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, $\S2(2)(C)$, added par. (3). Subsec. (b)(1)(A). Pub. L. 111–337, $\S2(3)$, substituted "hearing loss screening, evaluation, diagnosis, and intervention programs" for "hearing loss screening, evaluation, and intervention programs"

Subsec. (c)(2), (3). Pub. L. $\overline{111}$ -337, $\S2(4)$, substituted "hearing screening, evaluation, diagnosis, and intervention programs" for "hearing screening, evaluation

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

Subsec. (e)(6). Pub. L. 111–337, §2(5)(B), struck out ", after rescreening," after "infants who". Subsec. (f). Pub. L. 111–337, §2(6), substituted "fiscal years 2011 through 2015" for "fiscal year 2002" in pars. (1) to (3).

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

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

PURPOSES

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

"(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 sec-

§ 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

- (1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;
- (2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and
- (3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) Coordination of activities

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

(d) Definition

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

(e) Authorization of appropriations

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

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

§ 280g-3. Controlled substance monitoring program

(a) Grants

(1) In general

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

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

(2) Determination of amount

(A) Minimum amount

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

(B) Additional amounts

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

(3) Term of grants

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

(b) Development of minimum requirements

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

(c) Application approval process

(1) In general

To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

- (A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A) of this section—
 - (i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;
 - (ii) criteria for security for information handling and for the database maintained by the State under subsection (e) of this section generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;
 - (iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;
 - (iv) criteria for meeting the uniform electronic format requirement of subsection (h) of this section;
 - (v) criteria for availability of information and limitation on access to program personnel:
 - (vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;
 - (vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f) of this section:
 - (viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;
 - (ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and
 - (x) assurances of compliance with all other requirements of this section; or
- (B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B) of this section—
- (i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;
- (ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);
- (iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and
- (iv) assurances of compliance with all other requirements of this section or a