BILLING CODE: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children;

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: May 9, 2016, 9:00 a.m. to 5:00 p.m. (Meeting time is tentative.)

May 10, 2016, 9:00 a.m. to 3:00 p.m. (Meeting time is tentative.)

Place: Webcast and In-Person

Fishers Lane Conference Center

Terrace Level

5635 Fishers Lane

Rockville, MD 20852

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webcast. Whether attending in-person or via webcast, all participants must register for the meeting. The registration link will be made available at http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/. The registration deadline is Friday, April 29, 2016, 11:59 PM Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, title XI, section 1111 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113-240), was established to advise the Secretary of the Department of Health and Human Services about 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. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The Committee will hear presentations and discussions on topics including newborn screening long-term follow-up, the Newborn Sequencing in Genomic Medicine and Public Health projects, screening for lysosomal storage disorders, and prenatal education regarding newborn screening bloodspots. The Committee will also review draft reports from the Pilot Study and Cost Analysis workgroups and hear updates from the Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training Tentatively, the Committee is expected to review and/or vote on whether or not the nominated

condition Guanidinoacetate Methyltransferase Deficiency should be referred for a full evidence-based review. This vote does not involve a proposed addition of a condition to the Recommended Uniform Screening Panel. The meeting agenda will be available two (2) days prior to the meeting on the Committee's website: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Registration information will be on the Committee website at http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders. The registration deadline for public comments is of Friday April 29, 2016, 11:59 p.m. (Eastern Time). Written comments must be received by the deadline of Friday April 29, 2016, 11:59 p.m. (Eastern Time) in order to be included in the May meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below at least 10 days prior to the meeting. For additional information or questions on public comments, please contact Alaina

Harris, Maternal and Child Health Bureau, Health Resources and Services Administration; phone: (301) 443-0721; or email: aharris@hrsa.gov.

Contact Person: Anyone interested in obtaining other relevant information should contact Alaina Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W66, 5600 Fishers Lane, Rockville, Maryland 20857; phone: (301) 443-0721; or email: aharris@hrsa.gov.

More information on the Advisory Committee is available at http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.

Jackie Painter,

Director, Division of the Executive Secretariat.

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