BILLING CODE 4163-18-P

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 250 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 www.cdc.gov/cliac.

DATE: The meeting will be held on November 6, 2019, 8:30 a.m. to 5:30 p.m., EST and November 7, 2019, 8:30 a.m. to 12:00 p.m., EST.

ADDRESS: CDC, 1600 Clifton Road, N.E., Tom Harkin Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30329-4027 and via webcast at www.cdc.gov/cliac.

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, N.E., Mailstop V24-3, Atlanta, Georgia 30329-4027, telephone (404) 498-2741; NAnderson@cdc.gov.

SUPPLEMENTARY INFORMATION:

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.

All people attending the CLIAC meeting in-person are required to register for the meeting online at least five business days in advance for U.S. citizens and at least 15 business days in advance for international registrants. Register at: www.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 October 29, 2019 for U.S. registrants and October 15, 2019 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. At this meeting, CLIAC is specifically soliciting public comments to address the questions below. Information provided via public comments will not be considered advice directly addressed to HHS. Rather, it will be used by CLIAC to inform their deliberations and recommendations to HHS and to help focus a CLIAC workgroup that will be convened in response to an April

2019 CLIAC recommendation that such a workgroup be charged with providing input to CLIAC in advising how CLIA might be updated.

1. Are bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings?
2. What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging laboratory technologies and nontraditional testing workflow models, including next generation sequencing, biomarker testing, metagenomics, and others?
3. What data are available that could assist in answering how CLIA may need to be revised or where guidance may be needed to ensure the accuracy and reliability of emerging technologies?

In general, each individual or group requesting to make oral comments will be limited to a total time of ten minutes (unless otherwise indicated). To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting or that wish to provide data in response to the questions above, CLIAC accepts written comments until the date of the meeting (unless

otherwise stated). However, it is requested that comments be submitted at least five 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 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: www.cdc.gov/cliac.

MATTERS TO BE CONSIDERED: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on an update from the Association of Public Health Opioids Task Force; an update on the clinical laboratory workforce; return of research results to research participants; and improving integration of laboratory information systems with electronic health records. There will be an extended public comment session focusing on emerging technologies and the clinical laboratory. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit,

Office of the Chief Operating Officer,

Centers for Disease Control and Prevention.

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