



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with section 1111(g) of the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Thursday, May 13, 2021, and Friday, May 14, 2021. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Thursday, May 13, 2021, from 10:00 AM to 3:00 PM Eastern Time (ET) and Friday, May 14, 2021, from 10:00 AM to 3:00 PM ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at <https://www.achdncmeetings.org/registration/> by 12:00 PM ET on May 12, 2021. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality

in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the May 13-14, 2021, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

- (1) Mucopolysaccharidosis type II (MPS II) nomination summary;
- (2) Possible Committee vote on whether to move MPS II forward to a full evidence review;
- (3) Two oral public comment sessions: One session will be open to any newborn screening related topic. The other public comment period will specifically address the Committee's review of the evidence review process (e.g., nomination form, consumer-friendly guidance materials, review of conditions on the RUSP). Please note, if you wish to register to submit oral public comments on the review of the Committee's evidence review process we request that you also submit a written version of your remarks;
- (4) Committee discussion of Continuity of Operations Planning and COVID-19; and,

(5) Newborn screening data sources.

The agenda for this meeting does not include any plans for recommending a condition for inclusion in the RUSP. However, as noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (MPS II) to full evidence review, which may lead to such a recommendation at a future time. Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website previously listed.

As noted above, members of the public will have the opportunity to provide comments. Public participants providing general oral comments may submit written statements in advance of the scheduled meeting. We specifically request that public participants providing oral comment on the review of the Committee's evidence review process also submit a written version of their remarks. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 10:00 AM ET on Monday, May 10, 2021.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

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