THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

Advisory Committee on Heritable Disorders in Newborns and Children

Authority

The Advisory Committee on Heritable Disorders in Newborns and Children (Committee) is being re-established under the Public Health Service Act (PHS), Title XI, § 1111 (42 U.S.C. 300b-10). The Committee also is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

Objective and Scope of Activities

The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of Health and Human Services (HHS) for the development of policies and priorities that will enhance the ability of the State and local health agencies to provide for such screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders.

Description of Duties

The Committee shall:

(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded pursuant to 42 U.S.C. Sec. 300b-8;

(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants pursuant to 42 U.S.C. Sec. 300b-8;

(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 pursuant to 42 U.S.C. Sec. 300b-8; 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.

Agency or Official to Whom the Committee Reports

The Committee reports to the Secretary of HHS, or her delegate.

Support

Coordination, management, and operational services shall be provided by the Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA).

Estimated Annual Operating Costs and Staff Years

The estimated annual operating cost for the Committee, including compensation and travel expenses for members but excluding staff support, is $112,151. The estimated annual person year(s) of staff support required is 1.85 FTE, at an annual cost of $272,049. The estimated annual costs for future fiscal years are subject to the availability of appropriations.

Designated Federal Official

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Official (DFO) to attend each Committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will draft by-laws and operating procedures, approve and assist in the preparation of all meeting agendas, call all Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the Secretary or her delegate. The DFO and/or his/her delegate shall be present at all meetings of the full committee and subcommittees for the Committee.

Estimated Number and Frequency of Meetings

Meetings shall be held at least four times a year, as deemed necessary by the DFO or delegate, in consultation with the Chair.

Duration

The Committee shall operate during the 5-year time period set forth in PHS, Title XI, § 1111 (g)(1) (42 U.S.C. 300b-10(g)(1)), through the end of fiscal year 2019.

Termination

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

Membership and Designation

The Committee shall be comprised of an estimated number of 15 members appointed by the Secretary or his/her delegate. All members of the federal government shall be ex-officio members. All other members shall be Special Government Employees. Membership will be composed of the following members:

1. The Administrator of the Health Resource and Services Administration;
2. The Director of the Centers for Disease Control and Prevention;
3. The Director of the National Institutes of Health;
4. The Director of the Agency for Healthcare Research and Quality; and
5. The Commissioner of the Food and Drug Administration - or their delegates. Other members shall include:
6. Medical, technical, public health or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders;
7. Experts in ethics and heritable disorders who have worked and published material in the area of newborn screening;
8. Members from the public sector, having special expertise about or concern with heritable disorders, and
9. 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.

Subcommittees

HRSA or the DFO has the authority to create subcommittees composed of members and nonmembers of the full committee. The subcommittees must report back to the full Committee and shall not provide advice or work products directly to the Agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and

will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the Committee, established subcommittees, and other workgroups of the Committee, shall be managed in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

MAY 7 2015

Approved:

/s/

MAY 0 7 2015

Date

Sylvia M. Burwell