

“(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 demonstration 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.)

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