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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. The public is also welcome to view the meeting by webcast. Check the CLIAC website on the day of the meeting for the webcast link https://wwwn.cdc.gov/cliac/. Please see information regarding attending the meeting in the summary section below.

DATES: The meeting will be held on April 10, 2018, 8:30 a.m. to 5:30 p.m., EDT and April 11, 2018, 8:30 a.m. to 1:00 p.m., EDT.

ADDRESSES: Food and Drug Administration (FDA) White Oak Campus, 10903 New Hampshire Avenue, Building 31, Great Room, Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, 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 30329-4027 telephone (404) 498-2741; NAnderson@cdc.gov.

SUPPLEMENTARY INFORMATION: 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: https://wwwn.cdc.gov/cliac/. 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 April 2, 2018 for U.S. registrants and March 26, 2018 for international registrants.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments on agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes

(unless otherwise indicated). To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least 5 business days prior to the meeting date. 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 5 business days 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 at the mailing or email address below, and will be included in the meeting's Summary Report. 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:
https://wwwn.cdc.gov/cliac/.

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, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters to be Considered: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on the clinical laboratory workforce; implementation of next generation sequencing in clinical laboratories; laboratory interoperability; and using clinical laboratory data to improve quality and laboratory medicine practices. Agenda items are subject to change as priorities dictate.

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 both the Centers for Disease Control and Prevention 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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