

who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on November 10, 2014.

Dated: September 17, 2014.

James J. Berger,

Designated Federal Officer and Senior Advisor for Blood and Tissue Safety Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIA)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates: 8:30 a.m.–5:00 p.m.,
November 5, 2014; 8:30 a.m.–12:00 p.m.,
November 6, 2014.

Place: CDC, Century Center, 2500 Century Parkway NE., Room 1200/1201, Atlanta, Georgia 30345.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. This meeting will also be Webcast, please see information below.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

Matters for Discussion: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include the FDA Draft Guidance on

Laboratory Developed Tests; CLIA-waived testing, including the process and criteria for waiver approval; a report from the workgroup charged with providing input to CLIA regarding the acceptability and application of virtual cross-matching in lieu of serologic cross-matching for transplantation; and issues related to laboratory biosafety in the United States.

Agenda items are subject to change as priorities dictate.

Webcast: The meeting will also be Webcast. Persons interested in viewing the Webcast can access information at: <http://www.cdc.gov/cliac/default.aspx>

Online Registration Required: All people attending the CLIA meeting in-person are required to register for the meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for international registrants. Register at <http://www.cdc.gov/cliac/default.aspx> by scrolling down and clicking the link under "Meeting Registration" and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than October 29, 2014 for U.S. registrants and October 22, 2014 for international registrants.

Providing Oral or Written Comments: It is the policy of CLIA to accept written public comments and provide a brief period for oral public comments whenever possible.

Oral Comments: In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least one week prior to the meeting date.

Written Comments: For individuals or groups unable to attend the meeting, CLIA accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below, and will be included in the meeting's Summary Report.

Availability of Meeting Materials: To support the green initiatives of the federal government, the CLIA meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIA Web site on the day of the meeting for materials. Note: If using a mobile device to access the materials, please verify that the device's browser is able to download the files from the CDC's Web site before the meeting. http://www.cdc.gov/cliac/cliac_meeting_all_documents.aspx. Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An internet connection, power source and limited hard copies may be available at the meeting location, but cannot be guaranteed.

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice

Standards Branch, Division of Laboratory Science and Standards, Laboratory Science, Policy and Practice Program Office, Office of Surveillance, Epidemiology and Laboratory Services, CDC, 1600 Clifton Road NE., Mailstop F-11, Atlanta, Georgia 30329-4018; telephone (404) 498-2741; fax (404) 498-2210; or via email at NAnderson@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The Centers for Disease Control and Prevention (CDC) Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review, Epi-Centers for the Prevention of Healthcare-Associated Infections, Antimicrobial Resistance and Adverse Events, Funding Opportunity Announcement (FOA) CK11-0010401SUPP14, held an initial review of applications on June 3, 2014. Due to administrative oversight, a notice was not published in the **Federal Register**.

A notice should have published prior to May 16, 2014 according to the 15 day notice requirement of the Federal Advisory Committee Act (FACA) <http://intranet.cdc.gov/maso/cmppa/pdfs/faca.pdf> and the GSA Final Rule http://www.gsa.gov/graphics/ogp/FACAFinalRule_R2E-cNZ_0Z5RDZ-i34K-pR.pdf.

The intent of 15 day prior notice is to advise the public of scheduled meetings open to the public. The meeting of June 3, 2014 was a closed meeting, having met the standard for exemptions to open meeting requirements due to the personal and/or proprietary information included in grant applications. Public participation was not impacted as a result of the notice not getting published.

Contact Person for More Information: Catherine Ramadei, Acting Chief, Federal Advisory Committee Management Branch, Management