

(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."

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,

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

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

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;

(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders; and

(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases.

**(c) Membership**

**(1) In general**

The Secretary shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

**(2) Required members**

The Secretary shall appoint to the Advisory Committee under paragraph (1)—

(A) the Administrator of the Health Resources and Services Administration;

(B) the Director of the Centers for Disease Control and Prevention;

(C) the Director of the National Institutes of Health;

(D) the Director of the Agency for Healthcare Research and Quality;

(E) the Commissioner of the Food and Drug Administration;

(F) medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(G) individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;

(H) members of the public having special expertise about or concern with heritable disorders; and