Effective: December 18, 2014

United States Code Annotated Currentness
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter IX. Genetic Diseases, Hemophilia Programs, and Sudden Infant Death Syndrome (Refs & Annos)
Part A. Genetic Diseases (Refs & Annos)

§ 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 in-formation 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 follow-up.

(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) of this section.

(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.

(h) Repealed. Pub.L. 113-240, § 4(6), Dec. 18, 2014, 128 Stat. 2854