

assistance as may be necessary to ensure the quality of programs conducted under this section.

(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; Pub. L. 113-240, §2, Dec. 18, 2014, 128 Stat. 2851.)

Editorial Notes

AMENDMENTS

2014—Subsec. (a). Pub. L. 113-240, §2(1)(A), in introductory provisions, substituted “section 300b-16 of this title” for “subsection (j)” and “and taking into consideration the expertise of the Advisory Committee” for “and in consultation with the Advisory Committee”.

Subsec. (a)(2). Pub. L. 113-240, §2(1)(B), amended par. (2) generally. Prior to amendment, par. (2) read as follows: “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;”.

Subsec. (a)(4). Pub. L. 113-240, §2(1)(D)(i), substituted “followup and treatment” for “treatment”.

Subsec. (a)(5). Pub. L. 113-240, §2(1)(C), (D)(ii), (E), added par. (5).

Subsec. (c). Pub. L. 113-240, §2(2), substituted “application for a grant under this section” for “application submitted for a grant under subsection (a)(1)”.

Subsec. (h). Pub. L. 113-240, §2(3), substituted “application for a grant under this section” for “application submitted under subsection (c)(2) of this section” in pars. (1) and (2).

Subsec. (j). Pub. L. 113-240, §2(4), struck out subsec. (j) which authorized appropriations for fiscal years 2009 to 2013 to provide grants for carrying out activities under subsec. (a).

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 and followup programs

(a) In general

The Secretary shall award grants to eligible entities to provide for the conduct of demonstra-

tion programs to evaluate the effectiveness, including with respect to timeliness, of screening, followup, 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, treatment, counseling, testing, followup, or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders, including, as appropriate, through the assessment of health and development outcomes for such children through adolescence;

(2) the effectiveness of screening, treatment, counseling, testing, followup, or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children in a timely manner;

(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(4) methods that may be identified to improve quality in the diagnosis, treatment, and disease management of heritable disorders based on gaps in services or care; or

(5) methods or best practices by which the eligible entities described in section 300b-8 of this title can achieve in a timely manner—

(A) collection, delivery, receipt, and screening of newborn screening specimens; and

(B) diagnosis of heritable disorders in newborns.

(c) Eligible entities

To be eligible to receive a grant under subsection (a) 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.

(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; Pub. L. 113-240, §3, Dec. 18, 2014, 128 Stat. 2852.)

Editorial Notes

AMENDMENTS

2014—Pub. L. 113-240, §3(1), inserted “and followup” after “child screening” in section catchline.

Subsec. (a). Pub. L. 113-240, §3(2), substituted “, including with respect to timeliness, of screening, followup,” for “of screening,”.

Subsec. (b)(1). Pub. L. 113-240, §3(3)(A), substituted “treatment, counseling, testing, followup,” for “counseling, testing” and inserted before semicolon at end “, including, as appropriate, through the assessment of health and development outcomes for such children through adolescence”.

Subsec. (b)(2). Pub. L. 113-240, §3(3)(B)(i), (ii), substituted “treatment, counseling, testing, followup,” for “counseling, testing” and inserted “in a timely manner” after “in newborns and children”.

Subsec. (b)(4), (5). Pub. L. 113-240, §3(3)(B)(iii)-(D), added pars. (4) and (5).

Subsec. (d). Pub. L. 113-240, §3(4), struck out subsec. (d). Text read as follows: “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.”

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) provide technical assistance, as appropriate, to individuals and organizations regarding the submission of nominations to the uniform screening panel, including prior to the submission of such nominations;

(5) take appropriate steps, at its discretion, to prepare for the review of nominations prior to their submission, including for conditions for which a screening method has been validated but other nomination criteria are not yet met, in order to facilitate timely action by the Advisory Committee once such submission has been received by the Committee;

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

(7) 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

(8) 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 best practices in rapid

diagnosis and appropriate treatment 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, including information on cost and incidence;

(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;

(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; and

(L) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and followup.

(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;