

manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-18907 Filed 7-31-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: August 27, 2015, 9 a.m. to 5 p.m.

August 28, 2015, 10 a.m. to 1 p.m.

Place: Webinar and In-Person, National Institutes of Health, 5635 Fishers Lane, Rockville, Maryland 20857

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. Please register at <https://www.blsmmeetings.net/ACHDNCAugust2015>. The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113-240), 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/heritable disorders for screening that have been adopted by the Secretary are

included in the Recommended Uniform Screening Panel (RUSP) 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 and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A final evidence review report on the Adrenoleukodystrophy (ALD) condition nomination for inclusion in the RUSP; (2) a presentation by the Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) on their activities and the NewSTEPs data repository, a centralized and secure database designed for state newborn screening programs to explore data to meet program needs; (3) updates on the implementation of screening for Severe Combined Immunodeficiency, Critical Congenital Heart Disease, and Pompe Disease; and (4) updates from workgroups focused on cost analysis in newborn screening, newborn screening timeliness, and pilot studies for evidence-based reviews of conditions. Following the final evidence review report on ALD, the Committee also is expected to vote on whether or not to recommend to the Secretary the addition of ALD 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 will be located on the Advisory Committee's Web site 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 both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Please register at <https://www.blsmmeetings.net/ACHDNCAugust2015>. The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time. Written comments must be received by the deadline in order to be included in the August 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.

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, 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>.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015-18953 Filed 7-31-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: HIV Molecular Biology.

Date: August 7, 2015.

Time: 1:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, prasads@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: July 28, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-18875 Filed 7-31-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Science Moving TowArds Research Translation and Therapy (SMARTT), Coordinating Center—Program Extension.

Date: August 25, 2015.

Time: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301-435-0725, kristen.page@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Science Moving TowArds Research Translation and Therapy (SMARTT), Biologics Production Facility (PF), Program Extension.

Date: August 25, 2015.

Time: 3:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301-435-0725, kristen.page@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Science Moving TowArds Research Translation and Therapy (SMARTT), Non-Biological Production Facility (PF), Program Extension.

Date: August 25, 2015.

Time: 4:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301-435-0725, kristen.page@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel, Science Moving TowArds Research Translation and Therapy (SMARTT), Pharmacology and Toxicology, Program Extension.

Date: August 25, 2015.

Time: 4:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301-435-0725, kristen.page@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 28, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-18874 Filed 7-31-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.
ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://www.samhsa.gov/workplace>.

FOR FURTHER INFORMATION CONTACT:

Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7-1051, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and