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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 www.cdc.gov/cliac.

DATES: The meeting will be held on April 10, 2019, 8:30 a.m. to 6:00 p.m., EDT and April 11, 2019, 8:30 a.m. to 1:00 p.m., EDT.

ADDRESSES: The Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244 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 NE, Mailstop V24-3, Atlanta, Georgia 30329-4018, 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 April 2, 2019 for U.S. registrants and March 19, 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. 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 five 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 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, 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: 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 CDC's Office of Infectious Diseases Board of Scientific Counselors meeting and reports from three CLIAC workgroups: the CLIA Personnel Regulations Workgroup, the Nontraditional Testing Workflow Model Workgroup, and the Next Generation Sequencing Workgroup. Agenda items are subject to change as priorities dictate.

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.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control, NCIPC; Correction

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control; March 14, 2019, 02:00 p.m. to 05:00 p.m. EDT which was published in the **Federal Register** on January 30, 2019 Volume 84, Number 20, page 473.

The meeting is being changed to a partially open and partially closed meeting. This meeting will be open to the public from 02:00 p.m.–02:40 p.m. to update the public on the Opioid Prescribing Estimate project. The dial in number for the open portion of the meeting is as follows: 1-866-880-0098; Conference ID: 31769267. The meeting will be closed to the public from 02:45 p.m.–05:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, National Center for Injury Prevention and Control, CDC, 4770

Buford Highway NE, MS F-63, Atlanta, GA 30341, telephone (770) 488-3953; NCIPCBSC@cdc.gov.

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.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0978]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Emerging Infections Program to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on November 15, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget

is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Emerging Infections Program (OMB Control No. 0920-0978, Expiration Date 5/31/2021)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases.

Activities of the EIPs fall into the following general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) flexible response to public health emergencies. Activities of the EIPs are designed to: (1) Address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

A revision is being submitted to make existing collection instruments clearer and to add several new forms specifically surveying laboratory practices. These forms will allow the EIP to better detect, identify, track changes in laboratory testing methodology, gather information about laboratory utilization in the EIP catchment area to ensure that all cases are being captured, and survey EIP staff to evaluate program quality.

The total estimated burden is 40,601 hours per year, an increase of 612 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of responders	Number of responses per respondent	Average burden per response (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60
	ABCs Invasive Pneumococcal Disease in Children Case Report Form.	10	22	10/60
	ABCs <i>H. influenzae</i> Neonatal Sepsis Expanded Surveillance Form.	10	6	10/60
	ABCs Severe GAS Infection Supplemental Form.	10	136	20/60
	ABCs Neonatal Infection Expanded Tracking Form.	10	37	20/60
	FoodNet Campylobacter	10	942	21/60
	FoodNet Cyclospora	10	163	10/60
	FoodNet <i>Listeria monocytogenes</i>	10	15	20/60
	FoodNet Salmonella	10	789	21/60