

(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:

¹ So in original. Two pars. (2) have been enacted.

(A) Projects to provide comprehensive asthma services to children in accordance with the guidelines of the National Asthma Education and Prevention Program (through the National Heart, Lung and Blood Institute), including access to care and treatment for asthma in a community-based setting.

(B) Projects to fully equip mobile health care clinics that provide preventive asthma care including diagnosis, physical examinations, pharmacological therapy, skin testing, peak flow meter testing, and other asthma-related health care services.

(C) Projects to conduct validated asthma management education programs for patients with asthma and their families, including patient education regarding asthma management, family education on asthma management, and the distribution of materials, including displays and videos, to reinforce concepts presented by medical teams.

(2)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.

(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) 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.)

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

2004—Subsecs. (d), (e). Pub. L. 108-377 added subsec. (d) and redesignated former subsec. (d) as (e).

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 epineph-

rine 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 hearing loss in newborns and infants

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

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers, for the following purposes:

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns and infants; prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, and medical interventions for children identified with hearing loss. Early intervention includes referral to and delivery of information and services by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act [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. Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss.

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

(3) Other activities may include developing efficient models to ensure that newborns and infants who are identified with a hearing loss through screening receive follow-up by a qualified health care provider, and State agencies shall be encouraged to adopt models that

effectively increase the rate of occurrence of such follow-up.

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

(1) Centers for Disease Control and Prevention

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

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

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

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

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

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

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

(2) National Institutes of Health

The Director of the National Institutes of Health, acting through the Director of the National Institute on Deafness and Other Communication Disorders, shall for purposes of this section, continue a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, studies on efficacy of intervention, and related research.

(c) Coordination and collaboration

(1) In general

In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for early intervention services pursuant to title XIX of the Social Security Act [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

The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems.

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

The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States to establish newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems under subsection (a) of this section and to develop a data collection system under subsection (b) of this section.

(d) Rule of construction; religious accommodation

Nothing in this section shall be construed to preempt or prohibit any State law, including State laws which do not require the screening for hearing loss of newborn infants or young children of parents who object to the screening on the grounds that such screening conflicts with the parents' religious beliefs.

(e) Definitions

For purposes of this section:

(1) The term "audiologic evaluation" refers to procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act [20

U.S.C. 1431 et seq.] or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.

(2) The terms "audiologic rehabilitation" and "audiologic intervention" refer to procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.

(3) The term "early intervention" refers to providing appropriate services for the child with hearing loss, including nonmedical services, and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.

(4) The term "medical evaluation by a physician" refers to key components including history, examination, and medical decision making focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(5) The term "medical intervention" refers to the process by which a physician provides medical diagnosis and direction for medical and/or surgical treatment options of hearing loss and/or related medical disorder associated with hearing loss.

(6) The term "newborn and infant hearing screening" refers to objective physiologic procedures to detect possible hearing loss and to identify newborns and infants who require further audiologic and medical evaluations.

(f) Authorization of appropriations

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

For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated to the Health Resources and Services Administration such sums as may be necessary for fiscal years 2011 through 2015.

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

For the purpose of carrying out subsection (b)(1) of this section, there are authorized to be appropriated to the Centers for Disease Control and Prevention such sums as may be necessary for fiscal years 2011 through 2015.

(3) Technical assistance, data management, and applied research; national institute on deafness and other communication disorders

For the purpose of carrying out subsection (b)(2) of this section, 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.)

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsecs. (a)(1), (c)(1), and (e)(1), 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), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. 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.

AMENDMENTS

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 Serv-

ice 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 [this chapter] 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) of this section include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) Coordination of activities

The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) Definition

For purposes of this section, the term “childhood cancer” refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

(e) Authorization of appropriations

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

(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 shall award a grant to each State with an application approved under this section to enable the State—

- (A) to establish and implement a State controlled substance monitoring program; or
- (B) to make improvements to an existing State controlled substance monitoring program.

(2) Determination of amount

(A) Minimum amount

In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

(B) Additional amounts

In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for

the State’s controlled substance monitoring program.

(3) Term of grants

Grants awarded under this section shall be obligated in the year in which funds are allotted.

(b) Development of minimum requirements

Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A) of this section.

(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) of this section—

(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) of this section generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

(iv) criteria for meeting the uniform electronic format requirement of subsection (h) of this section;

(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) of this section;

(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) of this section—

(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

(2) State legislation

As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

(3) Interoperability

If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) of this section on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

(4) Approval

If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

(5) Return of funds

If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

(d) Reporting requirements

In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection

(a)(1)(B) of this section submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

(2) The State may exclude from the reporting requirement of this subsection—

(A) the direct administration of a controlled substance to the body of an ultimate user;

(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

(D) Identification of the drug by a national drug code number.

(E) Quantity dispensed.

(F) Number of refills ordered.

(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(H) Date of the dispensing.

(I) Date of origin of the prescription.

(J) Such other information as may be required by State law to be reported under this subsection.

(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h) of this section, except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

(e) Database

In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d) of this section.

(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) of this section, in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) of this section and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

(i) the State has an application approved under this section; and

(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

(2) Drug diversion

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a) of this section—

(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) of this section indicates an unlawful diversion or abuse of a controlled substance.

(g) Limitations

In implementing or improving a controlled substance monitoring program under this section, a State—

(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) of this section 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) of this section to nonidentifiable information.

(h) Electronic format

The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

(i) Rules of construction

(1) Functions otherwise authorized by law

Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) No preemption

Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this 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.

(j) 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) of this section.

(2) Progress report

Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

(A) complete a study that—

(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring pro-

gram, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

(B) submit a report to the Congress on the results of the study.

(k) Preference

Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

(l) Advisory council

(1) Establishment

A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

(2) Limitation

A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

(3) Sense of Congress

It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

(m) Definitions

For purposes of this section:

(1) The term “bona fide patient” means an individual who is a patient of the practitioner involved.

(2) The term “controlled substance” means a drug that is included in schedule II, III, or IV of section 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) of this section, with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The term “nonidentifiable information” means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(8) The term “State” means each of the 50 States and the District of Columbia.

(9) The term “ultimate user” means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

(n) Authorization of appropriations

To carry out this section, there are authorized to be appropriated—

(1) \$15,000,000 for each of fiscal years 2006 and 2007; and

(2) \$10,000,000 for each of fiscal years 2008, 2009, and 2010.

(July 1, 1944, ch. 373, title III, §399O, as added Pub. L. 109-60, §3, Aug. 11, 2005, 119 Stat. 1979.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (i)(4), is section 264(c) of Pub. L. 104-191, which is set out as a note under section 1320d-2 of this title.

PRIOR PROVISIONS

Another section 399O of act July 1, 1944, was renumbered section 399P and is classified to section 280g-4 of this title.

PURPOSE

Pub. L. 109-60, §2, Aug. 11, 2005, 119 Stat. 1979, 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 foster public health responses to domestic violence, dating violence, sexual assault, and stalking

(a) Authority to award grants

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Preven-

tion, shall award grants to eligible State, tribal, territorial, or local entities to strengthen the response of State, tribal, territorial, or local health care systems to domestic violence, dating violence, sexual assault, and stalking.

(2) Eligible entities

To be eligible to receive a grant under this section, an entity shall—

(A) be—

(i) a State department (or other division) of health, a State domestic or sexual assault coalition or service-based program, State law enforcement task force, or any other nonprofit, nongovernmental, tribal, territorial, or State entity with a history of effective work in the fields of domestic violence, dating violence, sexual assault or stalking, and health care; or

(ii) a local, nonprofit domestic violence, dating violence, sexual assault, or stalking service-based program, a local department (or other division) of health, a local health clinic, hospital, or health system, or any other nonprofit, tribal, or local entity with a history of effective work in the field of domestic or sexual violence and health;

(B) prepare and submit to the Secretary an application at such time, in such manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the grant is to be made; and

(C) demonstrate that the entity is representing a team of organizations and agencies working collaboratively to strengthen the response of the health care system involved to domestic violence, dating violence, sexual assault, or stalking and that such team includes domestic violence, dating violence, sexual assault or stalking and health care organizations.

(3) Duration

A program conducted under a grant awarded under this section shall not exceed 2 years.

(b) Use of funds

(1) In general

An entity shall use amounts received under a grant under this section to design and implement comprehensive strategies to improve the response of the health care system involved to domestic or sexual violence in clinical and public health settings, hospitals, clinics, managed care settings (including behavioral and mental health), and other health settings.

(2) Mandatory strategies

Strategies implemented under paragraph (1) shall include the following:

(A) The implementation, dissemination, and evaluation of policies and procedures to guide health care professionals and behavioral and public health staff in 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 prohibits insurance discrimination.

