''(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

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;

(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

(I) representatives from such Federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary, to fulfill the duties of the Advisory Committee, as established under subsection (b).

(d) Decision on recommendations

(1) In general

Not later than 120 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation. If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.

(2) Determinations to be made public

The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

(3) Deadline for review

For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory

Committee referred the nominated condition to the condition review workgroup.

(e) Annual report

Not later than 3 years after April 24, 2008, and each fiscal year thereafter, the Advisory Committee shall—

(1) publish a report on peer-reviewed newborn screening guidelines, including follow-up and treatment, in the United States;

(2) submit such report to the appropriate committees of Congress, the Secretary, the Interagency Coordinating Committee established under section 300b–13 of this title, and the State departments of health; and

(3) disseminate such report on as wide a basis as practicable, including through posting on the internet clearinghouse established under section 300b–11 of this title.

(f) Meetings

The Advisory Committee shall meet at least 4 times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

(g) Continuation of operation of Committee

(1) In general

Notwithstanding section 14 of the Federal Advisory Committee Act, the Advisory Committee shall continue to operate through the end of fiscal year 2019.

(2) Continuation if not reauthorized

If at the end of fiscal year 2019 the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of the Federal Advisory Committee Act, an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act.

(July 1, 1944, ch. 373, title XI, §1111, as added Pub. L. 106–310, div. A, title XXVI, §2601, Oct. 17, 2000, 114 Stat. 1166; amended Pub. L. 110–204, §4, Apr. 24, 2008, 122 Stat. 706; Pub. L. 110–237, §1(a)(3), (b)(2), May 27, 2008, 122 Stat. 1556, 1557; Pub. L. 113–240, §4, Dec. 18, 2014, 128 Stat. 2853.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (g), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2014—Subsec. (b)(4), (5). Pub. L. 113–240, §4(1)(B), added pars. (4) and (5). Former pars. (4) and (5) redesignated (6) and (7), respectively.

Subsec. (b)(6). Pub. L. 113–240, §4(1)(A), (C), redesignated par. (4) as (6) and inserted '', including the cost'' after ''public health impact''. Former par. (6) redesignated (8).

Subsec. (b)(7). Pub. L. 113–240, §4(1)(A), redesignated par. (5) as (7).

Subsec. (b)(8). Pub. L. 113–240, §4(1)(A), redesignated par. (6) as (8).

Subsec. (b)(8)(A). Pub. L. 113–240, §4(1)(D)(i), substituted ''achieve best practices in rapid diagnosis and appropriate treatment'' for ''achieve rapid diagnosis''.

Subsec. (b)(8)(D). Pub. L. 113–240, §4(1)(D)(ii), inserted '', including information on cost and incidence'' before semicolon at end.

Subsec. (b)(8)(L). Pub. L. 113–240, §4(1)(D)(iii)–(v), added subpar. (L).

Subsec. (d)(1). Pub. L. 113–240, §4(2)(A), substituted ''120 days'' for ''180 days'' and inserted at end ''If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.''

Subsec. (d)(2). Pub. L. 113–240, §4(2)(B), (C), redesignated par. (3) as (2) and struck out former par. (2). Prior to amendment, text of par. (2) read as follows: ''The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on April 24, 2008, by not later than 180 days after April 24, 2008.''

Subsec. (d)(3). Pub. L. 113–240, §4(2)(D), added par. (3). Former par. (3) redesignated (2).

Subsec. (f). Pub. L. 113–240, §4(4), added subsec. (f). Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 113–240, §4(3), (5), redesignated subsec. (f) as (g) and amended it generally. Prior to amendment, text read as follows: ''Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on April 24, 2008.''

Subsec. (h). Pub. L. 113–240, §4(3), (6), redesignated subsec. (g) as (h) and struck it out. Prior to amendment, text read as follows: ''There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.''

2008—Subsec. (b)(3) to (5). Pub. L. 110–204, §4(1)(B), (C), added pars. (3) to (5). Former par. (3) redesignated (6).

Subsec. (b)(6). Pub. L. 110–204, §4(1)(A), (D), redesignated par. (3) as (6), substituted '', which may include recommendations, advice, or information dealing with—'' for period at end, and added subpars. (A) to (K).

Subsec. (c)(2)(E) to (I). Pub. L. 110–204, §4(2), as amended by Pub. L. 110–237, §1(b)(2), added subpars. (E) and (G) and redesignated former subpars. (E), (F), and (G) as (F), (H), and (I), respectively.

Subsec. (d). Pub. L. 110–204, §4(3), added subsec. (d).

Subsec. (d)(2). Pub. L. 110–237, §1(a)(3)(A), made technical amendment to reference in original act which appears in text as the first reference to April 24, 2008.

Subsecs. (e), (f). Pub. L. 110–237, §1(a)(3)(B), (C), made technical amendment to references in original act which appear in text as references to April 24, 2008.

Pub. L. 110–204, §4(3), added subsecs. (e) and (f).

Subsec. (g). Pub. L. 110–237, §1(a)(3)(D), substituted ''2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.'' for ''2008, $1,012,500 for fiscal year 2009, $1,025,000 for fiscal year 2010, $1,037,500 for fiscal year 2011, and $1,050,000 for fiscal year 2012.''

Pub. L. 110–204, §4(3), added subsec. (g).

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§ 300b–11. Clearinghouse of newborn screening information

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the ''Administrator''), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

(1) enable parents and family members of newborns, health professionals, industry representatives, and other members of the public to increase their awareness, knowledge, and understanding of newborn screening;

(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families;

(3) maintain current information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 300b–10 of this title;

(4) maintain current information on the number of conditions for which screening is conducted in each State; and

(5) disseminate available evidence-based guidelines related to diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.

(b) Internet availability

The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

(1) is available on the Internet;

(2) includes an interactive forum;

(3) is updated on a regular basis, but not less than quarterly; and

(4) provides—

(A) links to Government-sponsored, nonprofit, and other Internet websites of laboratories that have demonstrated expertise in newborn screening that supply research-based information on newborn screening tests currently available throughout the United States;

(B) information about newborn conditions and screening services available in each State from laboratories certified under subpart 2 of part F of subchapter II, including information about supplemental screening that is available but not required, in the State where the infant is born;

(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;

(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Reauthorization Act of 2014; and

(E) other relevant information as determined appropriate by the Secretary.

(c) Nonduplication

In carrying out activities under this section, the Secretary shall ensure that such activities minimize duplication and supplement, not supplant, existing information sharing efforts.

(July 1, 1944, ch. 373, title XI, § 1112, as added Pub. L. 110–204, § 5, Apr. 24, 2008, 122 Stat. 708; amended Pub. L. 110–237, § 1(a)(4), May 27, 2008, 122 Stat. 1557; Pub. L. 113–240, § 5, Dec. 18, 2014, 128 Stat. 2854.)

REFERENCES IN TEXT

The Newborn Screening Saves Lives Reauthorization Act of 2014, referred to in subsec. (b)(4)(D), is Pub. L. 113–240, Dec. 18, 2014, 128 Stat. 2851. For complete classification of this Act to the Code, see Short Title of 2014 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2014—Subsec. (a)(3). Pub. L. 113–240, § 5(1)(B)(i), substituted ''information'' for ''data''.

Subsec. (a)(4), (5). Pub. L. 113–240, § 5(1)(A), (B)(ii), (C), added pars. (4) and (5).

Subsec. (b)(4)(D). Pub. L. 113–240, § 5(2), substituted ''Newborn Screening Saves Lives Reauthorization Act of 2014'' for ''Newborn Screening Saves Lives Act of 2008''.

Subsec. (c). Pub. L. 113–240, § 5(3), substituted ''carrying out activities'' for ''developing the clearinghouse'' and ''activities minimize duplication and supplement, not supplant'' for ''clearinghouse minimizes duplication and supplements, not supplants''.

Subsec. (d). Pub. L. 113–240, § 5(4), struck out subsec. (d). Text read as follows: ''There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.''

2008—Subsec. (b)(4)(D). Pub. L. 110–237, § 1(a)(4)(A), substituted ''2008'' for ''2007''.

Subsec. (d). Pub. L. 110–237, § 1(a)(4)(B), substituted ''2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.'' for ''2008, $2,531,250 for fiscal year 2009, $2,562,500 for fiscal year 2010, $2,593,750 for fiscal year 2011, and $2,625,000 for fiscal year 2012.''

§ 300b–12. Laboratory quality and surveillance

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 300b–10 of this title, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, timeliness for processing such tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

(b) Surveillance activities

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders