cant for the grant makes an agreement that the grant will not be expended for any purpose other than carrying out subparagraph (B). Such a grant may be made only if an application for the grant is submitted to the Secretary containing such agreement, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

(July 1, 1944, ch. 373, title III, § 399G, formerly § 399F, as added Pub. L. 102–531, title II, § 201, Oct. 27, 1992, 106 Stat. 3474; renumbered § 399G, Pub. L. 106–310, div. A, title V, § 502(3), Oct. 17, 2000, 114 Stat. 1115; amended Pub. L. 109–245, § 1, July 26, 2006, 120 Stat. 575; Pub. L. 117–286, § 4(c)(38), Dec. 27, 2022, 136 Stat. 4358.)

Editorial Notes

REFERENCES IN TEXT

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, 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

2022—Subsec. (h)(4)(A). Pub. L. 117–286 substituted ''chapter 131 of title 5,'' for ''the Ethics in Government Act,''.

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

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

CONGRESSIONAL FINDINGS AND PURPOSE

Pub. L. 105–392, title IV, § 419(b), (c), Nov. 13, 1998, 112 Stat. 3591, 3592, as amended by Pub. L. 111–256, § 2(g), Oct. 5, 2010, 124 Stat. 2644, provided findings and purpose related to prevention of Fetal Alcohol Syndrome and Fetal Alcohol Effect.

PART P—ADDITIONAL PROGRAMS

§ 280g. Children's asthma treatment grants program

(a) Authority to make grants

(1) In general

In addition to any other payments made under this chapter or title V of the Social Security Act [42 U.S.C. 701 et seq.], the Secretary shall award grants to eligible entities to carry out the following purposes:

(A) To provide access to quality medical care for children who live in areas that have a high prevalence of asthma and who lack access to medical care.

(B) To provide on-site education to parents, children, health care providers, and

medical teams to recognize the signs and symptoms of asthma, and to train them in the use of medications to treat asthma and prevent its exacerbations.

(C) To decrease preventable trips to the emergency room by making medication available to individuals who have not previously had access to treatment or education in the management of asthma.

(D) To provide other services, such as smoking cessation programs, home modification, and other direct and support services that ameliorate conditions that exacerbate or induce asthma.

(2)[1] Certain projects

In making grants under paragraph (1), the Secretary may make grants designed to develop and expand the following projects:

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

(B) Projects to fully equip mobile health care clinics that provide preventive asthma 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:

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

(A) In general

The State must require that each public elementary school and secondary school in that State will grant to any student in the school an authorization for the self-administration of medication to treat that student's asthma or anaphylaxis, if—

(i) a health care practitioner prescribed the medication for use by the student during school hours and instructed the student in the correct and responsible use of the medication;

(ii) the student has demonstrated to the health care practitioner (or such practitioner's designee) and the school nurse (if available) the skill level necessary to use the medication and any device that is necessary to administer such medication as prescribed;

(iii) the health care practitioner formulates a written treatment plan for managing asthma or anaphylaxis episodes of the student and for medication use by the student during school hours; and

(iv) the student's parent or guardian has completed and submitted to the school any written documentation required by the school, including the treatment plan formulated under clause (iii) and other documents related to liability.

(B) Scope

An authorization granted under subparagraph (A) must allow the student involved to possess and use his or her medication—

(i) while in school;

(ii) while at a school-sponsored activity, such as a sporting event; and

(iii) in transit to or from school or school-sponsored activities.

(C) Duration of authorization

An authorization granted under subparagraph (A)—

(i) must be effective only for the same school and school year for which it is granted; and

(ii) must be renewed by the parent or guardian each subsequent school year in accordance with this subsection.

(D) Backup medication

The State must require that backup medication, if provided by a student's parent or guardian, be kept at a student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(E) Maintenance of information

The State must require that information described in subparagraphs (A)(iii) and (A)(iv) be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(F) School personnel administration of epinephrine or school comprehensive allergies and asthma management program

(i) In general

In determining the preference (if any) to be given to a State under this subsection, the Secretary shall give additional preference to a State that provides to the Secretary the certification described in subparagraph (G) and that requires that each public elementary school and secondary school in the State satisfy the criteria described in clause (ii) or clause (iii).

(ii) Criteria for school personnel administration of epinephrine

For purposes of clause (i), the criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) permits trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;

(II) maintains a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and

(III) has in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

(iii) Criteria for school comprehensive allergies and asthma management program

For purposes of clause (i), the criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) has in place a plan for having on the premises of the school during all operating hours of the school a school nurse or one or more other individuals who are designated by the principal (or other appropriate administrative staff) of the school to direct and apply the program described in subclause (II) on a voluntary basis outside their scope of employment; and

(II) has in place, under the direction of a school nurse or other individual designated under subclause (I), a comprehensive school-based allergies and asthma management program that includes—

(aa) a method to identify all students of such school with a diagnosis of allergies and asthma;

(bb) an individual student allergies and asthma action plan for each student of such school with a diagnosis of allergies and asthma;

(cc) allergies and asthma education for school staff who are directly responsible for students who have been identified as having allergies or asthma, such as education regarding basics, management, trigger management, and comprehensive emergency responses with respect to allergies and asthma;

(dd) efforts to reduce the presence of environmental triggers of allergies and asthma; and

(ee) a system to support students with a diagnosis of allergies or asthma through coordination with family members of such students, primary care providers of such students, primary asthma or allergy care providers of such students, and others as necessary.

(G) Civil liability protection law

The certification required in subparagraph (F) shall be a certification made by the State attorney general that the State has reviewed any applicable civil liability protection law to determine the application of such law with regard to elementary and secondary school trained personnel who may administer epinephrine to a student reasonably believed to be having an anaphylactic reaction and has concluded that such law provides adequate civil liability protection applicable to such trained personnel. For purposes of the previous sentence, the term ''civil liability protection law'' means a State law offering legal protection to individuals who give aid on a voluntary basis in an emergency to an individual who is ill, in peril, or otherwise incapacitated.

(2) Rule of construction

Nothing in this subsection creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(3) Definitions

For purposes of this subsection:

(A) The terms ''elementary school'' and ''secondary school'' have the meaning given to those terms in section 7801 of title 20.

(B) The term ''health care practitioner'' means a person authorized under law to prescribe drugs subject to section 353(b) of title 21.

(C) The term ''medication'' means a drug as that term is defined in section 321 of title 21 and includes inhaled bronchodilators and auto-injectable epinephrine.

(D) The term ''self-administration'' means a student's discretionary use of his or her prescribed asthma or anaphylaxis medication, pursuant to a prescription or written direction from a health care practitioner.

(E) The term ''trained personnel'' means, with respect to an elementary or secondary school, an individual, such as the school nurse—

(i) who has been designated by the school nurse or principal (or other appropriate administrative staff) of the school to administer epinephrine on a voluntary basis outside their scope of employment;

(ii) who has received training in the administration of epinephrine; and

(iii) whose training in the administration of epinephrine meets appropriate medical standards and has been documented by appropriate administrative staff of the school.

(e) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399L, as added Pub. L. 106–310, div. A, title V, § 501, Oct. 17, 2000, 114 Stat. 1113; amended Pub. L. 108–377, § 3(a), Oct. 30, 2004, 118 Stat. 2203; Pub. L. 113–48, § 2, Nov. 13, 2013, 127 Stat. 575; Pub. L. 114–95, title IX, § 9215(kkk)(2), Dec. 10, 2015, 129 Stat. 2187; Pub. L. 116–292, § 2, Jan. 5, 2021, 134 Stat. 4896.)

Editorial Notes

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. 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, 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

2021—Subsec. (d)(1)(F). Pub. L. 116–292, § 2(1)(B), inserted ''or school comprehensive allergies and asthma management program'' after ''epinephrine'' in heading; designated introductory provisions as cl. (i), inserted heading, and substituted ''in the State satisfy the criteria described in clause (ii) or clause (iii).'' for ''in the State—''; inserted cl. (ii) heading and introductory provisions; redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii); added cl. (iii); and realigned margins.

Subsec. (d)(3)(E). Pub. L. 116–292, § 2(2)(A), inserted '', such as the school nurse'' after ''individual'' in introductory provisions.

Subsec. (d)(3)(E)(i). Pub. L. 116–292, § 2(2)(B), inserted ''school nurse or'' before ''principal''.

2015—Subsec. (d)(3)(A). Pub. L. 114–95 made technical amendment to reference in original act which appears in text as reference to section 7801 of title 20.

2013—Subsec. (d)(1)(F), (G). Pub. L. 113–48, § 2(1), added subpars. (F) and (G).

Subsec. (d)(3)(E). Pub. L. 113–48, § 2(2), added subpar. (E).

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

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–377, § 3(b), Oct. 30, 2004, 118 Stat. 2204, provided that: ''The amendments made by this section

[amending this section] shall apply only with respect to grants made on or after the date that is 9 months after the date of the enactment of this Act [Oct. 30, 2004].''

FINDINGS OF 2004 AMENDMENT

Pub. L. 108–377, § 2, Oct. 30, 2004, 118 Stat. 2202, provided that: ''The Congress finds the following:

''(1) Asthma is a chronic condition requiring lifetime, ongoing medical intervention.

''(2) In 1980, 6,700,000 Americans had asthma.

''(3) In 2001, 20,300,000 Americans had asthma; 6,300,000 children under age 18 had asthma.

''(4) The prevalence of asthma among African-American children was 40 percent greater than among Caucasian children, and more than 26 percent of all asthma deaths are in the African-American population.

''(5) In 2000, there were 1,800,000 asthma-related visits to emergency departments (more than 728,000 of these involved children under 18 years of age).

''(6) In 2000, there were 465,000 asthma-related hospitalizations (214,000 of these involved children under 18 years of age).

''(7) In 2000, 4,487 people died from asthma, and of these 223 were children.

''(8) According to the Centers for Disease Control and Prevention, asthma is a common cause of missed school days, accounting for approximately 14,000,000 missed school days annually.

''(9) According to the New England Journal of Medicine, working parents of children with asthma lose an estimated $1,000,000,000 a year in productivity.

''(10) At least 30 States have legislation protecting the rights of children to carry and self-administer asthma metered-dose inhalers, and at least 18 States expand this protection to epinephrine auto-injectors.

''(11) Tragic refusals of schools to permit students to carry their inhalers and auto-injectable epinephrine have occurred, some resulting in death and spawning litigation.

''(12) School district medication policies must be developed with the safety of all students in mind. The immediate and correct use of asthma inhalers and auto-injectable epinephrine are necessary to avoid serious respiratory complications and improve health care outcomes.

''(13) No school should interfere with the patient-physician relationship.

''(14) Anaphylaxis, or anaphylactic shock, is a systemic allergic reaction that can kill within minutes. Anaphylaxis occurs in some asthma patients. According to the American Academy of Allergy, Asthma, and Immunology, people who have experienced symptoms of anaphylaxis previously are at risk for subsequent reactions and should carry an epinephrine auto-injector with them at all times, if prescribed.

''(15) An increasing number of students and school staff have life-threatening allergies. Exposure to the affecting allergen can trigger anaphylaxis. Anaphylaxis requires prompt medical intervention with an injection of epinephrine.''

§ 280g–1. Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children

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

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

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns, infants, and young children (referred to in this section as ''children''); prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:

(A) Early intervention includes referral to, and delivery of, information and services by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated by part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.], which offer programs specifically designed to meet the unique language and communication needs of deaf and hard-of-hearing children.

(B) Information provided to families should be accurate, comprehensive, up-to-date, and evidence-based, as appropriate, to allow families to make important decisions for their children in a timely manner, including decisions with respect to the full range of assistive hearing technologies and communications modalities, as appropriate.

(C) Programs and systems under this paragraph shall offer mechanisms that foster family-to-family and deaf and hard-of-hearing consumer-to-family supports.

(2) To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs.

(3) To identify or develop efficient models (educational and medical) to ensure that children who are identified as deaf or hard-of-hearing through screening receive follow-up by qualified early intervention providers or qualified health care providers (including those at medical homes for children), and referrals, as appropriate, including to early intervention services under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]. State agencies shall be encouraged to effectively increase the rate of such follow-up and referral.

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

(1) Centers for Disease Control and Prevention

(A) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies or designated entities of States—

(i) to develop, maintain, and improve data collection systems related to newborn, infant, and young child hearing

screening, evaluation (including audiologic, medical, and language acquisition evaluations), diagnosis, and intervention services;

(ii) to conduct applied research related to newborn, infant, and young child hearing screening, evaluation, and intervention programs and outcomes;

(iii) to ensure quality monitoring of hearing screening, evaluation, and intervention programs and systems for newborns, infants, and young children; and

(iv) to support newborn, infant, and young child hearing screening, evaluation, and intervention programs, and information systems.

