



CHARTER AMENDMENT

ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

1. 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 re-established under the Public Health Service (PHS) Act, Title XI § 1111 (42 U.S.C. § 300b-10) and II § 222 (42 U.S.C. § 217a). ACHDNC will fulfill the functions previously undertaken by the former Advisory Committee on Heritable Disorders in Newborns and Children, established 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 (FACA) of 1972 (5 U.S.C. Appendix 2), as amended.
3. Objective and Scope of Activities: The ACHDNC advises the Secretary of Health and Human Services (HHS) 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. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, as well as fulfill the list of requirements stated in the original authorizing legislation.
4. Description of Duties: The ACHDNC shall:
 - (1) Provide advice and recommendations to the Secretary of HHS concerning grants and projects awarded or funded pursuant to 42 U.S.C. § 300b-8;
 - (2) Provide technical information to the Secretary of HHS 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 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. § 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 will approve by-laws.

5. Agency or Official to Whom the Committee Reports: The ACHDNC provides advice and recommendations to the Secretary of HHS.
6. Support: Management and support service 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 operating cost for the ACHDNC, including compensation and travel expenses for members but excluding staff support, is \$145,744. The estimated annual person year(s) of staff support required is 1.8 FTE, at an annual cost of \$276,861. The estimated annual costs for future fiscal years are subject to the availability of appropriations.
8. Designated Federal Official: A full-time or permanent part-time federal employee, appointed in accordance with agency procedure, will serve as the Designated Federal Official (DFO) and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO approves and prepares all meeting agendas, calls all Advisory Committee or subcommittee meetings, attends all Advisory Committee and subcommittee meetings, adjourns any meeting when the DFO determines adjournment to be in the public interest, and chairs meetings when directed to do so by the Secretary. In the event the appointed DFO is unavailable, a temporary DFO will be appointed to fulfill the responsibilities.

9. Estimated Number and Frequency of Meetings: The ACHDNC shall meet approximately four times per year as deemed necessary by the DFO, in consultation with the Committee Chair. 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 FACA, as amended (5 U.S.C. App.). 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.
10. Duration: Continuing.
11. Termination: Unless renewed by appropriate action prior to its expiration, the ACHDNC will terminate 2 years from the date the charter is filed.
12. Membership and Designation: The ACHDNC consists of up to 15 members, currently including 10 Special Government Employees and 5 federal ex-officio members appointed by the Secretary for a term of up to 4 years, and shall include:
 - (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 heritable disorders who have worked and published material in the area of newborn screening;
 - (3) Members from the public sector having special expertise about or concern with heritable disorders; and
 - (4) Representatives from such federal agencies, public health constituencies, and medical professional societies (as determined to be necessary by the Secretary of HHS) to fulfill the duties of the Committee.

In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number. The ACHDNC will have the following ex-officio members or their designees from these agencies:

- (1) Administrator of HRSA;
 - (2) Director of the Centers for Disease Control and Prevention;
 - (3) Director of the National Institutes of Health;
 - (4) Director of the Agency for Healthcare Research and Quality; and
 - (5) Commissioner of the Food and Drug Administration.
13. Subcommittees of the ACHDNC: Standing and ad hoc subcommittees, composed of members of the parent committee, may be established with the approval of the Secretary or designee to perform specific functions within the ACHDNC's jurisdiction. Subcommittees must report back to the parent Advisory Committee and do not provide advice or work products directly to the Department or HRSA. The Department's 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 the Advisory Committee, formally and informally established subcommittees, or 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, 2020

16. Date of Amendment: July 30, 2021

Approved:

July 29, 2021
Date

/S/ Diana Espinosa
Diana Espinosa
Acting Administrator