—The Working Group shall be composed of senior level representatives of—

''(A) the Department of Health and Human Services;

''(B) the Centers for Medicare & Medicaid Services;

''(C) the National Institutes of Health;

''(D) the Centers for Disease Control and Prevention;

''(E) the Food and Drug Administration;

''(F) the Health Resources and Services Administration;

''(G) the Agency for Healthcare Research and Quality;

''(H) the Office of the National Coordinator for Health Information Technology;

''(I) the Substance Abuse and Mental Health Services Administration;

''(J) the Administration for Children and Families;

''(K) the Department of Commerce;

''(L) the Office of Management and Budget;

''(M) the United States Coast Guard;

''(N) the Federal Bureau of Prisons;

''(O) the National Highway Traffic Safety Administration;

''(P) the Federal Trade Commission;

''(Q) the Social Security Administration;

''(R) the Department of Labor;

''(S) the United States Office of Personnel Management;

''(T) the Department of Defense;

''(U) the Department of Education;

''(V) the Department of Veterans Affairs;

''(W) the Veterans Health Administration; and

''(X) any other Federal agencies and departments with activities relating to improving health care quality and safety, as determined by the President.

''(2) CHAIR AND VICE-CHAIR.—

''(A) CHAIR.—The Working Group shall be chaired by the Secretary of Health and Human Services.

''(B) VICE CHAIR.—Members of the Working Group, other than the Secretary of Health and Human Services, shall serve as Vice Chair of the Group on a rotating basis, as determined by the Group.

''(d) REPORT TO CONGRESS.—Not later than December 31, 2010, and annually thereafter, the Working Group shall submit to the relevant Committees of Congress, and make public on an Internet website, a report describing the progress and recommendations of the Working Group in meeting the goals described in subsection (b).''

§ 280j–1. Collection and analysis of data for quality and resource use measures

(a) In general

(1) Establishment of strategic framework

The Secretary shall establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in section 280j–2 of this title. Such strategic framework may include methods and related timelines for implementing nationally consistent data collection, data aggregation, and analysis methods.

(2) Collection and aggregation of data

The Secretary shall collect and aggregate consistent data on quality and resource use

measures from information systems used to support health care delivery, and may award grants or contracts for this purpose. The Secretary shall align such collection and aggregation efforts with the requirements and assistance regarding the expansion of health information technology systems, the interoperability of such technology systems, and related standards that are in effect on March 23, 2010.

(3) Scope

The Secretary shall ensure that the data collection, data aggregation, and analysis systems described in paragraph (1) involve an increasingly broad range of patient populations, providers, and geographic areas over time.

(b) Grants or contracts for data collection

(1) In general

The Secretary may award grants or contracts to eligible entities to support new, or improve existing, efforts to collect and aggregate quality and resource use measures described under subsection (c).

(2) Eligible entities

To be eligible for a grant or contract under this subsection, an entity shall—

(A) be—

(i) a multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;

(ii) an entity capable of submitting such summary data for a particular population and providers, such as a disease registry, regional collaboration, health plan collaboration, or other population-wide source; or

(iii) a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 1603 of title 25);

(B) promote the use of the systems that provide data to improve and coordinate patient care;

(C) support the provision of timely, consistent quality and resource use information to health care providers, and other groups and organizations as appropriate, with an opportunity for providers to correct inaccurate measures; and

(D) agree to report, as determined by the Secretary, measures on quality and resource use to the public in accordance with the public reporting process established under section 280j–2 of this title.

(c) Consistent data aggregation

The Secretary may award grants or contracts under this section only to entities that enable summary data that can be integrated and compared across multiple sources. The Secretary shall provide standards for the protection of the security and privacy of patient data.

(d) Matching funds

The Secretary may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, § 399II, as added and amended Pub. L. 111–148, title III, § 3015, title X, § 10305, Mar. 23, 2010, 124 Stat. 387, 938.)

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, § 10305, amended subsec. (a) generally. Prior to amendment, text read as follows: ''The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance information, as described in section 280j–2 of this title, and may award grants or contracts for this purpose. The Secretary shall ensure that such collection, aggregation, and analysis systems span an increasingly broad range of patient populations, providers, and geographic areas over time.''

§ 280j–2. Public reporting of performance information

(a) Development of performance websites

The Secretary shall make available to the public, through standardized Internet websites, performance information summarizing data on quality measures. Such information shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.

(b) Information on conditions

The performance information made publicly available on an Internet website, as described in subsection (a), shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

(c) Consultation

(1) In general

In carrying out this section, the Secretary shall consult with the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)], and other entities, as appropriate, to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites.