(B) The development of on-site access to services to address the safety, medical, mental health, and economic needs of patients either by increasing the capacity of existing health care professionals and behavioral and public health staff to address domestic violence, dating violence, sexual assault, and stalking, by contracting with or hiring domestic or sexual assault advocates to provide the services, or to model other services appropriate to the geographic and cultural needs of a site.

(C) The evaluation of practice and the institutionalization of identification, intervention, and documentation including quality improvement measurements.

(D) The provision of training and followup technical assistance to health care professionals, behavioral and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual violence, or stalking.

(3) Permissive strategies

Strategies implemented under paragraph (1) may include the following:

(A) Where appropriate, 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 violence.

(B) The creation, adaptation, and implementation of public education campaigns for patients concerning domestic violence, dating violence, sexual assault, and stalking prevention.

(C) The development, adaptation, and dissemination of domestic violence, dating violence, sexual assault, and stalking education materials to patients and health care professionals and behavioral and public health staff.

(D) The promotion of the inclusion of domestic violence, dating violence, sexual assault, and stalking into health professional training schools, including medical, dental, nursing school, social work, and mental health curriculum.

(E) The integration 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.

(c) Allocation of funds

Funds appropriated under this section shall be distributed equally between State and local programs.

(d) Authorization of appropriations

There is authorized to be appropriated to award grants under this section, \$5,000,000 for each of fiscal years 2007 through 2011.

(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.)

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 signs of preterm labor, updated as new research results become available;

(B) the screening for and the treating of infections;

(c)¹ counseling on optimal weight and good nutrition, including folic acid;

(D) smoking cessation education and counseling;

(E) stress management; and

(F) appropriate prenatal care;

(2) programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section \$5,000,000 for each of fiscal years 2007 through 2011.

(July 1, 1944, ch. 373, title III, § 399Q, as added Pub. L. 109-450, § 4(2), Dec. 22, 2006, 120 Stat. 3342.)

§ 280g-6. Chronic kidney disease initiatives

(a) In general

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) Scope and duration

(1) Scope

The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) Duration

The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) Evaluation and report

The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

(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

¹ So in original. Probably should be “(C)”.

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;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases² and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

¹ So in original. Probably should be “national voluntary health associations;”.

² So in original. Probably should be followed by a semicolon.

(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

³ So in original. No par. (2) has been enacted.

(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-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 pa-

tients, 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 specific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, national and local peer support groups, and other education and support programs as described in subsection (b)(2).

(2) Informational requirements

Information provided under this subsection shall be—

(A) culturally and linguistically appropriate as needed by women receiving a positive prenatal diagnosis or the family of infants receiving a postnatal diagnosis; and

(B) approved by the Secretary.

(d) Report

Not later than 2 years after 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.)

¹ See References in Text note below.

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 pro-

grams, 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, review¹ interventions and update¹ 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

¹ So in original. Probably should be followed by “of”.

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 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 2864(c) 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.)

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

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.

§ 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-1¹ 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

¹ See References in Text note below.

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.)

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 par-

ticipating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) Preference in awarding demonstration grants

In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) Application

(1) In general

Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) Review panel

(A) In general

In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) Composition

(i) Nominations

The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) Appointment

The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) Chairperson

The Comptroller General, or an individual within the Government Accountability Office designated by the Comptroller General, shall be the chairperson of the review panel.

(D) Availability of information

The Comptroller General shall make available to the review panel such information,

personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) Information from agencies

The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) Reports

(1) By State

Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants 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 bearing on whether the complainant may proceed with a case.

(3) Measures

The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) Funding

The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MedPAC and MACPAC reports

(1) MedPAC

The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act [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 states¹ authority over or responsibility for their state¹ 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.)

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.

§ 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 work-

ing 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.)

¹ So in original. Probably should be capitalized.

PART Q—PROGRAMS TO IMPROVE THE HEALTH
OF CHILDREN

**§ 280h. Grants to promote childhood nutrition
and physical activity**

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote good nutrition and physical activity in children and adolescents.

(b) Eligibility

To be eligible to receive a grant under this section a State or political subdivision of a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

- (1) how the applicant proposes to develop a comprehensive program of school- and community-based approaches to encourage and promote good nutrition and appropriate levels of physical activity with respect to children or adolescents in local communities;
- (2) the manner in which the applicant shall coordinate with appropriate State and local authorities, such as State and local school departments, State departments of health, chronic disease directors, State directors of programs under section 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) of this section 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) of this section for a fiscal year may be used by the State or political subdivision for administrative expenses.

(f) Term

A grant awarded under subsection (a) of this section 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.)