

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

Dated: January 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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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.

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, February 10, 2022, and Friday, February 11, 2022. 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, February 10, 2022, from 10:00 a.m.–3:00 p.m. Eastern Time (ET) and Friday, February 11, 2022, from 10 a.m.–2:30 p.m. ET.

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

Please visit the ACHDNC website for information on registration: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. The deadline for registration is 12:00 p.m. ET on February 9, 2022. 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, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (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 on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA 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 non-grandfathered 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 February 10–11, 2022 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) Final evidence-based review report on the Mucopolysaccharidosis type II (MPS II) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding MPS II to the RUSP.

(2) A presentation on phase two of the evidence-based review for Guanidinoacetate methyltransferase (GAMT) deficiency.

(3) An update on the Krabbe disease condition nomination.

(4) A possible vote on whether to move Krabbe disease forward to full evidence-based review.

(5) Overview of ACHDNC consumer-friendly resources.

(6) A presentation on healthy equity in newborn screening.

The agenda for this meeting includes a potential vote which may lead to a decision to recommend a nominated condition (MPS II) to the RUSP. As

noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence-based review, and will hear presentations on the evidence-based review for Guanidinoacetate methyltransferase deficiency, any of which may lead to a recommendation to add or not add a condition/conditions to the RUSP 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 listed above.

Members of the public also will have the opportunity to provide comments. Public participants providing 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. Subject to change: Members of the public registered to submit oral public comments on MPS II are tentatively scheduled to provide their statements on Thursday, February 10, 2022. Members of the public registered to provide statements on all other newborn screening related topics are tentatively scheduled for Friday, February 11, 2022. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, February 4, 2022.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Publication of the Trusted Exchange Framework and Common Agreement

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice fulfills an obligation under the Public Health Service Act (PHSA), which requires the