(2) Consultation with stakeholders

The entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C.

1395aaa(a)] shall convene multi-stakeholder groups, as described in such section, to review the design and format of each Internet website made available under subsection (a) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

(d) Coordination

Where appropriate, the Secretary shall coordinate the manner in which data are presented through Internet websites described in subsection (a) and for public reporting of other quality measures by the Secretary, including such quality measures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, § 399JJ, as added Pub. L. 111–148, title III, § 3015, Mar. 23, 2010, 124 Stat. 388.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to subchapter XVIII (§ 1395 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.

§ 280j–3. Quality improvement program for hospitals with a high severity adjusted readmission rate

(a) Establishment

(1) In general

Not later than 2 years after March 23, 2010, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 299b–21(4) of this title).

(2) Eligible hospital defined

In this subsection, the term ''eligible hospital'' means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the conditions described in section 1395ww(q)(8)(A) of this title and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

(3) Risk adjustment

The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

(b) Report to the Secretary

As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

(July 1, 1944, ch. 373, title III, § 399KK, as added Pub. L. 111–148, title III, § 3025(b), Mar. 23, 2010, 124 Stat. 412.)

PART T—ORAL HEALTHCARE PREVENTION ACTIVITIES

§ 280k. Oral healthcare prevention education campaign

(a) Establishment

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with professional oral health organizations, shall, subject to the availability of appropriations, establish a 5-year national, public education campaign (referred to in this section as the ''campaign'') that is focused on oral healthcare prevention and education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer.

(b) Requirements

In establishing the campaign, the Secretary shall—

(1) ensure that activities are targeted towards specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and ethnic and racial minority populations, including Indians, Alaska Natives and Native Hawaiians (as defined in section 1603(c)[1] of title 25) in a culturally and linguistically appropriate manner; and

(2) utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants.

(c) Planning and implementation

Not later than 2 years after March 23, 2010, the Secretary shall begin implementing the 5-year campaign. During the 2-year period referred to in the previous sentence, the Secretary shall conduct planning activities with respect to the campaign.

(July 1, 1944, ch. 373, title III, § 399LL, as added Pub. L. 111–148, title IV, § 4102(a), Mar. 23, 2010, 124 Stat. 550.)

REFERENCES IN TEXT

Section 1603(c) of title 25, referred to in subsec. (b)(1), which defines ''Indians'', was redesignated section 1603(13) of title 25 by Pub. L. 111–148, title X, § 10221(a), Mar. 23, 2010, 124 Stat. 935.

§ 280k–1. Research-based dental caries disease management

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award demonstration grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities.

(b) Eligibility

To be eligible for a grant under this section, an entity shall—

(1) be a community-based provider of dental services (as defined by the Secretary), including a Federally-qualified health center, a clinic of a hospital owned or operated by a State (or by an instrumentality or a unit of govern-

[1] See References in Text note below.

ment within a State), a State or local department of health, a dental program of the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as such terms are defined in section 1603 of title 25), a health system provider, a private provider of dental services, medical, dental, public health, nursing, nutrition educational institutions, or national organizations involved in improving children's oral health; and

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

(c) Use of funds

A grantee shall use amounts received under a grant under this section to demonstrate the effectiveness of research-based dental caries disease management activities.

(d) Use of information

The Secretary shall utilize information generated from grantees under this section in planning and implementing the public education campaign under section 280k of this title.

(July 1, 1944, ch. 373, title III, § 399LL–1, as added Pub. L. 111–148, title IV, § 4102(a), Mar. 23, 2010, 124 Stat. 551.)

§ 280k–2. Authorization of appropriations

There is authorized to be appropriated to carry out this part, such sums as may be necessary.

(July 1, 1944, ch. 373, title III, § 399LL–2, as added Pub. L. 111–148, title IV, § 4102(a), Mar. 23, 2010, 124 Stat. 551.)

§ 280k–3. Updating national oral healthcare surveillance activities

(1) PRAMS

(A) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall carry out activities to update and improve the Pregnancy Risk Assessment Monitoring System (referred to in this section as ''PRAMS'') as it relates to oral healthcare.

(B) State reports and mandatory measurements

(i) In general

Not later than 5 years after March 23, 2010, and every 5 years thereafter, a State shall submit to the Secretary a report concerning activities conducted within the State under PRAMS.

(ii) Measurements

The oral healthcare measurements developed by the Secretary for use under PRAMS shall be mandatory with respect to States for purposes of the State reports under clause (i).

(C) Funding

There is authorized to be appropriated to carry out this paragraph, such sums as may be necessary.

(2) National Health and Nutrition Examination Survey

The Secretary shall develop oral healthcare components that shall include tooth-level surveillance for inclusion in the National Health and Nutrition Examination Survey. Such components shall be updated by the Secretary at least every 6 years. For purposes of this paragraph, the term ''tooth-level surveillance'' means a clinical examination where an examiner looks at each dental surface, on each tooth in the mouth and as expanded by the Division of Oral Health of the Centers for Disease Control and Prevention.

(3) Medical Expenditures Panel Survey

The Secretary shall ensure that the Medical Expenditures Panel Survey by the Agency for Healthcare Research and Quality includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(4) National Oral Health Surveillance System

(A) Appropriations

There is authorized to be appropriated, such sums as may be necessary for each of fiscal years 2010 through 2014 to increase the participation of States in the National Oral Health Surveillance System from 16 States to all 50 States, territories, and District of Columbia.

(B) Requirements

The Secretary shall ensure that the National Oral Health Surveillance System include the measurement of early childhood caries.

(Pub. L. 111–148, title IV, § 4102(d), Mar. 23, 2010, 124 Stat. 552.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PART U—EMPLOYER-BASED WELLNESS PROGRAM

§ 280*l*. Technical assistance for employer-based wellness programs

In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—

(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including—

(A) measuring the participation and methods to increase participation of employees in such programs;

(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and

(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and

(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs and ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.

(July 1, 1944, ch. 373, title III, § 399MM, as added and amended Pub. L. 111–148, title IV, § 4303, title X, § 10404, Mar. 23, 2010, 124 Stat. 583, 975.)

AMENDMENTS

2010—Par. (2). Pub. L. 111–148, § 10404, substituted ''and ensuring'' for ''by ensuring''.

GRANTS FOR SMALL BUSINESSES TO PROVIDE COMPREHENSIVE WORKPLACE WELLNESS PROGRAMS

Pub. L. 111–148, title X, § 10408, Mar. 23, 2010, 124 Stat. 977, provided that:

''(a) ESTABLISHMENT.—The Secretary shall award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs (as described under subsection (c)).

''(b) SCOPE.—

''(1) DURATION.—The grant program established under this section shall be conducted for a 5-year period.

''(2) ELIGIBLE EMPLOYER.—The term 'eligible employer' means an employer (including a non-profit employer) that—

''(A) employs less than 100 employees who work 25 hours or greater per week; and

''(B) does not provide a workplace wellness program as of the date of enactment of this Act [Mar. 23, 2010].

''(c) COMPREHENSIVE WORKPLACE WELLNESS PROGRAMS.—

''(1) CRITERIA.—The Secretary shall develop program criteria for comprehensive workplace wellness programs under this section that are based on and consistent with evidence-based research and best practices, including research and practices as provided in the Guide to Community Preventive Services, the Guide to Clinical Preventive Services, and the National Registry for Effective Programs.

''(2) REQUIREMENTS.—A comprehensive workplace wellness program shall be made available by an eligible employer to all employees and include the following components:

''(A) Health awareness initiatives (including health education, preventive screenings, and health risk assessments).

''(B) Efforts to maximize employee engagement (including mechanisms to encourage employee participation).

''(C) Initiatives to change unhealthy behaviors and lifestyle choices (including counseling, seminars, online programs, and self-help materials).

''(D) Supportive environment efforts (including workplace policies to encourage healthy lifestyles, healthy eating, increased physical activity, and improved mental health).

''(d) APPLICATION.—An eligible employer desiring to participate in the grant program under this section shall submit an application to the Secretary, in such manner and containing such information as the Secretary may require, which shall include a proposal for a comprehensive workplace wellness program that meet [sic] the criteria and requirements described under subsection (c).

''(e) AUTHORIZATION OF APPROPRIATION.—For purposes of carrying out the grant program under this section, there is authorized to be appropriated $200,000,000 for the period of fiscal years 2011 through 2015. Amounts appropriated pursuant to this subsection shall remain available until expended.''

§ 280*l*–1. National worksite health policies and programs study

(a) In general

In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not later than 2 years after March 23, 2010, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(b) Report

Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

(July 1, 1944, ch. 373, title III, § 399MM–1, as added Pub. L. 111–148, title IV, § 4303, Mar. 23, 2010, 124 Stat. 583.)

§ 280*l*–2. Prioritization of evaluation by Secretary

The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.

(July 1, 1944, ch. 373, title III, § 399MM–2, as added Pub. L. 111–148, title IV, § 4303, Mar. 23, 2010, 124 Stat. 583.)

§ 280*l*–3. Prohibition of Federal workplace wellness requirements

Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.

(July 1, 1944, ch. 373, title III, § 399MM–3, as added Pub. L. 111–148, title IV, § 4303, Mar. 23, 2010, 124 Stat. 583.)

PART V—PROGRAMS RELATING TO BREAST HEALTH AND CANCER

§ 280m. Young women's breast health awareness and support of young women diagnosed with breast cancer

(a) Public education campaign

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a national evidence-based education campaign to increase awareness of young women's knowledge regarding—

(A) breast health in young women of all racial, ethnic, and cultural backgrounds;

(B) breast awareness and good breast health habits;

(C) the occurrence of breast cancer and the general and specific risk factors in women

who may be at high risk for breast cancer based on familial, racial, ethnic, and cultural backgrounds such as Ashkenazi Jewish populations;

(D) evidence-based information that would encourage young women and their health care professional to increase early detection of breast cancers; and

(E) the availability of health information and other resources for young women diagnosed with breast cancer.

(2) Evidence-based, age appropriate messages

The campaign shall provide evidence-based, age-appropriate messages and materials as developed by the Centers for Disease Control and Prevention and the Advisory Committee established under paragraph (4).

(3) Media campaign

In conducting the education campaign under paragraph (1), the Secretary shall award grants to entities to establish national multimedia campaigns oriented to young women that may include advertising through television, radio, print media, billboards, posters, all forms of existing and especially emerging social networking media, other Internet media, and any other medium determined appropriate by the Secretary.

(4) Advisory committee

(A) Establishment

Not later than 60 days after March 23, 2010, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to assist in creating and conducting the education campaigns under paragraph (1) and subsection (b)(1).

(B) Membership

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall appoint to the advisory committee under subparagraph (A) such members as deemed necessary to properly advise the Secretary, and shall include organizations and individuals with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women.

(b) Health care professional education campaign

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Health Resources and Services Administration, shall conduct an education campaign among physicians and other health care professionals to increase awareness—

(1) of breast health, symptoms, and early diagnosis and treatment of breast cancer in young women, including specific risk factors such as family history of cancer and women that may be at high risk for breast cancer, such as Ashkenazi Jewish population;

(2) on how to provide counseling to young women about their breast health, including knowledge of their family cancer history and importance of providing regular clinical breast examinations;

(3) concerning the importance of discussing healthy behaviors, and increasing awareness of services and programs available to address overall health and wellness, and making patient referrals to address tobacco cessation, good nutrition, and physical activity;

(4) on when to refer patients to a health care provider with genetics expertise;

(5) on how to provide counseling that addresses long-term survivorship and health concerns of young women diagnosed with breast cancer; and

(6) on when to provide referrals to organizations and institutions that provide credible health information and substantive assistance and support to young women diagnosed with breast cancer.

(c) Prevention research activities

The Secretary, acting through—

(1) the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on breast cancer in younger women, including—

(A) behavioral, survivorship studies, and other research on the impact of breast cancer diagnosis on young women;

(B) formative research to assist with the development of educational messages and information for the public, targeted populations, and their families about breast health, breast cancer, and healthy lifestyles;

(C) testing and evaluating existing and new social marketing strategies targeted at young women; and

(D) surveys of health care providers and the public regarding knowledge, attitudes, and practices related to breast health and breast cancer prevention and control in high-risk populations; and

(2) the Director of the National Institutes of Health, shall conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

(d) Support for young women diagnosed with breast cancer

(1) In general

The Secretary shall award grants to organizations and institutions to provide health information from credible sources and substantive assistance directed to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

(2) Priority

In making grants under paragraph (1), the Secretary shall give priority to applicants that deal specifically with young women diagnosed with breast cancer and pre-neoplastic breast disease.

(e) No duplication of effort

In conducting an education campaign or other program under subsections (a), (b), (c), or (d), the Secretary shall avoid duplicating other existing Federal breast cancer education efforts.

(f) Measurement; reporting

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

(1) measure—

(A) young women's awareness regarding breast health, including knowledge of family cancer history, specific risk factors and early warning signs, and young women's proactive efforts at early detection;

(B) the number or percentage of young women utilizing information regarding lifestyle interventions that foster healthy behaviors;

(C) the number or percentage of young women receiving regular clinical breast exams; and

(D) the number or percentage of young women who perform breast self exams, and the frequency of such exams, before the implementation of this section;

(2) not less than every 3 years, measure the impact of such activities; and

(3) submit reports to the Congress on the results of such measurements.

(g) Definition

In this section, the term ''young women'' means women 15 to 44 years of age.

(h) Authorization of appropriations

To carry out subsections (a), (b), (c)(1), and (d), there are authorized to be appropriated $4,900,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title III, § 399NN, as added Pub. L. 111–148, title X, § 10413(b), Mar. 23, 2010, 124 Stat. 991; amended Pub. L. 113–265, § 2, Dec. 18, 2014, 128 Stat. 2942.)

AMENDMENTS

2014—Subsec. (h). Pub. L. 113–265 substituted ''$4,900,000 for each of fiscal years 2015 through 2019'' for ''$9,000,000 for each of the fiscal years 2010 through 2014''.

SUBCHAPTER III—NATIONAL RESEARCH INSTITUTES

CODIFICATION

Title IV of the Public Health Service Act, comprising this subchapter, was originally enacted by act July 1, 1944, ch. 373, 58 Stat. 707, at which time title IV related solely to the National Cancer Institute. Because of the extensive amendments, reorganization of the subject matter, and expansion of title IV by the acts listed below, title IV is shown herein as having been added by Pub. L. 99–158, without reference to intervening amendments.

The provisions of title IV as originally enacted were subsequently redesignated as part A of title IV and amended, and parts B to I of title IV were added and amended by the following acts: June 16, 1948, ch. 481, 62 Stat. 464; June 24, 1948, ch. 621, 62 Stat. 598; Aug. 15, 1950, ch. 714, 64 Stat. 443; Oct. 5, 1961, Pub. L. 87–395, 75 Stat. 824; Oct. 17, 1962, Pub. L. 87–838, 76 Stat. 1072; Aug. 16, 1968, Pub. L. 90–489, 82 Stat. 771; Oct. 30, 1970, Pub. L. 91–515, 84 Stat. 1297; Dec. 23, 1971, Pub. L. 92–218, 85 Stat. 778; May 19, 1972, Pub. L. 92–305, 86 Stat. 162; Sept. 19, 1972, Pub. L. 92–423, 86 Stat. 679; Apr. 22, 1974, Pub. L. 93–270, 88 Stat. 90; May 14, 1974, Pub. L. 93–282, 88 Stat. 126; May 31, 1974, Pub. L. 93–296, 88 Stat. 184; July 12, 1974, Pub. L. 93–348, 88 Stat. 342; July 23, 1974, Pub. L. 93–352, 88 Stat. 358; July 23, 1974, Pub. L. 93–354, 88 Stat. 373; Jan. 4, 1975, Pub. L. 93–640, 88 Stat. 2217; July 29, 1975, Pub. L. 94–63, 89 Stat. 304; Nov. 28, 1975, Pub. L. 94–135, 89 Stat. 713; Apr. 21, 1976, Pub. L. 94–273, 90 Stat. 375; Apr. 22, 1976, Pub. L. 94–278, 90 Stat. 401; Oct. 19, 1976, Pub. L. 94–562, 90 Stat. 2645; Aug. 1, 1977, Pub. L. 95–83, 91 Stat. 383; Nov. 9, 1978, Pub. L. 95–622, 92 Stat. 3412; Nov. 9, 1978, Pub. L. 95–623, 92 Stat. 3443; July 10, 1979, Pub. L. 96–32, 93 Stat. 82; Oct. 7, 1980, Pub. L. 96–398, 94 Stat. 1564; Dec. 17, 1980, Pub. L. 96–538, 94 Stat. 3183; Aug. 13, 1981, Pub. L. 97–35, 95 Stat. 358; Apr. 26, 1984, Pub. L. 98–24, 97 Stat. 175.

Title IV was subsequently amended generally and completely reorganized by Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 822.

PART A—NATIONAL INSTITUTES OF HEALTH

§ 281. Organization of National Institutes of Health

(a) Relation to Public Health Service

The National Institutes of Health is an agency of the Service.

(b) National research institutes and national centers

The following agencies of the National Institutes of Health are national research institutes or national centers:

(1) The National Cancer Institute.

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

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

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

(5) The National Institute on Aging.

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

(7) The Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(8) The National Institute of Dental and Craniofacial Research.

(9) The National Eye Institute.

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

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

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

(13) The National Institute on Drug Abuse.

(14) The National Institute of Mental Health.

(15) The National Institute of General Medical Sciences.

(16) The National Institute of Environmental Health Sciences.

(17) The National Institute of Nursing Research.

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

(19) The National Human Genome Research Institute.

(20) The National Library of Medicine.

(21) The National Center for Advancing Translational Sciences.

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

(23) The National Center for Complementary and Integrative Health.

(24) The National Institute on Minority Health and Health Disparities.

(25) Any other national center that, as an agency separate from any national research