



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) was established under Section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b-10, as amended in the Newborn Screening Saves Lives Act of 2008 (Act). The Committee 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 to the Secretary about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders.

Description of Duties

As part of its general duties, the Committee shall establish by-laws to specify its operating procedures. The Committee shall review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and shall engage in the activities delineated under Section 1111 of the PHS Act as amended (42 U.S.C. 300b-10). In addition, activities carried out under Sections 1112-1114 and 1116 are undertaken in consultation with the Committee.

Not later than three years after the date of enactment of the Act, and each fiscal year thereafter, the 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, and the State departments of health; and (3) disseminate such report including through posting on the internet clearinghouse.

Agency or Official to Whom the Committee Reports

The Committee provides advice to the Secretary of Health and Human Services (HHS).

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 in fiscal year (FY) 2009, including contracts and compensation and travel expenses for members is \$641,550. The estimated annual FY 2009 full-time equivalent is 1.00 at an estimated annual cost of \$190,805. The estimated annual costs for future fiscal years are subject to the availability of appropriations.

Designated Federal Officer

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (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 approve and prepare all meeting agendas, call all of the 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 official to whom the Committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held at least twice a year or more often as deemed necessary by the DFO or designee in consultation with the Chair.

Duration

The Committee shall operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008 (April 24, 2008).

Termination

Notwithstanding section 14 of the FACA (5 U.S.C. App), the Committee shall continue to operate during the 5 year period beginning on April 24, 2008.

Membership and Designation

The Committee structure shall not exceed 15 voting members appointed by the Secretary or his/her designee, including the Chair, Ex-officio members and Special Government Employees. The ex-officio members shall include the Administrator of HRSA; the Directors of the Centers for Disease Control and Prevention, the National Institutes of Health, and the Agency for Healthcare Research and Quality; and the Commissioner of the Food and Drug Administration - or their designees. The Chair and other voting members shall be (1) 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; (2) experts in ethics and infectious diseases who have worked and published material in the area of newborn screening; (3) and members from the public sector who have expertise about or concerning heritable disorders.

The Committee may also include nonvoting liaisons or 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 Committee. In addition, the Committee is encouraged to work closely with other relevant HHS entities that focus on reviewing scientific evidence and making recommendations on clinical preventive services.

Subcommittees

Subcommittees composed of members and nonmembers of the parent committee may be established with the approval of the Secretary, HHS or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the Committee, established subcommittees, or other subgroups 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

FEB 12 2009

Approved:

02/12/2009

Date


Acting Secretary