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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention,

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 meeting of the aforementioned committee:

TIMES AND DATES:

8:30 a.m. – 4:30 p.m., March 5, 2014

8:30 a.m. – 12:00 p.m., March 6, 2014

PLACE: CDC, 1600 Clifton Road, N.E., Tom Harkin Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30333. This meeting will also be Webcast, please see information below.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

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 TO BE DISCUSSED: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include the CMS implementation of Individualized Quality Control

Plan (IQCP) as a new CLIA quality control option based on risk management for laboratories performing nonwaived testing; CDC's strategic priority for strengthening public health and health care collaborations; and quality improvement tools for managing laboratory testing in ambulatory settings.

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://wwwn.cdc.gov/cliac/default.aspx

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/default.aspx by scrolling down and clicking the appropriate link under "Meeting Registration" (either U.S. Citizen Registration or Non-U.S. Citizen 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 February 26, 2014 for U.S. registrants and February 19, 2014 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 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, 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 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. 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. http://wwwn.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 Programs, Standards, and Services, 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.

Elaine L. Baker,

Director, Management Analysis and Services Office,

Centers for Disease Control and Prevention.

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