BILLING CODE: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary 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 (Public Law 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

NAME: Discretionary Advisory Committee on Heritable Disorders in Newborns and Children

DATES AND TIMES: September 11, 2014, 9:30 a.m. to 4:30 p.m.
September 12, 2014, 9:00 a.m. to 3:00 p.m.

PLACE: Webinar and In-Person
National Institute of Health
Natcher Conference Center (Building 45)
9000 Rockville Pike
Bethesda, MD 20892

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 webinar. Whether attending in-person or via webinar, all participants must register for the meeting at https://www.blsmeetings.net/ACHDNCSeptember2014/. The registration deadline is Thursday, August 28, 2014, 11:59 PM Eastern Time. If there are technical problems gaining access to the website, please contact Anthony Rodell, Director of Client Relations, at arodell@SeamonCorporation.com.

PURPOSE: The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees, 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/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel 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 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 1 year from the Secretary's adoption of the condition for screening.

AGENDA: The meeting will include: (1) presentations from the Newborn Screening Translational Research Network and the Region 4 Genetics Collaborative on long-term follow up activities as they relate to newborn screening; (2) an update on the Mucopolysaccharidosis 1 (MPS-1) condition review; (3) presentations and discussion on national activities addressing timeliness of newborn screening; (4) a presentation on the Region 4 Stork (R4S) database that facilitates the clinical validation of cutoff target ranges for metabolic disorders by tandem mass spectrometry; (5) a presentation of the National Committee on Vital and Health Statistics' recommendations regarding the adoption of electronic standards for public health information exchanges; (6) a presentation on the Clinical Laboratory Improvement Amendments (CLIA) Program and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule – Patients' Access to Test Reports; and (7) updates from the Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training subcommittees. Tentatively, the Committee is expected to review and/or vote on recommendations to the Secretary regarding educational activities that emphasize succinylacetone as the best marker for Tyrosinemia Type I screening, a condition on the Recommended Uniform Screening Panel (RUSP). This tentative vote does not involve any proposed addition of a condition to the RUSP.

Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials are located on the Advisory Committee's website at 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 September 11, 2014. Advance registration is required to present oral comments and/or submit written comments at https://www.blsmeetings.net/ACHDNCSeptember2014/. The registration deadline is Thursday, August 28, 2014, 11:59 PM Eastern Time. Written comments must be received by the deadline in order to be included in the September 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. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: lvasquez@hrsa.gov.

FOR MORE INFORMATION CONTACT: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: dsarkar@hrsa.gov.

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

Dated: August 1, 2014

Jackie Painter

Acting Director, Division of Policy and Information Coordination

[FR Doc. 2014-18737 Filed 08/07/2014 at 8:45 am; Publication Date: 08/08/2014]