(B) Use of awards

The awards made under subparagraph (A) may be used—

(i) to provide technical assistance on data collection and management, including to coordinate and develop standardized procedures for data management;

(ii) to assess and report on the cost and program effectiveness of newborn, infant, and young child hearing screening, evaluation, and intervention programs and systems;

(iii) to collect data and report on newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems for applied research, program evaluation, and policy improvement;

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

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

(vi) to promote the integration and interoperability of data regarding early hearing loss across multiple sources to increase the flow of information between clinical care and public health settings, including the ability of States and territories to exchange and share data.

(2) National Institutes of Health

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

(c) Coordination and collaboration

(1) In general

In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with—

(A) other Federal agencies;

(B) State and local agencies, including agencies responsible for early intervention services pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.] (State Children's Health Insurance Program); title V of the Social Security Act [42 U.S.C. 701 et seq.] (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.];

(C) consumer groups of, and that serve, individuals who are deaf and hard-of-hearing and their families;

(D) appropriate national medical and other health and education specialty organizations;

(E) individuals who are deaf or hard-of-hearing and their families;

(F) other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing children, and their families;

(G) third-party payers and managed care organizations; and

(H) related commercial industries.

(2) Policy development

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

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

The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States—

(A) to establish newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems under subsection (a); and

(B) to develop a data collection system under subsection (b).

(d) Rule of construction; religious accommodation

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

(e) Definitions

For purposes of this section:

(1) The term ''audiologic'', when used in connection with evaluation, means procedures—

(A) to assess the status of the auditory system;

(B) to establish the site of the auditory disorder, the type and degree of hearing loss, and the potential effects of hearing loss on communication; and

(C) to identify appropriate treatment and referral options, including—

(i) linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.] or other appropriate agencies;

(ii) medical evaluation;

(iii) assessment for the full range of assistive hearing technologies appropriate for newborns, infants, and young children;

(iv) audiologic rehabilitation treatment; and

(v) referral to national and local consumer, self-help, parent, family, and education organizations, and other family-centered services.

(2) The term ''early intervention'' means—

(A) providing appropriate services for the child who is deaf or hard-of-hearing, including nonmedical services; and

(B) ensuring that the family of the child is—

(i) provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language acquisition in oral and visual modalities; and

(ii) given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for the child from highly qualified providers.

(3) The term ''medical evaluation'' means key components performed by a physician including history, examination, and medical decisionmaking focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(4) The term ''medical intervention'' means the process by which a physician provides medical diagnosis and direction for medical or surgical treatment options for hearing loss or other medical disorders associated with hearing loss.

(5) The term ''newborn, infant, and young child hearing screening'' means objective physiologic procedures to detect possible hearing loss and to identify newborns, infants, and young children under 3 years of age who require further audiologic and medical evaluations.

(f) Authorization of appropriations

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

For the purpose of carrying out subsection (a), there are authorized to be appropriated to the Health Resources and Services Administration $17,818,000 for each of fiscal years 2023 through 2027.

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

For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated to the Centers for Disease Control and Prevention $10,760,000 for each of fiscal years 2023 through 2027.

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

For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated to the National Institute on Deafness and Other Communication Disorders such sums as may be necessary for fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, § 399M, as added Pub. L. 106–310, div. A, title VII, § 702, Oct. 17, 2000, 114 Stat. 1121; amended Pub. L. 111–337, § 2, Dec. 22, 2010, 124 Stat. 3588; Pub. L. 115–71, § 2, Oct. 18, 2017, 131 Stat. 1218; Pub. L. 117–241, § 2, Dec. 20, 2022, 136 Stat. 2332.)

Editorial Notes

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsecs. (a)(1)(A), (3), (c)(1)(B), and (e)(1)(C)(i), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Part C of the Act is classified generally to subchapter III (§ 1431 et seq.) of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Social Security Act, referred to in subsec. (c)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles 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

2022—Subsec. (e)(3). Pub. L. 117–241, § 2(1), inserted par. (3) designation before ''The term 'medical evaluation' ''.

Subsec. (f)(1). Pub. L. 117–241, § 2(2)(A), substituted ''$17,818,000 for each of fiscal years 2023 through 2027'' for ''$17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022''.

Subsec. (f)(2). Pub. L. 117–241, § 2(2)(B), substituted ''$10,760,000 for each of fiscal years 2023 through 2027'' for ''$10,800,000 for fiscal year 2018, $11,026,800 for fiscal year 2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022''.

2017—Pub. L. 115–71, § 2(a), substituted ''Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children'' for ''Early detection, diagnosis, and treatment regarding hearing loss in newborns and infants'' in section catchline.

Subsec. (a). Pub. L. 115–71, § 2(b)(2), substituted ''newborn, infant, and young child'' for ''newborn and infant'' and ''providers (including, as appropriate, education and training of family members),'' for ''providers,'' in introductory provisions.

Pub. L. 115–71, § 2(b)(1), substituted ''newborn, infant, and young child'' for ''newborn and infant'' in heading.

Subsec. (a)(1). Pub. L. 115–71, § 2(b)(3), in first sentence, substituted ''newborns, infants, and young children (referred to in this section as 'children')'' for ''newborns and infants'' and ''medical, and communica-

tion (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:'' for ''and medical interventions for children identified with hearing loss.''; designated second sentence as subpar. (A) and substituted '', and delivery of,'' for ''and delivery of'', ''by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated'' for ''by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated'', and ''hard-of-hearing children.'' for ''hard of hearing newborns, infants, toddlers, and children.''; struck out third sentence which read ''Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss.''; and added subpars. (B) and (C).

Subsec. (a)(2). Pub. L. 115–71, §2(b)(4), substituted ''To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs.'' for ''To collect data on statewide newborn and infant hearing screening, evaluation and intervention programs and systems that can be used for applied research, program evaluation and policy development.''

Subsec. (a)(3). Pub. L. 115–71, §2(b)(5), added par. (3) and struck out former par. (3) which read as follows: ''Other activities may include developing efficient models to ensure that newborns and infants who are identified with a hearing loss through screening receive follow-up by a qualified health care provider, and State agencies shall be encouraged to adopt models that effectively increase the rate of occurrence of such follow-up.''

Subsec. (b)(1). Pub. L. 115–71, §2(c), made extensive amendments to text and structure of par. (1). Prior to amendments, text of par. (1) read as follows: ''The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

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

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

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

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

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

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

Subsec. (c)(1). Pub. L. 115–71, §2(d)(1), substituted ''consult with—'' for ''consult with'', ''(A) other Federal'' for ''other Federal'', ''(B) State and local agencies, including agencies'' for ''State and local agencies, including those'', ''(C) consumer groups of, and that serve,'' for ''consumer groups of and that serve'', ''(D) appropriate national'' for ''appropriate national'', ''(E) individuals who are deaf or'' for ''persons who are deaf and'', ''(F) other qualified'' for ''other qualified'', ''children,'' for ''newborns, infants, toddlers, children,'', ''(G) third-party'' for ''third-party'', and ''(H) related commercial'' for ''related commercial''.

Subsec. (c)(3). Pub. L. 115–71, §2(d)(2), substituted ''States—'' for ''States'', ''(A) to establish newborn, infant, and young child'' for ''to establish newborn and infant'', ''subsection (a); and'' for ''subsection (a) and'', and ''(B) to develop'' for ''to develop''.

Subsec. (d). Pub. L. 115–71, §2(e), substituted ''that do not'' for ''which do not'' and ''parent's'' for ''parents' '' and struck out ''newborn infants or young'' after ''hearing loss of''.

Subsec. (e)(1). Pub. L. 115–71, §2(f)(1), made extensive amendments to text and structure of par. (1). Prior to amendments, par. (1) read as follows: ''The term 'audiologic evaluation' refers to procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.''

Subsec. (e)(2). Pub. L. 115–71, §2(f)(4), made extensive amendments to text and structure of par. (2). Prior to amendments, par. (2) read as follows: ''The term 'early intervention' refers to providing appropriate services for the child with hearing loss, including nonmedical services, and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.''

Pub. L. 115–71, §2(f)(2), (3), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: ''The terms 'audiologic rehabilitation' and 'audiologic intervention' refer to procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.''

Subsec. (e)(3). Pub. L. 115–71, §2(f)(5), substituted ''The term 'medical evaluation' means key components performed by a physician including history, examination, and medical decisionmaking'' for ''(3) The term 'medical evaluation by a physician' refers to key components including history, examination, and medical decision making''.

Pub. L. 115–71, §2(f)(3), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (e)(4). Pub. L. 115–71, §2(f)(6), substituted ''means'' for ''refers to'', ''or surgical'' for ''and/or surgical'', and ''for hearing loss or other medical disorders'' for ''of hearing loss and/or related medical disorder''.

Pub. L. 115–71, §2(f)(3), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (e)(5). Pub. L. 115–71, §2(f)(7), substituted ''The term 'newborn, infant, and young child hearing screening' means'' for ''The term 'newborn and infant hearing screening' refers to'' and '', infants, and young children under 3 years of age'' for ''and infants''.

Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5). Former par. (5) redesignated (4).

Subsec. (e)(6). Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5).

Subsec. (f)(1). Pub. L. 115–71, §2(g)(1), substituted ''$17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022.'' for ''such sums as may be necessary for fiscal years 2011 through 2015.''

Subsec. (f)(2). Pub. L. 115–71, §2(g)(2), substituted ''$10,800,000 for fiscal year 2018, $11,026,800 for fiscal year

2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022.'' for ''such sums as may be necessary for fiscal years 2011 through 2015.''

2010—Pub. L. 111–337, § 2(1), substituted ''newborns and infants'' for ''infants'' in section catchline.

Subsec. (a). Pub. L. 111–337, § 2(2)(A), substituted ''screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers,'' for ''screening, evaluation and intervention programs and systems'' in introductory provisions.

Subsec. (a)(1). Pub. L. 111–337, § 2(2)(B), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''To develop and monitor the efficacy of statewide newborn and infant hearing screening, evaluation and intervention programs and systems. Early intervention includes referral to schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act, which offer programs specifically designed to meet the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children.''

Subsec. (a)(3). Pub. L. 111–337, § 2(2)(C), added par. (3).

Subsec. (b)(1)(A). Pub. L. 111–337, § 2(3), substituted ''hearing loss screening, evaluation, diagnosis, and intervention programs'' for ''hearing loss screening, evaluation, and intervention programs''.

Subsec. (c)(2), (3). Pub. L. 111–337, § 2(4), substituted ''hearing screening, evaluation, diagnosis, and intervention programs'' for ''hearing screening, evaluation and intervention programs''.

Subsec. (e)(3). Pub. L. 111–337, § 2(5)(A), substituted ''ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers.'' for ''ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child.''

Subsec. (e)(6). Pub. L. 111–337, § 2(5)(B), struck out '', after rescreening,'' after ''infants who''.

Subsec. (f). Pub. L. 111–337, § 2(6), substituted ''fiscal years 2011 through 2015'' for ''fiscal year 2002'' in pars. (1) to (3).

Statutory Notes and Related Subsidiaries

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

Pub. L. 111–8, div. F, title II, § 224, Mar. 11, 2009, 123 Stat. 784, provided that: ''Hereafter, the activities authorized under section 399M of the Public Health Service Act [42 U.S.C. 280g–1] shall be known as the 'James T. Walsh Universal Newborn Hearing Screening Program.'''

PURPOSES

Pub. L. 106–310, div. A, title VII, § 701, Oct. 17, 2000, 114 Stat. 1120, provided that: ''The purposes of this title [enacting this section] are to clarify the authority within the Public Health Service Act [42 U.S.C. 201 et seq.] to authorize statewide newborn and infant hearing screening, evaluation and intervention programs and systems, technical assistance, a national applied research program, and interagency and private sector collaboration for policy development, in order to assist the States in making progress toward the following goals:

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

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

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

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

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

§ 280g–2. Childhood malignancies

(a) In general

The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) include—

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

(2) the development of a uniform reporting system under which treating physicians, 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. Prescription drug monitoring program

(a) Program

(1) In general

Each fiscal year, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, in coordination with the heads of other departments and agencies as appropriate, shall support States or localities for the purpose of improving the efficiency and use of PDMPs, including—

(A) establishment and implementation of a PDMP;

(B) maintenance of a PDMP;

(C) improvements to a PDMP by—

(i) enhancing functional components to work toward—

(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow;

(II) more timely inclusion of data within a PDMP;

(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

(IV) ensuring the highest level of ease in use of and access to PDMPs by providers and their delegates, to the extent that State laws allow;

(ii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the intrastate interoperability of PDMPs by—

(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

(II) linking PDMP data to other data systems within the State, including—

(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

(bb) worker's compensation data; and

(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

(iii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the interstate interoperability of PDMPs through—

(I) sharing of dispensing data in near-real time across State lines; and

(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or

(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

(2) Legislation

As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it has enacted legislation or regulations—

(A) to provide for the implementation of the PDMP; and

(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

(b) PDMP strategies

The Secretary shall encourage a State or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

(1) the reporting of dispensing in the State or locality of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event;

(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State or locality before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;

(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;

(5) the availability of data in the PDMP to other States, as allowable under State law; and

(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

(c) Drug misuse and abuse

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances;

(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance;

(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to

real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and provided that such reports shall not include protected health information; and

(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

(d) Evaluation and reporting

As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) Evaluation and reporting

A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

(2) to prepare and submit to the Congress the report required by subsection (i)(2).

(f) Education and access to the monitoring system

A State receiving support under this section shall take steps to—

(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

(g) Electronic format

The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

(h) Rules of construction

(1) Functions otherwise authorized by law

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

(2) Additional privacy protections

Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(3) Federal privacy requirements

Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 290dd–2 of this title.

(4) No Federal private cause of action

Nothing in this section shall be construed to create a Federal private cause of action.

(i) Progress report

Not later than 3 years after October 24, 2018, the Secretary shall—

(1) complete a study that—

(A) determines the progress of grantees in establishing and implementing PDMPs consistent with this section;

(B) provides an analysis of the extent to which the operation of PDMPs has—

(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

(iii) affected patient access to appropriate care in States operating PDMPs;

(C) determine[1] the progress of grantees in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

(D) determines the progress of grantees in implementing near real-time electronic PDMPs;

(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State or locality receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

(F) determines the progress of States or localities in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(G) evaluates the penalties that States or localities have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

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

(j) Advisory Council

(1) Establishment

A State or locality may establish an advisory council to assist in the establishment,

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

improvement, or maintenance of a PDMP consistent with this section.

(2) Limitation

A State or locality may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

(3) Sense of Congress

It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State or locality should consult with appropriate professional boards and other interested parties.

(k) Definitions

For purposes of this section:

(1) The term ''controlled substance'' means a controlled substance (as defined in section 802 of title 21) in schedule II, III, or IV of section 812 of such title.

(2) The term ''dispense'' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(3) The term ''dispenser'' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(4) The term ''interstate interoperability'' with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(5) The term ''intrastate interoperability'' with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

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

(7) The term ''PDMP'' means a prescription drug monitoring program that is State-controlled.

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

(9) The term ''State'' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(10) The term ''ultimate user'' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

(11) The term ''clinical workflow'' means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.

(July 1, 1944, ch. 373, title III, § 399O, as added Pub. L. 109–60, § 3, Aug. 11, 2005, 119 Stat. 1979; amended Pub. L. 114–198, title I, § 109(b), July 22, 2016, 130 Stat. 706; Pub. L. 115–271, title VII, § 7162, Oct. 24, 2018, 132 Stat. 4062.)

Editorial Notes

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(3), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

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

AMENDMENTS

2018—Pub. L. 115–271 amended section generally. Prior to amendment, section related to grants for State controlled substance monitoring programs.

2016—Subsec. (a)(1). Pub. L. 114–198, § 109(b)(1)(A), inserted '', in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention,'' after ''the Secretary'' in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 114–198, § 109(b)(1)(B)–(D), added subpar. (C).

Subsec. (b). Pub. L. 114–198, § 109(b)(2), amended subsec. (b) generally. Prior to amendment, text read as follows: ''Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A) of this section.''

Subsec. (c)(1)(A)(iv). Pub. L. 114–198, § 109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (c)(1)(B). Pub. L. 114–198, § 109(b)(3)(A)(i), substituted ''(a)(1)(B) or (a)(1)(C)'' for ''(a)(1)(B)'' in introductory provisions.

Subsec. (c)(1)(B)(i). Pub. L. 114–198, § 109(b)(3)(A)(ii), substituted ''program to be improved or maintained'' for ''program to be improved''.

Subsec. (c)(1)(B)(iii). Pub. L. 114–198, § 109(b)(3)(A)(iv), added cl. (iii). Former cl. (iii) redesignated (iv).

Subsec. (c)(1)(B)(iv). Pub. L. 114–198, § 109(b)(3)(A)(iii), (v), redesignated cl. (iii) as (iv) and substituted ''and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;'' for ''; and''. Former cl. (iv) redesignated (v).

Subsec. (c)(1)(B)(v). Pub. L. 114–198, § 109(b)(3)(A)(iii), (vi), redesignated cl. (iv) as (v) and substituted ''public

health or safety in such State; and'' for ''public health in such State.''

Subsec. (c)(1)(B)(vi). Pub. L. 114–198, §109(b)(3)(A)(vii), added cl. (vi).

Subsec. (c)(3). Pub. L. 114–198, §109(b)(3)(B), designated existing provisions as subpar. (A) and inserted heading, inserted before period at end ''and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability'', and added subpar. (B).

Subsec. (c)(5). Pub. L. 114–198, §109(b)(3)(C), substituted ''establish, improve, or maintain'' for ''implement or improve'' and inserted at end ''The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).''

Subsec. (d). Pub. L. 114–198, §109(b)(4)(A), in introductory provisions, substituted ''In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)'' for ''In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B)'' and ''public health or safety'' for ''public health''.

Subsec. (d)(4). Pub. L. 114–198, §109(b)(9), substituted ''subsection (i)'' for ''subsection (h)''.

Subsec. (d)(5). Pub. L. 114–198, §109(b)(4)(B), added par. (5).

Subsecs. (e), (f)(1). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsec. (f)(1)(B). Pub. L. 114–198, §109(b)(6)(A)(i), substituted ''misuse of a controlled substance included in schedule II, III, or IV of section 812(c) of title 21'' for ''misuse of a schedule II, III, or IV substance''.

Subsec. (f)(1)(D). Pub. L. 114–198, §109(b)(6)(A)(ii), inserted ''a State substance abuse agency,'' after ''State health department,'' and substituted ''such department, program, agency, or administration'' for ''such department, program, or administration'' in two places.

Subsec. (f)(3), (4). Pub. L. 114–198, §109(b)(6)(B), added pars. (3) and (4).

Subsec. (g). Pub. L. 114–198, §109(b)(5), substituted ''establishing, improving, or maintaining'' for ''implementing or improving'' in introductory provisions.

Subsecs. (h) to (j). Pub. L. 114–198, §109(b)(8), (10), added subsec. (h) and redesignated former subsecs. (h) and (i) as (i) and (j), respectively. Former subsec. (j) redesignated (k).

Subsec. (k). Pub. L. 114–198, §109(b)(7), (8), redesignated subsec. (j) as (k) and struck out former subsec. (k). Prior to amendment, text of subsec. (k) read as follows: ''Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).''

Subsec. (k)(2)(A)(ii). Pub. L. 114–198, §109(b)(11)(A), substituted '', established or strengthened initiatives to ensure linkages to substance use disorder services, or affected'' for ''or affected''.

Subsec. (k)(2)(A)(iii). Pub. L. 114–198, §109(b)(11)(B), substituted ''and between controlled substance monitoring programs and health information technology systems, including an assessment'' for ''including an assessment''.

Subsec. (*l*)(1). Pub. L. 114–198, §109(b)(12), substituted ''establishment, improvement, or maintenance'' for ''establishment, implementation, or improvement''.

Subsec. (m)(8). Pub. L. 114–198, §109(b)(13), substituted '', the District of Columbia, and any commonwealth or territory of the United States'' for ''and the District of Columbia''.

Subsec. (n). Pub. L. 114–198, §109(b)(14), amended subsec. (n) generally. Prior to amendment, subsec. (n) authorized appropriations for fiscal years 2006 to 2010.

Statutory Notes and Related Subsidiaries

PURPOSE

Pub. L. 109–60, §2, Aug. 11, 2005, 119 Stat. 1979, as amended by Pub. L. 114–198, title I, §109(a), July 22, 2016, 130 Stat. 706, provided that: ''It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

''(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

''(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.''

§ 280g–4. Grants to strengthen the healthcare system's response to domestic violence, dating violence, sexual assault, and stalking

(a) In general

The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, community health workers, violence prevention advocates working with health providers, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers (including midwives and doulas);

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the capacity of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to prevent and respond to domestic violence, dating violence, sexual assault, and stalking;

(4) the development or enhancement and implementation of training programs to improve the capacity of early childhood programs to address domestic violence, dating violence, sexual assault, and stalking among families they serve; and

(5) the development or enhancement and implementation of comprehensive statewide strategies for health and violence prevention programs to work together to promote primary prevention of domestic violence, dating violence, sexual assault, and stalking.

(b) Use of funds

(1) Required uses

Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to provide universal education on healthy relationships and provide trauma-informed health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking;

(ii) plan and develop training components that center the experiences of, and are developed in collaboration with, culturally specific individuals and American Indians and Alaska Natives, and include community-defined practices such as the use of doulas, midwives, and traditional healers, for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse (including labor and sex trafficking), focus on reducing health inequities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(iii) are designed to be inclusive of the experiences of all individuals, including LGBT individuals, and include training on improving equity and reducing disparities in access to health care services and prevention resources; and

(iv) include training on the use of a universal prevention education approach to both prevent and respond to domestic violence, dating violence, sexual assault, or stalking in health care settings;

(B) design and implement comprehensive strategies to improve the capacity of the health care system to prevent and respond to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—

(i) the implementation, dissemination, and evaluation of policies and procedures to guide health professionals and public health staff in identifying, responding to, and promoting prevention of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including strategies to ensure that health information is maintained in a manner that protects the patient's privacy and safety, and safely uses health information technology to improve documentation, identification, assessment, treatment, and follow-up care and to maximize victim choice on the use and sharing of their health information;

(ii) the development of services to address the safety, medical, and mental health needs of patients by—

(I) increasing the capacity of existing health care professionals (including professionals who specialize in trauma or in substance use disorders) in behavioral and mental health care, community health workers, and public health staff to address domestic violence, dating violence, sexual assault, stalking, and children exposed to violence;

(II) contracting with or hiring advocates for victims of domestic violence or sexual assault to provide such services; or

(III) providing funding to State domestic and sexual violence coalitions to improve the capacity of such coalitions to coordinate and support health advocates and other health system partnerships;

(iii) the development of measures and methods for the evaluation of the practice of prevention, intervention, and documentation regarding victims of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including the development and testing of quality improvement measurements, in accordance with the multistakeholder and quality measurement processes established under paragraphs (7) and (8) of section 1395aaa(b) of this title and section 1395aaa–1 of this title;

(iv) the provision of training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking, and promote prevention during in-person or virtual visits, including using tools and training materials already developed;

(v) the development, implementation, dissemination, and evaluation of best practices, tools, and training materials, including culturally relevant tools, for mental health, behavioral health, and substance use disorder professionals to identify and respond to domestic violence, sexual violence, stalking, and dating violence; and

(vi) the development and provision of culturally relevant training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking from culturally specific communities and promote prevention, using tools and training materials, developed by and for culturally specific communities, with priority given to trainings provided by culturally specific organizations; and

(C) design and implement comprehensive strategies to prevent domestic or sexual violence including through the use of universal education in clinical and public health settings, hospitals, clinics and other health settings.

(2) Permissible uses

(A) Child abuse and abuse in later life

To the extent consistent with the purpose of this section, a grantee may use amounts received under this section to address, as part of a comprehensive programmatic approach implemented under the grant, issues relating to child abuse or abuse in later life.

(B) Rural areas

Grants funded under paragraphs (1) and (2) of subsection (a) may be used to offer to rural areas community-based training opportunities, which may include the use of distance learning networks and other available technologies needed to reach isolated rural areas, for medical, nursing, and other health profession students and residents on domestic violence, dating violence, sexual assault, stalking, and, as appropriate, other forms of violence and abuse.

(C) Other uses

Grants funded under subsection (a)(3) may be used for—

(i) the development of training modules and policies that address the overlap of child abuse, domestic violence, dating violence, sexual assault, and stalking and abuse in later life, as well as childhood exposure to domestic and sexual violence;

(ii) the development, expansion, and implementation of programs that promote the prevention of sexual assault as well as sexual assault forensic medical examination or sexual assault nurse examiner programs;

(iii) the inclusion of the health effects of lifetime exposure to violence and abuse and exposure to violence across generations as well as related protective factors and behavioral risk factors in health professional training schools including medical, dental, nursing, social work, and mental and behavioral health curricula, and allied health service training courses;

(iv) the integration of knowledge of domestic violence, dating violence, sexual assault, and stalking into health care accreditation and professional licensing examinations, such as medical, dental, mental health, social work, and nursing boards, and where appropriate, other allied health exams and certifications;

(v) providing funding to culturally specific organizations to improve the capacity of such organizations to engage and partner with health care providers to support victims and meet increased referrals from health systems;

(vi) developing a State-level pilot program to—

(I) improve the response of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to domestic violence, dating violence, sexual assault, and stalking;

(II) improve the capacity of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to serve survivors of domestic violence, dating violence, sexual assault, and stalking dealing with substance use disorder; and

(III) improve the capacity of domestic violence, dating violence, sexual assault, and stalking programs to serve survivors who have substance use history; or

(vii) developing and utilizing existing technical assistance and training resources to improve the capacity of substance use disorder treatment programs and harm reduction programs for people who use substances to address domestic violence, dating violence, sexual assault, and stalking among patients the programs serve.

(c) Requirements for grantees

(1) Confidentiality and safety

(A) In general

Grantees under this section shall ensure that all programs developed with grant funds address issues of confidentiality and patient safety and comply with applicable confidentiality and nondisclosure requirements under section 12291(b)(2) of title 34 and the Family Violence Prevention and Services Act [42 U.S.C. 10401 et seq.], and that faculty and staff associated with delivering educational components are fully trained in procedures that will protect the immediate and ongoing security and confidentiality of the patients, patient records, and staff. Such grantees shall consult entities with demonstrated expertise in the confidentiality and safety needs of victims of domestic violence, dating violence, sexual assault, and stalking on the development and adequacy of confidentially and security procedures, and provide documentation of such consultation.

(B) Advance notice of information disclosure

Grantees under this section shall provide to patients advance notice about any circumstances under which information may be disclosed, such as mandatory reporting laws, and shall give patients the option to receive information and referrals without affirmatively disclosing abuse.

(2) Limitation on administrative expenses

A grantee shall use not more than 10 percent of the amounts received under a grant under this section for administrative expenses.

(3) Application

(A) Preference

In selecting grant recipients under this section, the Secretary shall give preference to applicants based on the strength of their evaluation strategies, with priority given to—

(i) outcome based evaluations;

(ii) culturally specific and population specific organizations; and

(iii) programs developing and implementing community-driven solutions to address domestic violence, dating violence, sexual assault, or stalking.

(B) Subsection (a)(1) and (2) grantees

Applications for grants under paragraphs (1) and (2) of subsection (a) shall include—

(i) documentation that the applicant represents a team of entities working collaboratively to strengthen the response of the health care system to domestic violence, dating violence, sexual assault, or stalking, and which includes at least one of each of—

(I) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or other health field;

(II) a health care facility or system; or

(III) a government or nonprofit entity, including a culturally specific organization or community-based organization working to address the social determinants of health, with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking; and

(ii) strategies for the dissemination and sharing of curricula and other educational materials developed under the grant, if any, with other interested health professions schools and national resource repositories for materials on domestic violence, dating violence, sexual assault, and stalking.

(C) Subsection (a)(3) grantees

An entity desiring a grant under subsection (a)(3) shall submit an application to the Secretary at such time, in such a manner, and containing such information and assurances as the Secretary may require, including—

(i) documentation that all training, education, screening, assessment, services, treatment, and any other approach to patient care will be informed by an understanding of violence and abuse victimization and trauma-specific approaches that will be integrated into prevention, intervention, and treatment activities;

(ii) strategies—

(I) for the development and implementation of policies to prevent and address domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations in health care settings; and

(II) to address primary prevention of domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations, including strategies that address related social determinants of health, economic justice, and equity issues, and that are inclusive of LGBT individuals;

(iii) a plan for consulting with State and tribal domestic violence or sexual assault coalitions, national nonprofit victim advocacy organizations, culturally specific organizations, and population specific organizations with demonstrated expertise in domestic violence, dating violence, sexual assault, or stalking;

(iv) with respect to an application for a grant under which the grantee will have contact with patients, a plan, developed in collaboration with local victim service providers (including culturally specific organizations), to respond appropriately to and make correct referrals for individuals who disclose that they are victims of domestic violence, dating violence, sexual assault, stalking, or other types of violence, and documentation provided by the grantee of an ongoing collaborative relationship with a local victim service provider; and

(v) with respect to an application for a grant proposing to fund a program described in subsection (b)(2)(C)(ii), a certification that any sexual assault forensic medical examination and sexual assault nurse examiner programs supported with such grant funds will adhere to the guidelines set forth by the Attorney General.

(d) Eligible entities

(1) In general

To be eligible to receive funding under paragraph (1) or (2) of subsection (a), an entity shall be—

(A) a nonprofit organization with a history of effective work in the field of training health professionals with an understanding of, and clinical skills pertinent to, domestic violence, dating violence, sexual assault, or stalking, and lifetime exposure to violence and abuse;

(B) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or allied health;

(C) a health care provider membership or professional organization, or a health care system; or

(D) a State, tribal, territorial, or local entity.

(2) Subsection (a)(3) grantees

To be eligible to receive funding under subsection (a)(3), an entity shall be—

(A) a State department (or other division) of health (including mental health or substance abuse agencies), a State, tribal, or territorial domestic violence or sexual assault coalition or victim service provider, or any other nonprofit, nongovernmental organization with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking, and health care, including physical or behavioral health care and substance use disorder prevention and treatment; or

(B) a local victim service provider, a local department (or other division) of health, a local health clinic, hospital, behavioral health treatment system, or health system, a community-based organization with a history of effective work in the field of domestic violence, dating violence, sexual assault,

or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment, or a community-based organization with a history of partnership with programs in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment.

(e) Technical assistance

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may make grants or enter into contracts to provide technical assistance with respect to the planning, development, and operation of any program, activity or service carried out pursuant to this section. Not more than 8 percent of the funds appropriated under this section in each fiscal year may be used to fund technical assistance under this subsection.

(2) Availability of materials

The Secretary shall make publicly available materials developed by grantees under this section, including materials on training, best practices, and research and evaluation.

(3) Reporting

The Secretary shall publish a biennial report on—

(A) the distribution of funds under this section; and

(B) the programs and activities supported by such funds.

(f) Research and evaluation

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may use not more than 20 percent to make a grant or enter into a contract for research and evaluation of—

(A) grants awarded under this section; and

(B) other training for health professionals and effective interventions in the health care setting that prevent domestic violence, dating violence, and sexual assault across the lifespan, prevent the health effects of such violence, and improve the safety and health of individuals who are currently being victimized.

(2) Research

Research authorized in paragraph (1) may include—

(A) research on the effects of domestic violence, dating violence, sexual assault, and childhood exposure to domestic, dating or sexual violence on health behaviors, health conditions, and health status of individuals, families, and populations, including underserved populations;

(B) research to determine effective health care interventions to respond to and prevent domestic violence, dating violence, sexual assault, and stalking;

(C) research on the impact of domestic, dating and sexual violence, childhood exposure to such violence, and stalking on the health care system, health care utilization, health care costs, and health status; and

(D) research on the impact of adverse childhood experiences on adult experience with domestic violence, dating violence, sexual assault, stalking, and adult health outcomes, including how to reduce or prevent the impact of adverse childhood experiences through the health care setting.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $20,000,000 for each of fiscal years 2023 through 2027.

(h) Definitions

Except as otherwise provided, the definitions in section 12291 of title 34 shall apply to this section.

(July 1, 1944, ch. 373, title III, § 399P, formerly § 399O, as added Pub. L. 109–162, title V, § 504, Jan. 5, 2006, 119 Stat. 3026; renumbered § 399P, Pub. L. 109–450, § 4(1), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–4, title V, § 501(a), Mar. 7, 2013, 127 Stat. 96; Pub. L. 117–103, div. W, title V, § 501, Mar. 15, 2022, 136 Stat. 869.)

Editorial Notes

REFERENCES IN TEXT

The Family Violence Prevention and Services Act, referred to in subsec. (c)(1)(A), is title III of Pub. L. 98–457, Oct. 9, 1984, 98 Stat. 1757, which is classified generally to chapter 110 (§ 10401 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10401 of this title and Tables.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–103, § 501(1)(A), inserted ''community health workers, violence prevention advocates working with health providers,'' after ''health staff,''.

Subsec. (a)(2). Pub. L. 117–103, § 501(1)(B), substituted ''for medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers (including midwives and doulas);'' for ''for medical, nursing, dental, and other health profession students and residents to prevent and respond to domestic violence, dating violence, sexual assault, and stalking; and''.

Subsec. (a)(3). Pub. L. 117–103, § 501(1)(C)(i), (ii), substituted ''capacity'' for ''response'' and inserted ''prevent and respond to'' after ''(including behavioral and mental health programs) to''.

Subsec. (a)(4), (5). Pub. L. 117–103, § 501(1)(C)(iii), (D), added pars. (4) and (5).

Subsec. (b)(1)(A)(i). Pub. L. 117–103, § 501(2)(A)(i), substituted ''to provide universal education on healthy relationships and provide trauma-informed'' for ''to identify and provide''.

Subsec. (b)(1)(A)(ii). Pub. L. 117–103, § 501(2)(B), substituted ''training components that center the experiences of, and are developed in collaboration with, culturally specific individuals and American Indians and Alaska Natives, and include community-defined practices such as the use of doulas, midwives, and traditional healers,'' for ''culturally competent clinical training components'' and ''inequities'' for ''disparities'' and inserted ''(including labor and sex trafficking)'' after ''other forms of violence and abuse''.

Subsec. (b)(1)(A)(iii), (iv). Pub. L. 117–103, § 501(2)(A)(ii), (C), added cls. (iii) and (iv).

Subsec. (b)(1)(B). Pub. L. 117–103, § 501(2)(D), substituted ''capacity of the health care system to prevent and respond'' for ''response of the health care system'' in introductory provisions.

Subsec. (b)(1)(B)(i). Pub. L. 117–103, § 501(2)(E), substituted ''identifying, responding to, and promoting prevention of'' for ''identifying and responding to'' and inserted ''during in-person or virtual visits'' after ''and stalking'' and ''and to maximize victim choice on the use and sharing of their health information'' before semicolon at end.

Subsec. (b)(1)(B)(ii). Pub. L. 117–103, § 501(2)(F), substituted ''services to address the safety, medical, and mental health needs of patients by—'' and subcls. (I) to (III) for ''on-site access to services to address the safety, medical, and mental health needs of patients by increasing the capacity of existing health care professionals and public health staff to address domestic violence, dating violence, sexual assault, and stalking, or by contracting with or hiring domestic or sexual assault advocates to provide such services or to model other services appropriate to the geographic and cultural needs of a site;''.

Subsec. (b)(1)(B)(iii). Pub. L. 117–103, § 501(2)(G)(i), (ii), substituted ''of prevention'' for ''of identification'' and inserted ''during in-person or virtual visits'' after ''and stalking''.

Subsec. (b)(1)(B)(iv). Pub. L. 117–103, § 501(2)(H)(i), inserted ''and promote prevention during in-person or virtual visits,'' after ''or stalking,''.

Subsec. (b)(1)(B)(v), (vi). Pub. L. 117–103, § 501(2)(G)(iii), (H)(ii), (I), added cls. (v) and (vi).

Subsec. (b)(1)(C). Pub. L. 117–103, § 501(2)(J), added subpar. (C).

Subsec. (b)(2)(A). Pub. L. 117–103, § 501(3), substituted ''Child abuse and abuse in later life'' for ''Child and elder abuse'' in heading and ''child abuse or abuse in later life'' for ''child or elder abuse'' in text.

Subsec. (b)(2)(C)(i). Pub. L. 117–103, § 501(4), substituted ''abuse in later life'' for ''elder abuse''.

Subsec. (b)(2)(C)(ii). Pub. L. 117–103, § 501(5), inserted ''programs that promote the prevention of sexual assault as well as'' after ''implementation of''.

Subsec. (b)(2)(C)(iii). Pub. L. 117–103, § 501(6)(A), inserted ''and exposure to violence across generations'' after ''abuse''.

Subsec. (b)(2)(C)(iv). Pub. L. 117–103, § 501(7), inserted ''mental health,'' after ''dental,'' and substituted ''exams and certifications;'' for ''exams.''.

Subsec. (b)(2)(C)(v) to (vii). Pub. L. 117–103, § 501(6)(B), (8), added cls. (v) to (vii).

Subsec. (c)(3)(A). Pub. L. 117–103, § 501(9), substituted ''given to—'' and cls. (i) to (iii) for ''given to outcome based evaluations.''

Subsec. (c)(3)(B)(i)(III). Pub. L. 117–103, § 501(10), inserted '', including a culturally specific organization or community-based organization working to address the social determinants of health,'' after ''nonprofit entity''.

Subsec. (c)(3)(C)(ii). Pub. L. 117–103, § 501(11), substituted ''strategies—'' for ''strategies'', inserted subcl. (I) designation before ''for the development'', inserted ''and generations'' after ''lifespan'' and added subcl. (II).

Subsec. (c)(3)(C)(iii). Pub. L. 117–103, § 501(12), substituted ''culturally specific organizations'' for ''State or tribal law enforcement task forces (where appropriate)''.

Subsec. (c)(3)(C)(iv). Pub. L. 117–103, § 501(13), inserted ''(including culturally specific organizations)'' after ''service providers''.

Subsec. (d)(2)(A). Pub. L. 117–103, § 501(14)(C), which directed insertion of ''and substance use disorder prevention and treatment'' before ''the semicolon at the end'', was executed by making the insertion before ''; or'', to reflect the probable intent of Congress.

Pub. L. 117–103, § 501(14)(A), (B), inserted ''(including mental health or substance abuse agencies)'' after ''of health'' and substituted ''or behavioral'' for ''or mental''.

Subsec. (d)(2)(B). Pub. L. 117–103, § 501(15), substituted ''hospital, behavioral health treatment system, or health system, a community-based'' for ''hospital, or health system, or any other community-based'' and inserted ''or substance use disorder prevention and treatment, or a community-based organization with a history of partnership with programs in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment'' after ''mental health care''.

Subsec. (g). Pub. L. 117–103, § 501(16), substituted ''$20,000,000'' for ''$10,000,000'' and ''2023 through 2027'' for ''2014 through 2018''.

Subsec. (h). Pub. L. 117–103, § 501(17), struck out ''herein'' after ''otherwise provided'' and ''provided for'' after ''definitions''.

2013—Pub. L. 113–4 amended section generally. Prior to amendment, section related to grants to foster public health responses to domestic violence, dating violence, sexual assault, and stalking.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–103 not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as an Effective Date note under section 6851 of Title 15, Commerce and Trade.

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–4a. Understanding sexual assault care in health systems

(a) Purpose

It is the purpose of this section to identify areas for improvement in health care delivery systems providing forensic examinations to survivors of sexual assault.

(b) Grants

The Secretary of Health and Human Services (referred to in this section as ''the Secretary'') shall award grants to States and Indian Tribes to develop and implement State and Tribal surveys to identify—

(1) the availability of, and patient access to, medical forensic examinations;

(2) the training level of the health care providers who perform medical forensic examinations;

(3) the hospitals or clinics that offer medical forensic examinations and whether each hospital or clinic has full-time, part-time, or on-call coverage;

(4) barriers to medical forensic examinations provided through sexual assault care and services;

(5) billing and reimbursement practices for medical forensic examinations;

(6) State and Tribal requirements, minimum standards, and protocols for training sexual assault examiners for sexual assault forensic examiners and for other personnel involved in medical forensic examinations;

(7) the availability of sexual assault forensic examiner training, the frequency of such training, the providers of such training, the State's or Indian Tribe's role in such training, and the processes or procedures in place for continuing education of such examiners; and

(8) the dedicated Federal and State funding available to support sexual assault forensic examiner training.

(c) Eligibility

To be eligible to receive a grant under this section, a State or Indian Tribe shall submit to the Secretary an application through a competitive process to be determined by the Secretary.

(d) Public dissemination and campaign

(1) Public availability

The results of the surveys conducted under grants awarded under this section shall be published by the Secretary on the website of the Department of Health and Human Services on a biennial basis.

(2) Campaigns

A State or Indian Tribe that receives a grant under this section shall carry out the following activities:

(A) Make the findings of the survey conducted using amounts received under the grant public, including a map showing health care providers who perform medical forensic examinations, based on the findings from the State and Tribal surveys under subsection (b)(3).

(B) Use the findings to develop a strategic action plan to increase the number of trained medical forensic examiners available in the State or Tribal community and create policies to increase survivor access to trained examiners.

(C) Use the findings to develop and implement a public awareness campaign that includes the following:

(i) An online toolkit describing how and where sexual assault survivors can obtain assistance and care, including medical forensic examinations, in the State or Tribal community.

(ii) A model standard response protocol for health care providers to implement upon arrival of a patient seeking care for sexual assault.

(iii) A model sexual assault response team protocol incorporating interdisciplinary community coordination between hospitals, emergency departments, hospital administration, local rape crisis programs, law enforcement, prosecuting attorneys, and other health and human service agencies and stakeholders with respect to delivering survivor-centered sexual assault care and medical forensic examinations.

(iv) A notice of applicable laws prohibiting charging or billing survivors of sexual assault for care and services related to sexual assault.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section $7,000,000 for each of fiscal years 2023 through 2027.

(Pub. L. 117–103, div. W, title V, § 503, Mar. 15, 2022, 136 Stat. 874.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of

div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

NATIONAL REPORT ON SEXUAL ASSAULT SERVICES IN OUR NATION'S HEALTH SYSTEM

Pub. L. 117–103, div. W, title V, §504, Mar. 15, 2022, 136 Stat. 876, provided that:

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Mar. 15, 2022], and annually thereafter, the Agency for Healthcare Research and Quality, in consultation with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office for Victims of Crime of the Department of Justice, the Office on Women's Health of the Department of Health and Human Services, and the Office of Violence Against Women of the Department of Justice (collectively referred to in this section as the 'Agencies'), shall submit to the Secretary of Health and Human Services (referred to in this section as 'the Secretary') a report of existing Federal, Indian Tribe, and State practices relating to medical forensic examinations which may include the findings of the surveys developed under section 503 [42 U.S.C. 280g–4a].

''(b) CORE COMPETENCIES.—In conducting activities under this section, the Agencies shall address sexual assault forensic examination competencies, including—

''(1) providing medical care to sexual assault patients;

''(2) demonstrating the ability to conduct a medical forensic examination, including an evaluation for evidence collection;

''(3) showing compassion and sensitivity towards survivors of sexual assault;

''(4) testifying in Federal, State, local, and Tribal courts; and

''(5) other competencies, as the Agencies determine appropriate.

''(c) PUBLICATION.—The Agency for Healthcare Research and Quality shall establish, maintain, and publish on the website of the Department of Health and Human Services an online public map of availability of sexual assault forensic examinations. Such maps shall clarify if there is full-time, part-time, or on-call coverage.

''(d) REPORT TO CONGRESS.—Not later than 60 days after receiving the report described in subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on Education and Labor [now Committee on Education and the Workforce] of the House of Representatives recommendations for improving sexual assault forensic examination competencies based on the report described in subsection (a).''

[For definition of terms used in section 504 of div. W of Pub. L. 117–103, set out above, see section 12291 Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34].

DEFINITIONS

For definitions of terms used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§ 280g–4b. Expanding access to unified care

(a) Establishment of program

The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a program (referred to in this section as the ''program'') to award grants to eligible entities for the clinical training of sexual assault forensic examiners (including registered nurses, nurse practitioners, nurse midwives, clinical nurse specialists, physician assistants, and physicians) to administer medical forensic examinations and treatments to survivors of sexual assault.

(b) Purpose

The purpose of the program is to enable each grant recipient to expand access to medical forensic examination services by providing new providers with the clinical training necessary to establish and maintain competency in such services and to test the provisions of such services at new facilities in expanded health care settings.

(c) Grants

Under the program, the Secretary shall award 3-year grants to eligible entities that meet the requirements established by the Secretary.

(d) Eligible entities

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

(1) be—

(A) a safety net clinic acting in partnership with a high-volume emergency services provider or a hospital currently providing sexual assault medical forensic examinations performed by sexual assault forensic examiners, that will use grant funds to—

(i) assign rural health care service providers to the high-volume hospitals for clinical practicum hours to qualify such providers as sexual assault forensic examiners; or

(ii) assign practitioners at high-volume hospitals to rural health care services providers to instruct, oversee, and approve clinical practicum hours in the community to be served;

(B) an organization described in section 501(c)(3) of title 26 and exempt from taxation under 501(a) of such title, that provides legal training and technical assistance to Tribal communities and to organizations and agencies serving Indians; or

(C) an Indian Tribe (as defined in section 5304 of title 25); and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of whether the applicant will provide services described in subparagraph (A) or (B) of paragraph (1).

(e) Grant amount

Each grant awarded under this section shall be in an amount not to exceed $400,000 per year. A grant recipient may carry over funds from one fiscal year to the next without obtaining approval from the Secretary.

(f) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2023 through 2027.

(2) Set-aside

Of the amount appropriated under this subsection for a fiscal year, the Secretary shall

reserve 15 percent of such amount for purposes of making grants to entities that are affiliated with Indian Tribes or Tribal organizations (as defined in section 5304 of title 25), or Urban Indian organizations (as defined in section 1603 of title 25). Amounts reserved may be used to support referrals and the delivery of emergency first aid, culturally competent support, and forensic evidence collection training.

(Pub. L. 117–103, div. W, title V, § 506, Mar. 15, 2022, 136 Stat. 878.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

IMPROVING AND STRENGTHENING THE SEXUAL ASSAULT EXAMINER WORKFORCE CLINICAL AND CONTINUING EDUCATION PILOT PROGRAM

Pub. L. 117–103, div. W, title V, § 505, Mar. 15, 2022, 136 Stat. 876, provided that:

''(a) PURPOSE.—It is the purpose of this section to establish a pilot program to develop, test, and implement training and continuing education that expands and supports the availability of medical forensic examination services for survivors of sexual assault.

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Mar. 15, 2022], the Secretary of Health and Human Services (referred to in this section as 'the Secretary') shall establish a National Continuing and Clinical Education Pilot Program for sexual assault forensic examiners, sexual assault nurse examiners, and other individuals who perform medical forensic examinations.

''(2) CONSULTATION.—In establishing such program, the Secretary shall consult with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office for Victims of Crime of the Department of Justice, the Office on Violence Against Women of the Department of Justice, and the Office on Women's Health of the Department of Health and Human Services, and shall solicit input from regional, national, and Tribal organizations with expertise in forensic nursing, rape trauma or crisis counseling, investigating rape and gender violence cases, survivors' advocacy and support, sexual assault prevention education, rural health, and responding to sexual violence in Tribal communities.

''(c) FUNCTIONS.—The pilot program established under subsection (b) shall develop, pilot, implement, and update, as appropriate, continuing and clinical education program modules, webinars, and programs for all hospitals and providers to increase access to medical forensic examination services and address ongoing competency issues in medical forensic examination services, including—

''(1) training and continuing education to help support sexual assault forensic examiners practicing in rural or underserved areas;

''(2) training to help connect sexual assault survivors who are Indian with sexual assault forensic examiners, including through emergency first aid, referrals, culturally competent support, and forensic evidence collection in rural communities;

''(3) replication of successful sexual assault forensic examination programs to help develop and improve the evidence base for medical forensic examinations; and

''(4) training to increase the number of medical professionals who are considered sexual assault forensic examiners based on the recommendations of the National Sexual Assault Forensic Examination Training Standards issued by the Office on Violence Against Women of the Department of Justice.

''(d) ELIGIBILITY TO PARTICIPATE IN PILOT PROGRAMS.—The Secretary shall ensure that medical forensic examination services provided under the pilot program established under subsection (b), and other medical forensic examiner services under the pilot program are provided by health care providers who are also one of the following:

''(1) A physician, including a resident physician.

''(2) A nurse practitioner.

''(3) A nurse midwife.

''(4) A physician assistant.

''(5) A certified nurse specialist.

''(6) A registered nurse.

''(7) A community health practitioner or a community health aide who has completed level III or level IV certification and training requirements.

''(e) NATURE OF TRAINING.—The continuing education program established under this section shall incorporate and reflect current best practices and standards on medical forensic examination services consistent with the purpose of this section.

''(f) AVAILABILITY.—After termination of the pilot program established under subsection (b)(1), the training and continuing education program established under such program shall be available to all sexual assault forensic examiners and other providers employed by, or any individual providing services through, facilities that receive Federal funding.

''(g) EFFECTIVE DATE.—The pilot program established under this section shall terminate on the date that is 2 years after the date of such establishment.

''(h) AUTHORIZATION.—There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2025.''

[For definition of terms used in section 505 of div. W of Pub. L. 117–103, set out above, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34].

DEFINITIONS

For definitions of terms used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§ 280g–4c. Expanding access to forensics for victims of interpersonal violence

(a) Definitions

In this section:

(1) Community health aide; community health practitioner

The terms ''community health aide'' and ''community health practitioner'' have the meanings given such terms for purposes of section 1616*l* of title 25.

(2) Health care provider

The term ''health care provider'' has the meaning given such term by the Secretary, and includes registered nurses, nurse practi-

tioners, nurse midwives, clinical nurse specialists, physician assistants, and physicians.

(3) Indian tribe; Tribal organization

The terms ''Indian Tribe'' and ''Tribal organization'' shall have the meanings given such terms in section 5304 of title 25.

(4) Institution of higher education

The term ''institution of higher education'' has the meaning given such term in section 1001 of title 20.

(5) Interpersonal violence

The term ''interpersonal violence'' means any form of violence that is emotional and trauma-inducing for victims, families of victims, perpetrators, and communities.

(6) Native Hawaiian organization

The term ''Native Hawaiian organization'' has the meaning given such term in section 11711 of this title.

(7) Secretary

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

(8) Trauma-informed care

The term ''trauma-informed care'' means care received by trauma survivors that is culturally competent in accordance with professional standards of practice and accounting for patients' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the patient.

(9) Urban Indian organization

The term ''Urban Indian organization'' has the meaning given such term in section 1603 of title 25.

(b) Demonstration grants for comprehensive forensic training

(1) Establishment of program

The Secretary shall establish a demonstration program to award grants to eligible entities for the clinical training of health care providers to provide generalist forensic services and trauma-informed care to survivors of interpersonal violence of all ages.

(2) Purpose

The purpose of the demonstration program under this subsection is to develop training and curriculum to provide health care providers with the skills to support the provision of forensic assessment and trauma-informed care to individuals, families, and communities that have experienced violence or trauma and to be available to collaborate with members of an inter-professional forensic team.

(3) Term

Grants under this subsection shall be for a term of 5 years.

(4) Eligible entities

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

(A) be an institute of higher education, including a minority serving institution as described in section 1067q of title 20; and

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

(5) Grant amount

Each grant awarded under this subsection shall be in an amount that does not exceed $400,000 per year. A grant recipient may carry over funds from one fiscal year to the next without obtaining approval from the Secretary.

(6) Authorization of appropriations

(A) In general

There is authorized to be appropriated to carry out this subsection $5,000,000 for each of fiscal years 2023 through 2027.

(B) Set-aside

Of the amount appropriated under this paragraph for a fiscal year, the Secretary shall reserve 10 percent for purposes of making grants to support training and curricula that addresses the unique needs of Indian Tribes, Tribal organizations, Urban Indian organizations, and Native Hawaiian organizations. Amounts so reserved may be used to support training, referrals, and the delivery of emergency first aid, culturally competent support, and forensic evidence collection training.

(c) Technical assistance grants and learning collectives

(1) In general

The Secretary shall establish a State and Tribal forensic provider technical resource center to provide technical assistance and support collaboration and best practices for health care providers, community health aides, and community health practitioners to improve the quality of, and increase access to, forensic services for all survivors of interpersonal violence. The Secretary may enter into contracts with national experts for purposes of carrying out this subsection.

(2) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, $2,000,000 for each of fiscal years 2023 through 2027.

(d) National report

Not later than 1 year after March 15, 2022, and annually thereafter, the Office for Victims of Crime of the Department of Justice, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office on Women's Health of the Department of Health and Human Services, and the Office on Violence Against Women of the Department of Justice shall jointly submit to the Secretary a report on the need for, throughout the States, Indian Tribes, and territories—

(1) access to generalist medical forensic services, evidence collection, and documentation that aids in meeting the needs of health care patients and improves future law enforcement investigation and prosecution; and

(2) data for research to support the response to and prevention of interpersonal violence, improved ability of health care providers to

adequately respond to patients who exhibit signs of victimization, and address the unique needs of Tribal communities.

(Pub. L. 117–103, div. W, title V, § 507, Mar. 15, 2022, 136 Stat. 879.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

DEFINITIONS

For definition of ''law enforcement'' and ''State'' as used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§ 280g–5. Public and health care provider education and support services

(a) In general

The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct activities, which may include demonstration projects for the purpose of improving the provision of information on prematurity to health professionals and other health care providers and the public and improving the treatment and outcomes mothers[1] of infants born preterm, and infants born preterm, as appropriate.

(b) Activities

Activities to be carried out under subsection (a) may include the establishment of—

(1) programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of information and education to health professionals, other health care providers, and the public concerning—

(A) the core risk factors for preterm labor and delivery;

(B) evidence-based strategies to prevent preterm birth and associated outcomes;

(C) medically indicated deliveries before full term, and the risks of non-medically indicated deliveries before full term;

(D) the importance of preconception and prenatal care, including—

(i) smoking cessation;

(ii) weight maintenance and good nutrition, including folic acid intake;

(iii) the screening for and the treatment of infections;

(iv) screening for and treatment of substance use disorders;

(v) screening for and treatment of maternal depression;

(vi) maternal immunization; and

(vii) stress management;

(E) treatments and outcomes for premature infants, including late preterm infants; and

(F) the informational needs of families during the stay of an infant in a neonatal intensive care unit.

(2) programs to increase the availability, awareness, and use of pregnancy and post-term information services that provide evidence-based, clinical information through counselors, community outreach efforts, electronic or telephonic communication, or other appropriate means regarding causes associated with prematurity, birth defects, or health risks to a post-term infant, as well as prevention of a future preterm birth;

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

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

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section $1,900,000 for each of fiscal years 2014 through 2018.

(July 1, 1944, ch. 373, title III, § 399Q, as added Pub. L. 109–450, § 4(2), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–55, title I, § 103(b), Nov. 27, 2013, 127 Stat. 642; Pub. L. 115–328, § 3, Dec. 18, 2018, 132 Stat. 4472.)

Editorial Notes

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–328, § 3(1), substituted ''conduct activities, which may include demonstration projects'' for ''conduct demonstration projects'' and ''mothers of infants born preterm, and infants born preterm, as appropriate'' for ''for babies born preterm''.

Subsec. (b). Pub. L. 115–328, § 3(2)(A), struck out ''under the demonstration project'' after ''to be carried out'' in introductory provisions.

Subsec. (b)(1). Pub. L. 115–328, § 3(2)(B)(i), substituted ''programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of'' for ''programs to test and evaluate various strategies to provide'' in introductory provisions.

Subsec. (b)(1)(B). Pub. L. 115–328, § 3(2)(B)(iii), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (b)(1)(C). Pub. L. 115–328, § 3(2)(B)(ii), (iv), redesignated subpar. (B) as (C) and inserted '', and the risks of non-medically indicated deliveries before full term'' before semicolon at end. Former subpar. (C) redesignated (D).

Subsec. (b)(1)(D). Pub. L. 115–328, § 3(2)(B)(ii), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (b)(1)(D)(ii). Pub. L. 115–328, § 3(2)(B)(v)(I), inserted ''intake'' after ''folic acid''.

Subsec. (b)(1)(D)(iv) to (vii). Pub. L. 115–328, § 3(2)(B)(v)(II)–(IV), added cls. (iv) to (vi) and redesignated former cl. (iv) as (vii).

Subsec. (b)(1)(E) to (G). Pub. L. 115–328, § 3(2)(B)(ii), (vi)–(viii), redesignated subpars. (D) to (F) as (E) to (G),

[1] So in original. Probably should be preceded by ''for''.

respectively, and struck out subpar. (G), as redesignated, which read as follows: ''utilization of evidence-based strategies to prevent birth injuries;''.

Subsec. (b)(2). Pub. L. 115–328, §3(2)(C), inserted '', as well as prevention of a future preterm birth'' before semicolon at end.

2013—Subsec. (b)(1). Pub. L. 113–55, §103(b)(1)(A), added subpars. (A) to (F) and struck out former subpars. (A) to (F) which read as follows:

''(A) the signs of preterm labor, updated as new research results become available;

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

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

''(D) smoking cessation education and counseling;

''(E) stress management; and

''(F) appropriate prenatal care;''.

Subsec. (b)(2). Pub. L. 113–55, §103(b)(1)(B), added par. (2) and struck out former par. (2) which read as follows: ''programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;''.

Subsec. (c). Pub. L. 113–55, §103(b)(2), substituted ''$1,900,000 for each of fiscal years 2014 through 2018.'' for ''$5,000,000 for each of fiscal years 2007 through 2011.''

§ 280g–6. Chronic kidney disease initiatives

(a) In general

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) 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.)

Editorial Notes

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.

Executive Documents

EX. ORD. NO. 13879. ADVANCING AMERICAN KIDNEY HEALTH

Ex. Ord. No. 13879, July 10, 2019, 84 F.R. 33817, provided:

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

SECTION 1. *Purpose*. My Administration is dedicated to advancing American kidney health. The state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

SEC. 2. *Policy*. It is the policy of the United States to:

(a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;

(b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and

(c) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

SEC. 3. *Announcing an Awareness Initiative on Kidney and Related Diseases*. Within 120 days of the date of this order [July 10, 2019], the Secretary of Health and Human Services (Secretary) shall launch an awareness initiative at the Department of Health and Human Services (Department) to aid the Secretary's efforts to educate patients and support programs that promote kidney disease awareness. The initiative shall develop proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease; to improve kidney transplantation; and to share information with patients and providers to enhance awareness of the causes and consequences of kidney disease.

SEC. 4. *Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development*. Within 30 days of the date of this order, the Secretary shall select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis. The se-

lected model shall include options for flexible advance payments for nephrologists to better support their management and coordination of care for patients with kidney disease.

SEC. 5. *Payment Model to Increase Home Dialysis and Kidney Transplants.* Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider's attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis and may eliminate the need for dialysis altogether for many patients.

SEC. 6. *Encouraging the Development of an Artificial Kidney.* Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology.

SEC. 7. *Increasing Utilization of Available Organs.* (a) Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.

(b) Within 180 days of the date of this order, the Secretary shall streamline and expedite the process of kidney matching and delivery to reduce the discard rate. Removing process inefficiencies in matching and delivery that result in delayed acceptance by transplant centers will reduce the detrimental effects on organ quality of prolonged time with reduced or cut-off blood supply.

SEC. 8. *Supporting Living Organ Donors.* Within 90 days of the date of this order, the Secretary shall propose a regulation to remove financial barriers to living organ donation. The regulation should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

SEC. 9. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

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

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

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

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

DONALD J. TRUMP.

§ 280g–7. Amyotrophic lateral sclerosis registry

(a) Establishment

(1) In general

Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as ''ALS'') and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) Purpose

It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) Advisory Committee

(1) Establishment

Not later than 180 days after October 8, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ''Advisory Committee''). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations;[1]

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases[2] and

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

(2) Duties

The Advisory Committee may review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) Report

Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) Grants

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

(d) Coordination with State, local, and Federal registries

(1)[3] In general

In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries;

(vi) the National Vital Statistics System; and

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) Definition

For the purposes of this section, the term ''national voluntary health association'' means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

(July 1, 1944, ch. 373, title III, § 399S, formerly § 399R, as added Pub. L. 110–373, § 2, Oct. 8, 2008, 122 Stat. 4047; renumbered § 399S, Pub. L. 111–148, title IV, § 4003(b)(2)(A), Mar. 23, 2010, 124 Stat. 544.)

[1] So in original. Probably should be ''national voluntary health associations;''.

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

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

Editorial Notes

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(1)(A)(ii), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

§ 280g–7a. Surveillance of neurological diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

(b) Research

The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) Content

In carrying out subsection (a), the Secretary—

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the natural history of the diseases;

(B) the prevention of the diseases;

(C) the detection, management, and treatment approaches for the diseases; and

(D) the development of outcomes measures;

(4) may address issues identified during the consultation process under subsection (d); and

(5) initially may address a limited number of neurological diseases.

(d) Consultation

In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases; and

(B) have demonstrated experience in research, care, or patient services;

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

(4) clinicians with expertise in neurological diseases; and

(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) Grants

The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) Coordination with other Federal, State, and local agencies

Subject to subsection (h), the Secretary shall—

(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

(B) to State and local agencies; and

(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(g) Public access

Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

(h) Privacy

The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(i) Reports

(1) Report on information and analyses

Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

(2) Implementation report

Not later than 4 years after December 13, 2016, the Secretary shall submit a report to

the Congress concerning the implementation of this section. Such report shall include information on—

(A) the development and maintenance of the National Neurological Conditions Surveillance System;

(B) the type of information collected and stored in the surveillance system;

(C) the use and availability of such information, including guidelines for such use; and

(D) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) Definition

In this section, the term ''national voluntary health association'' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

(k) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 399S–1, as added Pub. L. 114–255, div. A, title II, § 2061, Dec. 13, 2016, 130 Stat. 1076.)

§ 280g–7b. HHS public-private partnership for rare neurodegenerative diseases

(a) Establishment

Not later than one year after December 23, 2021, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish and implement a Public-Private Partnership for Neurodegenerative Diseases between the National Institutes of Health, the Food and Drug Administration, and one or more eligible entities (to be known and referred to in this section as the ''Partnership'') through cooperative agreements, contracts, or other appropriate mechanisms with such eligible entities, for the purpose of advancing the understanding of neurodegenerative diseases and fostering the development of treatments for amytrophic lateral sclerosis and other rare neurodegenerative diseases. The Partnership shall—

(1) establish partnerships and consortia with other public and private entities and individuals with expertise in amyotrophic lateral sclerosis and other rare neurodegenerative diseases for the purposes described in this subsection;

(2) focus on advancing regulatory science and scientific research that will support and accelerate the development and review of drugs for patients with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(3) foster the development of effective drugs that improve the lives of people that suffer from amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) Eligible entity

In this section, the term ''eligible entity'' means an entity that—

(1) is—

(A) an institution of higher education (as such term is defined in section 1001[1] of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under subsection (a) of such section;

(2) has experienced personnel with clinical and other technical expertise in the field of biomedical sciences and demonstrated connection to the patient population;

(3) demonstrates to the Secretary's satisfaction that the entity is capable of identifying and establishing collaborations between public and private entities and individuals with expertise in neurodegenerative diseases, including patients, in order to facilitate—

(A) development and critical evaluation of tools, methods, and processes—

(i) to characterize neurodegenerative diseases and their natural history;

(ii) to identify molecular targets for neurodegenerative diseases; and

(iii) to increase efficiency, predictability, and productivity of clinical development of therapies, including advancement of rational therapeutic development and establishment of clinical trial networks; and

(B) securing funding for the Partnership from Federal and non-Federal governmental sources, foundations, and private individuals; and

(4) provides an assurance that the entity will not accept funding for a Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Secretary that the results of the project will not be influenced by any source of funding.

(c) Gifts

(1) In general

The Partnership may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of basic research and research associated with phase 3 clinical trials conducted with respect to investigational drugs that are the subjects of expanded access requests under section 360bbb of title 21.

(2) Use

In addition to any amounts appropriated for purposes of carrying out this section, the Partnership may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to paragraph (1).

(Pub. L. 117–79, § 3, Dec. 23, 2021, 135 Stat. 1535.)

Editorial Notes

REFERENCES IN TEXT

Section 1001 of title 20, referred to in subsec. (b)(1)(A), was in the original ''section 1001 of the Higher Edu-

[1] See References in Text note below.

cation Act of 1965'' and was translated as if it had read ''section 101 of the Higher Education Act of 1965'' to reflect the probable intent of Congress. Section 101 of the Higher Education Act of 1965 is classified to section 1001 of Title 20, Education, and defines ''institution of higher education''.

CODIFICATION

Section was enacted as part of the Accelerating Access to Critical Therapies for ALS Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 280g–8. Support for patients receiving a positive diagnosis of Down syndrome or other prenatally or postnatally diagnosed conditions

(a) Definitions

In this section:

(1) Down syndrome

The term ''Down syndrome'' refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) Health care provider

The term ''health care provider'' means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) Postnatally diagnosed condition

The term ''postnatally diagnosed condition'' means any health condition identified during the 12-month period beginning at birth.

(4) Prenatally diagnosed condition

The term ''prenatally diagnosed condition'' means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) Prenatal test

The term ''prenatal test'' means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) Information and support services

(1) In general

The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1)[1] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) Eligible entity

In this subsection, the term ''eligible entity'' means—

(A) a State or a political subdivision of a State;

(B) a consortium of 2 or more States or political subdivisions of States;

(C) a territory;

(D) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(E) any other entity with appropriate expertise in prenatally and postnatally diagnosed conditions (including nationally recognized disability groups), as determined by the Secretary.

(3) Distribution

In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care professional groups and disability advocacy organizations.

(c) Provision of information to providers

(1) In general

A grantee under this section shall make available to health care providers of parents

[1] See References in Text note below.

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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

PURPOSES

Pub. L. 110–374, § 2, Oct. 8, 2008, 122 Stat. 4051, provided that: ''It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

''(1) increase patient referrals to providers of key support services for women who have received a positive diagnosis for Down syndrome, or other prenatally or postnatally diagnosed conditions, as well as to provide up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

''(2) strengthen existing networks of support through the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and other patient and provider outreach programs; and

''(3) ensure that patients receive up-to-date, evidence-based information about the accuracy of the test.''

§ 280g–9. Programs to improve quality of life for persons with paralysis and other physical disabilities

(a) In general

The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') may study the unique health challenges associated with paralysis and other physical disabilities and carry out projects and interventions to improve the quality of life and long-term health status of persons with paralysis and other physical disabilities. The Secretary may carry out such projects directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) may include—

(1) the development of a national paralysis and physical disability quality of life action plan, to promote health and wellness in order to enhance full participation, independent living, self-sufficiency, and equality of opportunity in partnership with voluntary health agencies focused on paralysis and other physical disabilities, to be carried out in coordination with the State-based Disability and Health Program of the Centers for Disease Control and Prevention;

(2) support for programs to disseminate information involving care and rehabilitation options and quality of life grant programs supportive of community-based programs and support systems for persons with paralysis and other physical disabilities;

(3) in collaboration with other centers and national voluntary health agencies, the establishment of a population-based database that may be used for longitudinal and other research on paralysis and other disabling conditions; and

(4) the replication and translation of best practices and the sharing of information across States, as well as the development of comprehensive, unique, and innovative programs, services, and demonstrations within existing State-based disability and health programs of the Centers for Disease Control and Prevention which are designed to support and advance quality of life programs for persons living with paralysis and other physical disabilities focusing on—

(A) caregiver education;

(B) promoting proper nutrition, increasing physical activity, and reducing tobacco use;

(C) education and awareness programs for health care providers;

(D) prevention of secondary complications;

(E) home- and community-based interventions;

(F) coordinating services and removing barriers that prevent full participation and integration into the community; and

(G) recognizing the unique needs of underserved populations.

(c) Grants

The Secretary may award grants in accordance with the following:

(1) To State and local health and disability agencies for the purpose of—

(A) establishing a population-based database that may be used for longitudinal and

other research on paralysis and other disabling conditions;

(B) developing comprehensive paralysis and other physical disability action plans and activities focused on the items listed in subsection (b)(4);

(C) assisting State-based programs in establishing and implementing partnerships and collaborations that maximize the input and support of people with paralysis and other physical disabilities and their constituent organizations;

(D) coordinating paralysis and physical disability activities with existing State-based disability and health programs;

(E) providing education and training opportunities and programs for health professionals and allied caregivers; and

(F) developing, testing, evaluating, and replicating effective intervention programs to maintain or improve health and quality of life.

(2) To private health and disability organizations for the purpose of—

(A) disseminating information to the public;

(B) improving access to services for persons living with paralysis and other physical disabilities and their caregivers;

(C) testing model intervention programs to improve health and quality of life; and

(D) coordinating existing services with State-based disability and health programs.

(d) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate by the agencies of the Department of Health and Human Services.

(e) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $25,000,000 for each of fiscal years 2008 through 2011.

(Pub. L. 111–11, title XIV, §14301, Mar. 30, 2009, 123 Stat. 1454.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

§ 280g–10. Community Preventive Services Task Force

(a) Establishment and purpose

The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the ''Task Force'') to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the ''Guide''), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

(b) Duties

The duties of the Task Force shall include—

(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

(2) at least once during every 5-year period, review[1] interventions and update[1] recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

(3) improved integration with Federal Government health objectives and related target setting for health improvement;

(4) the enhanced dissemination of recommendations;

(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(c) Role of agency

The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

(d) Coordination with Preventive Services Task Force

The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(e) Operation

In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of chapter 10 of title 5.

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

(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; amended Pub. L. 117–286, § 4(a)(230), Dec. 27, 2022, 136 Stat. 4331.)

Editorial Notes

AMENDMENTS

2022—Subsec. (e). Pub. L. 117–286 substituted ''chapter 10 of title 5.'' for ''Appendix 2 of title 5.''

§ 280g–11. Awards to support community health workers and community health

(a) In general

The Secretary shall award grants, contracts, or cooperative agreements to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities by leveraging community health workers, including by addressing ongoing and longer-term community health needs, and by building the capacity of the community health worker workforce. Such grants, contracts, and cooperative agreements shall be awarded in alignment and coordination with existing funding arrangements supporting community health workers.

(b) Use of funds

Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to—

(1) recruit, hire, train, and retain community health workers that reflect the needs of the community;

(2) support community health workers in providing education and outreach, in a community setting, regarding—

(A) health conditions prevalent in—

(i) medically underserved communities (as defined in section 295p of this title), particularly racial and ethnic minority populations; and

(ii) other such at-risk populations or geographic areas that may require additional support during public health emergencies, which may include counties identified by the Secretary using applicable measures developed by the Centers for Disease Control and Prevention or other Federal agencies; and

(B) addressing health disparities, including by—

(i) promoting awareness of services and resources to increase access to health care, mental health and substance use disorder services, child services, technology, housing services, educational services, nutrition services, employment services, and other services; and

(ii) assisting in conducting individual and community needs assessments;

(3) educate community members, including regarding effective strategies to promote healthy behaviors;

(4) educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act [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.];

(5) identify and refer underserved populations to appropriate health care agencies and community-based programs and organizations in order to increase access to quality health care services and to streamline care, including serving as a liaison between communities and health care agencies; and

(6) support community health workers in educating, guiding, or providing home visitation services regarding chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes.

(c) Application

To be eligible to receive an award under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Priority

In making awards under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to serve—

(A) areas with populations that have a high rate of chronic disease, infant mortality, or maternal morbidity and mortality;

(B) low-income populations, including medically underserved populations (as defined in section 254b(b)(3) of this title);

(C) populations residing in health professional shortage areas (as defined in section 254e(a) of this title);

(D) populations residing in maternity care health professional target areas identified under section 254e(k) of this title; or

(E) rural or traditionally underserved populations, including racial and ethnic minority populations or low-income populations;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services, including rural populations and racial and ethnic minority populations;

(3) have documented community activity and experience and established relationships with community health workers in the communities expected to be served by the program;

(4) develop a plan for providing services to the extent practicable, in the language and cultural context most appropriate to individuals expected to be served by the program; and

(5) propose to use evidence-informed or evidence-based practices, as applicable and appropriate.

(e) Collaboration with academic institutions and the one-stop delivery system

The Secretary shall encourage eligible entities receiving funds under this section to collaborate with academic institutions, health professions

schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of title 20), area health education centers under section 294a of this title, and one-stop delivery systems under section 3151 of title 29. Nothing in this section shall be construed to require such collaboration.

(f) Technical assistance

The Secretary may provide to eligible entities that receive awards under subsection (a) technical assistance with respect to planning, development, and operation of community health worker programs authorized or supported under this section.

(g) Dissemination of best practices

Not later than 4 years after December 29, 2022, the Secretary shall, based on activities carried out under this section and in consultation with relevant stakeholders, identify and disseminate evidence-based or evidence-informed practices regarding recruitment and retention of community health workers and paraprofessionals to address ongoing public health and community health needs, and to prepare for, and respond to, future public health emergencies.

(h) Report to Congress

Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report concerning the effectiveness of the program under this section in addressing ongoing public health and community health needs. Such report shall include recommendations regarding any improvements to such program, including recommendations for how to improve recruitment, training, and retention of the community health workforce.

(i) Authorization of appropriations

For purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for each of fiscal years 2023 through 2027.

(j) Definitions

In this section:

(1) Eligible entity

The term ''eligible entity'' means a public or nonprofit private entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization, a public health department, a free health clinic, a hospital, or a Federally-qualified health center ((as[1] defined in section 1861(aa)(4) of the Social Security Act [42 U.S.C. 1395x(aa)(4)]), or a consortium of any such entities.

(2) Indian Tribe; Tribal organization

The terms ''Indian Tribe'' and ''Tribal organization'' have the meanings given the terms ''Indian tribe'' and ''tribal organization'', respectively, in section 5304 of title 25.

(3) Urban Indian organization

The term ''urban Indian organization'' has the meaning given such term in section 1603 of title 25.

(July 1, 1944, ch. 373, title III, § 399V, as added and amended Pub. L. 111–148, title V, § 5313(a), title X, § 10501(c), Mar. 23, 2010, 124 Stat. 633, 994; Pub. L. 113–128, title V, § 512(z)(1), July 22, 2014, 128 Stat. 1716; Pub. L. 117–328, div. FF, title II, § 2222(a), Dec. 29, 2022, 136 Stat. 5744.)

Editorial Notes

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(4), 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

2022—Pub. L. 117–328, § 2222(a)(1), amended section catchline generally. Prior to amendment, section catchline read as follows: ''Grants to promote positive health behaviors and outcomes''.

Subsec. (a). Pub. L. 117–328, § 2222(a)(2), amended subsec. (a) generally. Prior to amendment, text read as follows: ''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.''

Subsec. (b). Pub. L. 117–328, § 2222(a)(3)(A), substituted ''Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded'' for ''Grants awarded'' and struck out ''support community health workers'' after ''used to'' in introductory provisions.

Subsec. (b)(1) to (3). Pub. L. 117–328, § 2222(a)(3)(C), added pars. (1) to (3) and struck out former pars. (1) and (2). Former par. (3) redesignated (4). Prior to amendment, pars. (1) and (2) read as follows:

''(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;''.

Subsec. (b)(4). Pub. L. 117–328, § 2222(a)(3)(D), substituted ''educate'' for ''to educate''.

Pub. L. 117–328, § 2222(a)(3)(B), redesignated par. (3) as (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 117–328, § 2222(a)(3)(E), substituted ''identify'' for ''to identify'', ''health care agencies'' for ''healthcare agencies'', and ''health care services and to streamline care, including serving as a liaison between communities and health care agencies; and'' for ''healthcare services and to eliminate duplicative care; or''.

Pub. L. 117–328, § 2222(a)(3)(B), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 117–328, § 2222(a)(3)(F), substituted ''support community health workers in educating, guiding, or providing'' for ''to educate, guide, and provide'' and ''chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes'' for ''maternal health and prenatal care''.

[1] So in original.

Pub. L. 117–328, § 2222(a)(3)(B), redesignated par. (5) as (6).

Subsec. (c). Pub. L. 117–328, § 2222(a)(4), substituted ''To be eligible to receive an award under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing'' for ''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''.

Subsec. (d). Pub. L. 117–328, § 2222(a)(5)(A), substituted ''making awards'' for ''awarding grants'' in introductory provisions.

Subsec. (d)(1). Pub. L. 117–328, § 2222(a)(5)(B), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''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;''.

Subsec. (d)(2). Pub. L. 117–328, § 2222(a)(5)(C), substituted '', including rural populations and racial and ethnic minority populations;'' for ''; and''.

Subsec. (d)(3). Pub. L. 117–328, § 2222(a)(5)(D), substituted ''and established relationships with community health workers in the communities expected to be served by the program;'' for ''with community health workers.''

Subsec. (d)(4), (5). Pub. L. 117–328, § 2222(a)(5)(E), added pars. (4) and (5).

Subsec. (e). Pub. L. 117–328, § 2222(a)(6), substituted ''eligible entities'' for ''community health worker programs'' and '', health professions schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of such title), area health education centers under section 294a of this title, and one-stop delivery systems under section 3151'' for ''and one-stop delivery systems under section 3151(e)''.

Subsecs. (f) to (i). Pub. L. 117–328, § 2222(a)(7), added subsecs. (f) to (i) and struck out former subsecs. (f) to (i) which read as follows:

''(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.''

Subsec. (j). Pub. L. 117–328, § 2222(a)(7), (8), redesignated subsec. (k) as (j) and struck out former subsec. (j). Prior to amendment, text of subsec. (j) read as follows: ''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.''

Subsec. (j)(1). Pub. L. 117–328, § 2222(a)(9)(C), substituted ''entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization'' for ''entity (including a State or public subdivision of a State'' and ''(as defined in section 1861(aa)(4) of the Social Security Act)'' for ''as defined in section 1861(aa) of the Social Security Act))''.

Pub. L. 117–328, § 2222(a)(9)(A), (B), redesignated par. (3) as (1) and struck out former par. (1) which defined ''community health worker''.

Subsec. (j)(2) to (4). Pub. L. 117–328, § 2222(a)(9)(A), (D), added pars. (2) and (3) and struck out former pars. (2) and (4) which defined ''community setting'' and ''medically underserved community'', respectively. Former par. (3) redesignated (1).

Subsec. (k). Pub. L. 117–328, § 2222(a)(8), redesignated subsec. (k) as (j).

2014—Subsec. (e). Pub. L. 113–128 substituted ''one-stop delivery systems under section 3151(e) of title 29'' for ''one-stop delivery systems under section 2864(c) of title 29''.

2010—Subsec. (b)(4). Pub. L. 111–148, § 10501(c)(1), substituted ''identify and refer'' for ''identify, educate, refer, and enroll''.

Subsec. (k)(1). Pub. L. 111–148, § 10501(c)(2), struck out '', as defined by the Department of Labor as Standard Occupational Classification [21–1094]'' before ''means'' in introductory provisions.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

§ 280g–12. Primary Care Extension Program

(a) Establishment, purpose and definition

(1) In general

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

(2) Purpose

The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as ''Health Extension Agents'').

(3) Definitions

In this section:

(A) Health Extension Agent

The term ''Health Extension Agent'' means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

(B) Primary care provider

The term ''primary care provider'' means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

(b) Grants to establish State Hubs and local Primary Care Extension Agencies

(1) Grants

The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as ''Hubs'').

(2) Composition of Hubs

A Hub established by a State pursuant to paragraph (1)—

(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments that train providers in primary care in 1 or more health professions schools in the State; and

(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1320c–2 of this title, consumer groups, and other appropriate entities.

(c) State and local activities

(1) Hub activities

Hubs established under a grant under subsection (b) shall—

(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);

(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

(2) Local Primary Care Extension Agency activities

(A) Required activities

Primary Care Extension Agencies established by a Hub under paragraph (1) shall—

(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

(B) Discretionary activities

Primary Care Extension Agencies established by a Hub under paragraph (1) may—

(i) provide technical assistance, training, and organizational support for community health teams established under section 256a–1[1] of this title;

(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

(v) participate in other activities, as determined appropriate by the Secretary.

(d) Federal program administration

(1) Grants; types

Grants awarded under subsection (b) shall be—

(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

(2) Applications

To be eligible for a grant under subsection (b), a State or multistate entity shall submit

[1] See References in Text note below.

to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(3) Evaluation

A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

(4) Continuing support

After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

(5) Limitation

A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

(e) Requirements on the Secretary

In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

(f) Authorization of appropriations

To awards grants as provided in subsection (d), there are authorized to be appropriated $120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.

(July 1, 1944, ch. 373, title III, § 399V–1, formerly § 399W, as added, amended, and renumbered § 399V–1, Pub. L. 111–148, title V, § 5405, title X, § 10501(f)(1), (2), Mar. 23, 2010, 124 Stat. 649, 996.)

Editorial Notes

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 research, surveillance, and awareness

(a) In general

The Secretary shall, as appropriate—

(1) enhance and expand research and data collection efforts related to congenital heart disease, including to study and track the epidemiology of congenital heart disease to understand health outcomes for individuals with congenital heart disease across all ages;

(2) conduct activities to improve public awareness of, and education related to, congenital heart disease, including care of individuals with such disease; and

(3) award grants to entities to undertake the activities described in this section.

(b) Activities

(1) In general

The Secretary shall carry out activities, including, as appropriate, through a national cohort study and a nationally-representative, population-based surveillance system, to improve the understanding of the epidemiology of congenital heart disease in all age groups, with particular attention to—

(A) the incidence and prevalence of congenital heart disease in the United States;

(B) causation and risk factors associated with, and natural history of, congenital heart disease;

(C) health care utilization by individuals with congenital heart disease;

(D) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease; and

(E) evidence-based practices related to care and treatment for individuals with congenital heart disease.

(2) Permissible considerations

In carrying out the activities under this section, the Secretary may, as appropriate—

(A) collect data on the health outcomes, including behavioral and mental health outcomes, of a diverse population of individuals of all ages with congenital heart disease, such that analysis of the outcomes will inform evidence-based practices for individuals with congenital heart disease; and

(B) consider health disparities among individuals with congenital heart disease, which may include the consideration of prenatal exposures.

(c) Awareness campaign

The Secretary may carry out awareness and educational activities related to congenital heart disease in individuals of all ages, which may include information for patients, family members, and health care providers, on topics such as the prevalence of such disease, the effect of such disease on individuals of all ages, and the importance of long-term, specialized care for individuals with such disease.

(d) Public access

The Secretary shall ensure that, subject to subsection (e), information collected under this section is made available, as appropriate, to the public, including researchers.

(e) Patient privacy

The Secretary shall ensure that the data and information collected under this section are made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law.

(f) Eligibility for grants

To be eligible to receive a grant under subsection (a)(3), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

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

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2020 through 2024.

(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; amended Pub. L. 115–342, § 2, Dec. 21, 2018, 132 Stat. 5040.)

Editorial Notes

AMENDMENTS

2018—Pub. L. 115–342 amended section generally. Prior to amendment, section related to National Congenital Heart Disease Surveillance System.

§ 280g–14. National diabetes prevention program

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the ''program'') targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) Program activities

The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) Eligible entities

To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based non-profits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

(d) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399V–3, as added Pub. L. 111–148, title X, § 10501(g), Mar. 23, 2010, 124 Stat. 996.)

§ 280g–15. State demonstration programs to evaluate alternatives to current medical tort litigation

(a) In general

The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) Duration

The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) Conditions for demonstration grants

(1) Requirements

Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) Alternative to current tort litigation

Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) Sources of compensation

Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) Scope

(A) In general

Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) Notification of patients

A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) Preference in awarding demonstration grants

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

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

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

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

(d) Application

(1) In general

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

(2) Review panel

(A) In general

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

(B) Composition

(i) Nominations

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

(ii) Appointment

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

(I) Patient advocates.

(II) Health care providers and health care organizations.

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

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) Chairperson

The Comptroller General shall designate a member of the review panel to be the chairperson of the review panel.

(D) Availability of information

The Secretary shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) Information from agencies

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

(e) Reports

(1) By State

Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) By Secretary

The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) Technical assistance

(1) In general

The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) Requirements

Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) Use of common definitions, formats, and data collection infrastructure

States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) Evaluation

(1) In general

The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) Contents

The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to March 23, 2010, any cap on non-economic damages; and

(iii) States that have enacted, prior to March 23, 2010, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no 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 states'[1] authority over or responsibility for their state[1] justice systems.

(July 1, 1944, ch. 373, title III, §399V–4, as added Pub. L. 111–148, title X, §10607, Mar. 23, 2010, 124 Stat. 1009; amended Pub. L. 114–301, §3(d), Dec. 16, 2016, 130 Stat. 1515.)

Editorial Notes

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (h)(1), (2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2016—Subsec. (d)(2)(C). Pub. L. 114–301, §3(d)(1), substituted ''shall designate a member of the review panel to'' for '', or an individual within the Government Accountability Office designated by the Comptroller General, shall''.

Subsec. (d)(2)(D). Pub. L. 114–301, §3(d)(2), substituted ''Secretary'' for ''Comptroller General''.

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

§ 280g–16. Food Safety Integrated Centers of Excellence

(a) In general

Not later than 1 year after January 4, 2011, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the ''Centers of Excellence'') to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

(b) Selection of Centers of Excellence

(1) Eligible entities

To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) Working group

Not later than 180 days after January 4, 2011, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) Additional Centers of Excellence

The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) Activities

Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

(5) training and coordinating State and local personnel;

(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

(d) Report to Congress

Not later than 2 years after January 4, 2011, the Secretary shall submit to Congress a report that—

(1) describes the effectiveness of the Centers of Excellence; and

(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

(e) Authorization of appropriations

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

(f) No duplication of effort

In carrying out activities of the Centers of Excellence or other programs under this section, the Secretary shall not duplicate other Federal foodborne illness response efforts.

(July 1, 1944, ch. 373, title III, § 399V–5, as added Pub. L. 111–353, title II, § 210(b), Jan. 4, 2011, 124 Stat. 3950.)

§ 280g–17. Designation and investigation of potential cancer clusters

(a) Definitions

In this section:

(1) Cancer cluster

The term ''cancer cluster'' means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

(2) Particular cancer

The term ''particular cancer'' means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

(3) Population group

The term ''population group'' means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

(b) Criteria for designation of potential cancer clusters

(1) Development of criteria

The Secretary shall develop criteria for the designation of potential cancer clusters.

(2) Requirements

The criteria developed under paragraph (1) shall consider, as appropriate—

(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

(c) Guidelines for investigation of potential cancer clusters

The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

(1) recommend that investigations of cancer clusters—

(A) use the criteria developed under subsection (b);

(B) use the best available science; and

(C) rely on a weight of the scientific evidence;

(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

(d) Investigation of cancer clusters

(1) Secretary discretion

The Secretary—

(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

(2) Coordination

In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

(3) Biomonitoring

In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

(e) Duties

The Secretary shall—

(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.

(July 1, 1944, ch. 373, title III, § 399V–6, as added Pub. L. 114–182, title I, § 21(b), June 22, 2016, 130 Stat. 510.)

Statutory Notes and Related Subsidiaries

PURPOSES OF TREVOR'S LAW

Pub. L. 114–182, title I, § 21(a), June 22, 2016, 130 Stat. 510, provided that: ''The purposes of this section [enacting this section] are—

''(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

''(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

''(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.''

§ 280g–18. Maternal mental health hotline

(a) In general

The Secretary shall maintain, by grant or contract, a national maternal mental health hotline to provide emotional support, information, brief intervention, and mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and to their families or household members.

(b) Requirements for hotline

The hotline under subsection (a) shall—

(1) be a 24/7 real-time hotline;

(2) provide voice and text support;

(3) be staffed by certified peer specialists, licensed health care professionals, or licensed mental health professionals who are trained on—

(A) maternal mental health and substance use disorder prevention, identification, and intervention; and

(B) providing culturally and linguistically appropriate support; and

(4) provide maternal mental health and substance use disorder assistance and referral services to meet the needs of underserved populations, individuals with disabilities, and family and household members of pregnant or postpartum women at risk of experiencing maternal mental health and substance use disorders.

(c) Additional requirements

In maintaining the hotline under subsection (a), the Secretary shall—

(1) consult with the Domestic Violence Hotline, National Suicide Prevention Lifeline, and Veterans Crisis Line to ensure that pregnant and postpartum women are connected in real-time to the appropriate specialized hotline service, when applicable;

(2) conduct a public awareness campaign for the hotline;

(3) consult with Federal departments and agencies, including the Substance Abuse and Mental Health Services Administration and the Department of Veterans Affairs, to increase awareness regarding the hotline; and

(4) consult with appropriate State, local, and Tribal public health officials, including officials who administer programs that serve low-income pregnant and postpartum individuals.

(d) Annual report

The Secretary shall submit an annual report to the Congress on the hotline under subsection (a) and implementation of this section, including—

(1) an evaluation of the effectiveness of activities conducted or supported under subsection (a);

(2) a directory of entities or organizations to which staff maintaining the hotline funded under this section may make referrals; and

(3) such additional information as the Secretary determines appropriate.

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, § 399V–7, as added Pub. L. 117–328, div. FF, title I, § 1112, Dec. 29, 2022, 136 Stat. 5643.)

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

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

(a) In general

The Secretary, acting though the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote