

CHARTER

Advisory Committee on Heritable Disorders in Newborns and Children

1. Advisory Committee's Official Designation: The Committee shall be known as the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).
2. Authority: ACHDNC is authorized by the Public Health Service (PHS) Act, Titles XI § 1111 (42 U.S.C. § 300b-10) and II § 222 (42 U.S.C. § 217a). ACHDNC will fulfill the functions undertaken by the former, congressionally established Advisory Committee on Heritable Disorders in Newborns and Children, under the PHS Act, Title XI § 1111 (42 U.S.C. § 300b-10). The ACHDNC is also governed by the provisions of the Federal Advisory Committee Act (5 U.S.C. 10) as amended.
3. Objectives and Scope of Activities: ACHDNC advises the Secretary of Health and Human Services (HHS) about aspects of newborn and childhood screening for heritable disorders and technical information for the development of policies and priorities that will enhance the ability of 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. ACHDNC will review and report regularly on newborn and childhood screening practices; recommend improvements in newborn and childhood screening programs and practices, including follow-up activities; and fulfill the requirements stated in the authorizing legislation.
4. Description of Duties: ACHDNC shall:
 - (1) Provide advice and recommendations to the Secretary of HHS (Secretary) concerning grants and projects awarded or funded pursuant to 42 U.S.C. § 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. § 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 recommended 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, 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. § 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.

As part of its general duties, the ACHDNC follows approved by-laws.

5. Agency or Federal Officer Receiving the Advisory Committee's Advice/Recommendations: ACHDNC provides advice and recommendations to the Secretary.
6. Support: Management and support services for ACHDNC are provided by the Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA).
7. Estimated Annual Operating Costs and Staff Years: The estimated annual cost for operating ACHDNC, including compensation and travel expenses for members but excluding staff support, is \$1,694,626. Estimated staff support required is 1.8 FTE years at an estimated annual cost of \$312,016.
8. Designated Federal Officer (DFO): A full-time federal employee, appointed in accordance with agency procedure, will serve as the DFO and ensure that all procedures are within applicable statutory, regulatory, and HHS directives and policy. The DFO approves and prepares all meeting agendas, calls all ACHDNC or subcommittee meetings, attends all ACHDNC and subcommittee meetings, adjourns any meeting when adjournment has been determined to be in the public interest, and chairs meetings when directed to do so by the Secretary or Administrator of HRSA. In the event the appointed DFO is unavailable, a temporary acting DFO will be appointed to fulfill the responsibilities.
9. Estimated Number and Frequency of Meetings: ACHDNC shall meet approximately four times per year as deemed necessary by the DFO, in consultation with the Committee Chair. Each meeting must be called or approved by the DFO. Quorum is defined as a majority of the appointed members. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act of 1972 (5 U.S.C. 10). Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

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10. Duration: Continuing.
11. Termination: Unless renewed by appropriate action prior to its expiration, ACHDNC will terminate 2 years from the date the charter is filed.
12. Membership: ACHDNC shall be composed of the following:
- (1) Up to 10 Special Government Employees appointed by the Secretary shall include:
 - (A) 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;
 - (B) Individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;
 - (C) Members of the public having special expertise about, or concern with, heritable disorders (e.g., parents of children with heritable disorders, individuals with lived experience associated with heritable disorders); and
 - (D) 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.
 - (2) ACHDNC also will have the following five ex-officio members (or their delegated designees):
 - (A) Administrator of HRSA;
 - (B) Director of the Centers for Disease Control and Prevention;
 - (C) Director of the National Institutes of Health;
 - (D) Director of the Agency for Healthcare Research and Quality; and
 - (E) Commissioner of the Food and Drug Administration.

The 10 members appointed by the Secretary will serve for a term of up to 4 years and may serve after the expiration of their term until their successors have taken office. The 10 members appointed by the Secretary who are not officers or employees of the federal government shall serve as Special Government Employees. The ex-officio members shall be regular government employees and serve on ACHDNC without compensation in addition to that received in their regular public employment. In appointing such members, the Secretary will ensure that the total membership of ACHDNC is no more than 15 members and that the total membership is an odd number.

- 13. Subcommittees: Standing and ad hoc subcommittees, composed of members of ACHDNC, may be established with the approval of the Secretary, the HRSA Administrator, or designee to perform specific functions within ACHDNC’s jurisdiction. Subcommittees must report back to the parent advisory committee, and do not provide advice or work products directly to HHS or HRSA. HHS’ Committee Management Officer will be notified upon the establishment of each subcommittee and will be provided information on the subcommittee’s name, membership, function, and estimated frequency of meetings.

- 14. Recordkeeping: Records of ACHDNC, subcommittees, working groups, and other subgroups of the advisory committee shall be handled in accordance with General Records Schedule 6.2, 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.

- 15. Filing Date: November 10, 2024

Approved:

October 29, 2024
Date

_____/s/ Carole Johnson_____
Carole Johnson
Administrator