

sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, § 399L, as added Pub. L. 106-310, div. A, title V, § 501, Oct. 17, 2000, 114 Stat. 1113; amended Pub. L. 108-377, § 3(a), Oct. 30, 2004, 118 Stat. 2203.)

REFERENCES IN TEXT

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

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

PRIOR PROVISIONS

A prior section 399L of act July 1, 1944, was renumbered section 399F and is classified to section 280e-4 of this title.

AMENDMENTS

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

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108-377, § 3(b), Oct. 30, 2004, 118 Stat. 2204, provided that: "The amendments made by this section [amending this section] shall apply only with respect to grants made on or after the date that is 9 months after the date of the enactment of this Act [Oct. 30, 2004]."

FINDINGS OF 2004 AMENDMENT

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

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

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

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

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

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

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

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

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

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

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

"(11) Tragic refusals of schools to permit students to carry their inhalers and auto-injectable epineph-

rine have occurred, some resulting in death and spawning litigation.

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

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

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

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

§ 280g-1. Early detection, diagnosis, and treatment regarding hearing loss in newborns and infants

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

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

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns and infants; prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, and medical interventions for children identified with hearing loss. Early intervention includes referral to and delivery of information and services by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.], which offer programs specifically designed to meet the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children. Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss.

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

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

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

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

(1) Centers for Disease Control and Prevention

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

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

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

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

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

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

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

(2) National Institutes of Health

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

(c) Coordination and collaboration

(1) In general

In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for early intervention services pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of

the Social Security Act [42 U.S.C. 1397aa et seq.] (State Children's Health Insurance Program); title V of the Social Security Act [42 U.S.C. 701 et seq.] (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; consumer groups of and that serve individuals who are deaf and hard-of-hearing and their families; appropriate national medical and other health and education specialty organizations; persons who are deaf and hard-of-hearing and their families; other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing newborns, infants, toddlers, children, and their families; third-party payers and managed care organizations; and related commercial industries.

(2) Policy development

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

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

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

(d) Rule of construction; religious accommodation

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

(e) Definitions

For purposes of this section:

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

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

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

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

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

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

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

(f) Authorization of appropriations

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

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

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

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

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

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

(July 1, 1944, ch. 373, title III, §399M, as added Pub. L. 106-310, div. A, title VII, §702, Oct. 17, 2000, 114 Stat. 1121; amended Pub. L. 111-337, §2, Dec. 22, 2010, 124 Stat. 3588.)

REFERENCES IN TEXT

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

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

AMENDMENTS

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

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

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

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

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

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

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

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

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

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

Pub. L. 111-8, div. F, title II, §224, Mar. 11, 2009, 123 Stat. 784, provided that: “Hereafter, the activities authorized under section 399M of the Public Health Serv-

ice Act [42 U.S.C. 280g-1] shall be known as the ‘James T. Walsh Universal Newborn Hearing Screening Program.’”

PURPOSES

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

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

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

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

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

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

§ 280g-2. Childhood malignancies

(a) In general

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

(b) Certain activities

Activities under subsection (a) of this section include—

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

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

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

(c) Coordination of activities

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

(d) Definition

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

(e) Authorization of appropriations

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

(July 1, 1944, ch. 373, title III, § 399N, as added Pub. L. 106-310, div. A, title XI, § 1101, Oct. 17, 2000, 114 Stat. 1131.)

§ 280g-3. Controlled substance monitoring program

(a) Grants

(1) In general

Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

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

(2) Determination of amount

(A) Minimum amount

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

(B) Additional amounts

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