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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 (Pub. L. 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: May 29, 2014, 9:30 a.m. to 4:30 p.m.
May 30, 2014, 9:30 a.m. to 3:00 p.m.

Place: Webinar and In-Person
U.S. Pharmacopeial Convention (USP) Headquarters
12601 Twinbrook Parkway
Rockville, Maryland 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 webinar. Whether attending in-person or via webinar, all participants must register for the meeting at

<https://www.blsm meetings.net/ACHDNCMay2014>. The registration deadline is Friday, May 2, 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. Note: 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 (HRSA). 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) A discussion and vote on a systematic approach to evaluate the impact of adding newborn screening conditions on state public health systems; (2) a presentation on the impact of the rapid implementation of electronic health records on the Early Hearing Detection and Intervention State programs; (3) a discussion on a potential national infrastructure to conduct research on population-based screening; (4) a presentation on the impact of new CPT codes for molecular diagnostics on laboratories; and (5) updates from the Committee's Laboratory Standards and Procedures, Follow-up and Treatment, and Education

and Training subcommittees. Tentatively, the Committee is expected to review and/or vote on a systematic approach to evaluate the impact of adding newborn screening conditions on state public health systems. This tentative vote does not involve any proposed addition of a condition to the Recommended Uniform Screening Panel.

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. Public comment periods are tentatively scheduled for both May 29 and May 30, 2014. Advance registration is required to present oral comments and/or submit written comments at <https://www.blsm meetings.net/ACHDNCMay2014>. The registration deadline is Friday, May 2, 2014, 11:59 p.m. Eastern Time. Written comments must be received by the deadline 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. 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 Further 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: April 3, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

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