

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's 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. 2), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times:

May 17, 2012, 8:30 a.m. to 5 p.m.

May 18, 2012, 8:30 a.m. to 2:30 p.m.

Place: Hilton Alexandria Old Town Hotel, 1767 King Street, Alexandria, VA 22314.

Status: The meeting will be open to the public, but seating will be limited by the space available. Participants are asked to register for the meeting by going to the registration Web site at <http://altarum.cvent.com/sachdncmay2012>. The registration deadline is Tuesday, May 15, 2012. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, May 11, 2012. If there are technical problems gaining access to the registration Web site, please contact Maureen Ball, Meetings Coordinator, at conferences@altarum.org.

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (the Advisory Committee), as authorized by Public Law 106-310, which added section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b-10, was established by Congress to advise the Secretary of the Department of Health and Human Services in connection with 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. The Advisory Committee's recommendations regarding additional conditions/inherited disorders for screening that are adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP), which forms a 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 provided for in the comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market these are known as policy years) beginning on or after the date that is one year from the Secretary's adoption of the screening. The Advisory Committee also provides advice and recommendations concerning grants and projects authorized

under section 1109 of the Public Health Service Act (42 U.S.C. 300b-8).

Agenda: The meeting will include: (1) Updates on the policies and procedures of the Advisory Committee; (2) presentation on the newborn screening case definitions project; (3) discussion and prioritization of plans and projects for the standing subcommittees; (4) updates from the Nomination and Prioritization Workgroup and the Condition Review Workgroup; (5) reports on medical foods, medical home and carrier screening; and (6) presentations on the continued work and reports of the Advisory Committee's subcommittees: Laboratory Standards and Procedures; Follow-up and Treatment; and Education and Training. Tentatively, the Advisory Committee is expected to review and/or vote on the following items (none of which involve proposed addition of conditions to the RUSP): (1) Priorities for the subcommittees; (2) whether to refer the MPS I condition nomination package and the Pompe condition nomination package to the Condition Review Workgroup for further evaluation; (3) Condition Review Process Report; (3) Medical Home Manuscript; (4) Medical Foods Manuscript; and (5) NBS Awareness Campaign Strategy Report.

Proposed agenda items are subject to change as priorities dictate. The agenda, Committee Roster and Charter, presentations, and meeting materials can be found at the homepage of the Advisory Committee's Web site at <http://www.hrsa.gov/heritabledisorderscommittee/>.

Public Comments: Members of the public can submit written comments and/or present oral comments during the public comment periods of the meeting. All comments, whether oral or written, are part of the official Committee record and will be available for public inspection and copying. All written and oral comments should contain the name, address, telephone number, and professional or business affiliation of the author. Those individuals who want to make oral comments must note this as part of the online registration process by 5 p.m. EDT, Tuesday, May 15, 2012 at <http://altarum.cvent.com/sachdncmay2012>. Pre-registration is required in order to present oral comments. Presentations will be limited to five to ten minutes depending on the number of presenters. Oral comments will be heard on May 17, 2012. Individuals who are associated with groups having similar interests are requested to combine their comments and present them through a single representative. To ensure that all pre-registered individuals who wish to make oral comments have the opportunity to share their comments, no audiovisual presentations are permitted. Written comments should be sent or emailed by Tuesday, May 15, 2012 to Maureen Ball (conferences@altarum.org), Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street NW., Suite 700, Washington, DC 20036. Comments may also be faxed (202-785-3083). If you have additional questions regarding the submission of comments, please contact Ms. Ball at 202-828-5100.

Contact Person: Anyone interested in obtaining other relevant information should

contact or write to Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: 301-443-1080; email: dsarkar@hrsa.gov. More information on the Advisory Committee is available at <http://mchb.hrsa.gov/heritabledisorderscommittee>.

Dated: April 10, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

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

Name: Advisory Council on Blood Stem Cell Transplantation.

Date and Times: May 9, 2012, 8 a.m. to 4:30 p.m.

Place: Georgetown University Hotel and Conference Center, 3800 Reservoir Road NW., Washington, DC 20057.

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109-129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended), the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) advises the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program.

Agenda: The Council will hear reports from five ACBSCT Work Groups: (1) Realizing the Potential of Cord Blood, (2) Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, (3) Cord Blood Thawing and Washing, (4) Access to Transplantation, and (5) Advancing Hematopoietic Stem Cell Transplantation for Hemoglobinopathies. The Council also will hear presentations and discussions on topics including: Collection of information on Cellular Therapies; Adverse Event Reporting; and Unmet Need. Agenda items are subject to change as priorities dictate.

After the presentations and Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the timeframe in which to cover the agenda topics, public comments will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting