

peal by Pub. L. 94-278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

**§ 300b-5. Repealed. Pub. L. 97-35, title XXI, § 2193(b)(4), Aug. 13, 1981, 95 Stat. 827**

Section, act July 1, 1944, ch. 373, title XI, §1106, as added Apr. 22, 1976, Pub. L. 94-278, title IV, §403(a), 90 Stat. 409, related to an annual report to President and Congress on administration of this part.

A prior section 300b-5, act July 1, 1944, ch. 373, title XI, §1106, as added May 16, 1972, Pub. L. 92-294, §3(c), 86 Stat. 139; amended Aug. 29, 1972, Pub. L. 92-414, §4(3), 86 Stat. 652, related to an annual report to President and Congress on administration of this part, prior to repeal by Pub. L. 94-278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

EFFECTIVE DATE OF REPEAL, SAVINGS, AND  
TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to repeal by Pub. L. 97-35, see section 2194 of Pub. L. 97-35, set out as a note under section 701 of this title.

**§ 300b-6. Applied technology**

The Secretary, acting through an identifiable administrative unit, shall—

(1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases;

(2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; and

(3) on the basis of the assessments and surveillance described in paragraph (1), provide technical assistance to States to implement the programs developed under paragraph (2) and train appropriate personnel for such programs.

In carrying out this section, the Secretary may, from funds allotted for use under section 702(a) of this title, make grants to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).

(July 1, 1944, ch. 373, title XI, §1107, as added Pub. L. 95-626, title II, §205(d)(1), Nov. 10, 1978, 92 Stat. 3584; amended Pub. L. 97-35, title XXI, §2193(b)(5), Aug. 13, 1981, 95 Stat. 827.)

AMENDMENTS

1981—Pub. L. 97-35 substituted provisions relating to allotments under section 702(a) of this title for provisions relating to appropriations under section 300b(b) of this title.

EFFECTIVE DATE OF 1981 AMENDMENT, SAVINGS, AND  
TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97-35, see section 2194 of Pub. L. 97-35, set out as a note under section 701 of this title.

**§ 300b-7. Tourette Syndrome**

**(a) In general**

The Secretary shall develop and implement outreach programs to educate the public, health care providers, educators and community based organizations about the etiology, symptoms, diagnosis and treatment of Tourette Syndrome, with a particular emphasis on children with Tourette Syndrome. Such programs may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities.

**(b) Certain activities**

Activities under subsection (a) of this section shall include—

(1) the production and translation of educational materials, including public service announcements;

(2) the development of training material for health care providers, educators and community based organizations; and

(3) outreach efforts directed at the misdiagnosis and underdiagnosis of Tourette Syndrome in children and in minority groups.

**(c) Authorization of appropriations**

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

(July 1, 1944, ch. 373, title XI, §1108, as added Pub. L. 106-310, div. A, title XXIII, §2301, Oct. 17, 2000, 114 Stat. 1157.)

**§ 300b-8. Improved newborn and child screening for heritable disorders**

**(a) Authorization of grant program**

From amounts appropriated under subsection (j), the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the “Administrator”) and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the “Advisory Committee”), shall award grants to eligible entities to enable such entities—

(1) to enhance, improve or expand the ability of State and local public health agencies to provide screening, counseling, or health care services to newborns and children having or at risk for heritable disorders;

(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups; and

(4) to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

**(b) Eligible entity**

In this section, the term “eligible entity” means—

- (1) a State or a political subdivision of a State;
- (2) a consortium of 2 or more States or political subdivisions of States;
- (3) a territory;
- (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or
- (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

**(c) Approval factors**

An application submitted for a grant under subsection (a)(1) shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

**(d) Coordination**

The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section and to coordinate with existing newborn screening activities.

**(e) Limitation**

An eligible entity may not use amounts received under this section to—

- (1) provide cash payments to or on behalf of affected individuals;
- (2) provide inpatient services;
- (3) purchase land or make capital improvements to property; or
- (4) provide for proprietary research or training.

**(f) Voluntary participation**

The participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another Federal or State program.

**(g) Supplement not supplant**

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities of the type described in this section.

**(h) Publication****(1) In general**

An application submitted under subsection (c)(2)<sup>1</sup> of this section shall be made public by the State in such a manner as to facilitate comment from any person, including through

hearings and other methods used to facilitate comments from the public.

**(2) Comments**

Comments received by the State after the publication described in paragraph (1) shall be addressed in the application submitted under subsection (c)(2)<sup>1</sup> of this section.

**(i) Technical assistance**

The Secretary shall provide to entities receiving grants under subsection (a) of this section such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

**(j) Authorization of appropriations**

There are authorized to be appropriated—

(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), \$15,000,000 for fiscal year 2009;<sup>2</sup> \$15,187,500 for fiscal year 2010, \$15,375,000 for fiscal year 2011, \$15,562,500 for fiscal year 2012, and \$15,750,000 for fiscal year 2013; and

(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), \$15,000,000 for fiscal year 2009, \$15,187,500 for fiscal year 2010, \$15,375,000 for fiscal year 2011, \$15,562,500 for fiscal year 2012, and \$15,750,000 for fiscal year 2013.

(July 1, 1944, ch. 373, title XI, §1109, as added Pub. L. 106-310, div. A, title XXVI, §2601, Oct. 17, 2000, 114 Stat. 1164; amended Pub. L. 110-204, §2, Apr. 24, 2008, 122 Stat. 705; Pub. L. 110-237, §1(a)(1), May 27, 2008, 122 Stat. 1556.)

## REFERENCES IN TEXT

Subsection (c)(2) of this section, referred to in subsec. (h)(1), (2), was struck out and a new subsec. (c) added by Pub. L. 110-204, §2(1), Apr. 24, 2008, 122 Stat. 705.

## AMENDMENTS

2008—Subsecs. (a) to (c). Pub. L. 110-204, §2(1), added subsecs. (a) to (c) and struck out former subsecs. (a) to (c) which provided for grants to promote screening, counseling, or health care services to newborns and children having or at risk for heritable disorders, enumerated permissible uses of grants, and set out grant applicants' eligibility requirements.

Subsecs. (d) to (i). Pub. L. 110-204, §2(2), (3), added subsec. (d) and redesignated former subsecs. (d) to (h) as (e) to (i), respectively. Former subsec. (i) redesignated (j).

Subsec. (j). Pub. L. 110-237 added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: “There is authorized to be appropriated—

“(1) to provide grants for the purpose of carrying activities under section (a)(1), \$15,000,000 for fiscal year 2008; \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012; and

“(2) to provide grant for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), \$15,000,000 for fiscal year 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012.”

Pub. L. 110-204, §2(4), added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: “There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.”

<sup>1</sup> See References in Text note below.

<sup>2</sup> So in original. The semicolon probably should be a comma.

Pub. L. 110-204, §2(2), redesignated subsec. (i) as (j).

**§ 300b-9. Evaluating the effectiveness of newborn and child screening programs**

**(a) In general**

The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness of screening, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

**(b) Demonstration programs**

A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

- (1) the effectiveness of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders;
- (2) the effectiveness of screening, counseling, testing or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children; or
- (3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders.

**(c) Eligible entities**

To be eligible to receive a grant under subsection (a) of this section an entity shall be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States.

**(d) Authorization of appropriations**

There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 2009, \$5,062,500 for fiscal year 2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fiscal year 2012, and \$5,250,000 for fiscal year 2013.

(July 1, 1944, ch. 373, title XI, §1110, as added Pub. L. 106-310, div. A, title XXVI, §2601, Oct. 17, 2000, 114 Stat. 1165; amended Pub. L. 110-204, §3, Apr. 24, 2008, 122 Stat. 706; Pub. L. 110-237, §1(a)(2), May 27, 2008, 122 Stat. 1556.)

AMENDMENTS

2008—Subsec. (d). Pub. L. 110-237 substituted “2009, \$5,062,500 for fiscal year 2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fiscal year 2012, and \$5,250,000 for fiscal year 2013.” for “2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.”

Pub. L. 110-204 added subsec. (d).

**§ 300b-10. Advisory Committee on Heritable Disorders in Newborns and Children**

**(a) Establishment**

The Secretary shall establish an advisory committee to be known as the “Advisory Committee on Heritable Disorders in Newborns and Children” (referred to in this section as the “Advisory Committee”).

**(b) Duties**

The Advisory Committee shall—

- (1) provide advice and recommendations to the Secretary concerning grants and projects

awarded or funded under section 300b-8 of this title;

(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 300b-8 of this title;

(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

(4) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

(5) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 300b-8 of this title; and

(6) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders, which may include recommendations, advice, or information dealing with—

(A) follow-up activities, including those necessary to achieve rapid diagnosis in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

(B) implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;

(C) diagnostic and other technology used in screening;

(D) the availability and reporting of testing for conditions for which there is no existing treatment;

(E) conditions not included in the recommended uniform screening panel that are treatable with Food and Drug Administration-approved products or other safe and effective treatments, as determined by scientific evidence and peer review;

(F) minimum standards and related policies and procedures used by State newborn screening programs, such as language and terminology used by State newborn screening programs to include standardization of case definitions and names of disorders for which newborn screening tests are performed;

(G) quality assurance, oversight, and evaluation of State newborn screening programs, including ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results;

(H) public and provider awareness and education;

(I) the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs;