

² Up to 30 states and/or territories will be asked to complete a follow-up survey.

³ Up to two conditions may be reviewed per year.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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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 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, August 12, 2021, and Friday, August 13, 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, August 12, 2021, from 10:00 a.m. to 2:15 p.m. Eastern Time (ET) and Friday, August 13, 2021, from 10:00 a.m. to 2:00 p.m. 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 the deadline of 12:00 p.m. ET on August 11, 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 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 one year from the Secretary's adoption of the condition for screening.

During the August 12-13, 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) Overview of the Committee's review of its evidence-review processes and proposed updates,
- (2) A presentation on phase one of the mucopolysaccharidosis type II evidence review,
- (3) Guanidinoacetate methyltransferase (GAMT) deficiency nomination summary,
- (4) Possible Committee vote on whether to move GAMT deficiency forward to a full evidence review,
- (5) Committee discussion on emerging issues for newborn screening,
- (6) A panel presentation on national registries followed by Committee discussion,
- (7) A panel presentation on emerging issues facing the newborn screening

workforce followed by Committee discussion, and

(8) Public comments on any newborn screening related topic.

The public is also encouraged to provide public comment on the proposed updates to the Committee's evidence review processes. For reference, a summary of questions for public consideration is on the ACHDNC website. We request that public participants providing oral comments on the review of the Committee's evidence review process also submit a written version of their remarks.

The agenda for this meeting does not include any vote or decision to recommend a condition for inclusion in the Recommended Uniform Screening Panel. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (GAMT deficiency) 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 available on the ACHDNC website listed above.

As previously noted, 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. 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 a.m. ET on Monday, August 9, 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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