

Advisory Committee on Heritable Disorders in Newborns and Children May 9 - 10, 2018



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ACHDNC Business

- **Welcome**
- **Roll Call**
- **Vote - November Minutes**
- **Vote – February Minutes**
- **New Organization Representatives**
- **Committee Business**
- **Today's Meeting Topics**

ROLL CALL

NOVEMBER 2017 MEETING MINUTES VOTE

FEBRUARY 2018 MEETING MINUTES VOTE

THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS:

**NEW ORGANIZATIONAL REPRESENTATIVE:
JED MILLER, MD, MPH**

**OUTGOING ORGANIZATIONAL REPRESENTATIVE:
KATE TULLIS, PHD**

SOCIETY FOR INHERITED METABOLIC DISORDERS:

**NEW ORGANIZATIONAL REPRESENTATIVE:
SHAWN E. MCCANDLESS, MD**

**OUTGOING ORGANIZATIONAL REPRESENTATIVE:
CAROL GREENE, MD**

COMMITTEE BUSINESS

- **COMMITTEE CORRESPONDANCE**
 - SMA Recommendation
- **CALL FOR NEW MEMBERS**
- **CALL FOR ORGANIZATION REPRESENTATIVES**

COMMITTEE BUSINESS

■ THE EVIDENCE REVIEW PROCESS

- Conduction of the evidence review
- Presentation of the evidence and its review
- Assessment of the decision-matrix effectiveness
- What would a process look like for potentially nominating conditions for removal from the RUSP?

COMMITTEE BUSINESS

- **ASSESSING THE TIME TO IMPLEMENTATION OF CONDITIONS ADDED TO THE RUSP**
 - **Were the estimated timeframes accurate?**
 - **What barriers and challenges were encountered?**
 - **What have been the clinical and public health implications?**

NEXT MEETINGS

- **August 2, 2018 (Webinar)**
- **November 1-2, 2018**
- **Meeting dates have been set up through 2020 and can be found on the Committee's website:
<https://www.hrsa.gov/advisory-committees/heritable-disorders/meetings/index.html>**

MEETING TOPICS

WEDNESDAY, MAY 9, 2018

- **Newborn Screening Education and Training Tools**
- **CDC Quality Assurance and Harmonization Activities**
- **Cutoffs and Risk Assessment in Newborn Screening**
- **Timeliness in Newborn Screening: Lessons Learned from States**
- **Assessing the Public Health System Impact of Adding Conditions to the RUSP**

MEETING TOPICS

THURSDAY, MAY 10, 2018

- **Update on Newborn Screening Pilot Studies for Guanidinoacetate Methyltransferase (GAMT) Deficiency**
- **Public comment**
- **Workgroup Updates**
- **Public Health System Impact Assessment - Survey Tools**

Advisory Committee on Heritable Disorders in Newborns and Children

- **Established under the Public Health Service Act, Title XI, § 1109 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240)**
- **All federal committees governed by the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App. 2), and by 41 C.F.R. Parts 101-6 and 102-3**
- **FACA sets the standards for the establishment, utilization, and management of Federal Advisory committees**

Ethics and COIs

- **Advisory to the Secretary of HHS**
- **Inquiries about the Committee**
- **When to recuse:**
 - **In all matters likely to affect the financial interests of any organization with which you serve as an officer, director, trustee, or general partner unless you are also an employee of the organization or unless you have received a waiver from HHS authorizing them to participate.**

Meeting Participation

- All Committee meetings are open to the public.
- If the public wish to participate in the discussion, the procedures for doing so are published in the Federal Register and/or announced at the opening of a meeting.
- The Notice of Meeting in Federal Register indicated two options for public comment:
 - Request to make oral comments at the meeting
 - Public Comments are scheduled for **Thursday, May 10th from 10:15am – 10:45am**
 - Submit written statements
 - Committee members receive copies of all written statements submitted
- Any further public participation will be solely at the discretion of the Chair and DFO

5600 Fishers Lane Building Info

- **Visitors only have access the Pavilion, cafeteria, restrooms, and meeting rooms.**
 - **All areas of the facility are restricted and require an escort by a HRSA staff member. No exceptions.**
- **If you need to leave and re-enter, you will be required to go through security screening again and will require a HRSA escort to meet you at Security to escort you in the building.**
 - **15 minutes prior to and after the lunch break ends a HRSA escort will be at the main entrance for those who need to leave and return.**
 - **For other re-entry needs, please notify a HRSA staff member or a registration team member.**

5600 Fishers Lane Building Info

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- **Please do not take any items with you if there is an evacuation, as it would delay your reentry into the building.**