



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Service Administration**

**Advisory Committee on Heritable Disorders in Newborns and Children**

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

**ACTION:** Notice of Meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

**DATES:** Thursday, February 8, 2018, from 9:30 a.m. to 5:00 p.m. and Friday, February 9, 2018, from 9:30 a.m. to 3:00 p.m. ET (meeting times are tentative).

**ADDRESSES:** The address for the meeting is 5600 Fishers Lane, 5<sup>th</sup> Floor Pavilion, Rockville, MD 20857. Participants may also access the meeting through Webcast. Advanced registration is required. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. ET on February 5, 2018. Instructions on how to access the meeting via Webcast will be provided upon registration.

Please note that the 5600 Fishers Lane building requires security screening on entry. Visitors must provide a driver's license, passport, or other form of government-issued photo identification or they cannot enter the facility. Non-US Citizens planning to attend in person will need to provide additional information to HRSA by January 24, 2018, 12:00 p.m. Eastern Time. Please see contact information below.

**FOR FURTHER INFORMATION CONTACT:** Anyone requesting information regarding the ACHDNC should contact Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three ways: 1) send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; 2) call 301-443-3999; or 3) send an email to: AFerrero@hrsa.gov.

**SUPPLEMENTARY INFORMATION:** The ACHDNC provides advice to the Secretary of HHS 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. In addition, ACHDNC's recommendations regarding inclusion of additional conditions and inherited disorders for screening which have been adopted by the Secretary are then included in the Recommended Uniform Screening Panel (RUSP). Conditions listed on the RUSP constitute part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13. Under this provision, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible 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.

Information about the ACHDNC is available on the following website:

<https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

The meeting agenda will include a final evidence-based review report on the spinal muscular atrophy (SMA) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding SMA to the RUSP. ACHDNC members will also hear presentations on states' activities to achieve newborn screening timeliness goals. An overview of cutoff determinations and risk assessment methods used for dried bloodspot newborn screening will also be given. The Committee expects to vote on whether to support a guidance document on cutoff determinations and risk assessment methods. Finally, the ACHDNC members will hear updates from the Laboratory Standards and Procedures workgroup; the Follow-up and Treatment workgroup, including a presentation of the final draft of a report on Quality Measures in Newborn Screening; and the Education and Training workgroup, including a presentation of the final draft of a Communication Guide for relaying Newborn Screening results.

HRSA will post the agenda two days prior to the meeting on the Committee's website:

<https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. Please note that agenda items are subject to changes as priorities dictate.

Members of the public will have the opportunity to provide comments and may submit written comments in advance of the meeting. All comments are part of the official Committee record.

To submit written comments or request time for an oral comment at the meeting, please register

online by 12:00 p.m. ET on January 31, 2018, at <http://www.achdncmeetings.org/>. To accommodate all individuals who have registered and requested time for oral comments, the allocated time for comments may be limited. The ACHDNC may ask individuals associated with groups, or individuals who plan to provide comments on similar topics, to combine their comments and present them through a single representative. Audiovisual presentations are not permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (i.e., parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Ann Ferrero using the address and phone number above at least 10 days prior to the meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

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