BILLING CODE: 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Meeting: Clinical Laboratory Improvement Advisory Committee**

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 committee meeting.

TIMES AND DATES:

8:30 a.m. – 5 p.m., November 18, 2015

8:30 a.m. – 12 p.m., November 19, 2015

PLACE: CDC, 2500 Century Center Boulevard, Rooms 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 laboratory information exchange (interoperability); noninvasive prenatal testing; CLIA waiver guidance; the Institute of Medicine (IOM) report "Improving Diagnosis in Health Care;" and FDA guidance for laboratory developed tests.

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://cdclabtraining.adobeconnect.com/novcliac/

ONLINE REGISTRATION REQUIRED: All people attending the CLIAC 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://wwwn.cdc.gov/cliac/Meetings/MeetingDetails.aspx#. Register by scrolling down and clicking the "**Register for this Meeting**" button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than

November 13, 2015 for U.S. registrants and November 8, 2015 for international registrants.

PROVIDING ORAL OR WRITTEN COMMENTS: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments on agenda items 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, CLIAC 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, to include the original signature of the submitter, should be provided to the contact person at the mailing or email address 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 CLIAC 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 CLIAC website on the day of the meeting for materials:

http://wwwn.cdc.gov/cliac/cliac_meeting_all_documents.aspx.

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 website before the meeting.

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 Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop F-11, Atlanta, Georgia 30329-4018; telephone (404) 498-2741; or via e-mail 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 CDC and the Agency for Toxic Substances and Disease Registry.

**Catherine Ramadei,**

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*Centers for Disease Control and Prevention.*

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