

are involved in an overdose or encountered by first responders, as it is critical to identify and classify the types of drugs involved in an overdose, how often they are involved, and how that involvement may change over time. By understanding which drugs are present, appropriate prevention and response activities can be implemented.

The Centers for Disease Control and Prevention (CDC) is leading the development of Traceable Opioid Material\* Kits (TOM Kits\*) to support detection of emerging opioids. CDC maintains the contents of the TOM Kits\* based on new needs identified, in part, through DEA Emerging Threat Reports. The DEA 2018 mid-year data indicate that fentanyl and fentanyl-related compounds account for approximately 75 percent of their opioid identifications. These kits are reference materials and do not eliminate the need to meet analytical method requirements of other federal agencies. TOM Kits\* are not intended for diagnostic use. The kits are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains.

To equitably distribute these TOM Kits\*, the CDC conducted an emergency

information collection, titled “Distribution of Traceable Opioid Material\* Kits (TOM Kits\*) across U.S. Laboratories,” under the Health and Human Services (HHS) Secretary’s Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver mechanism for the period from 03/20/2019 to 05/10/2019. From 05/10/2019, CDC continued distributing kits using a generic information collection (GenIC) under “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” (OMB Control No. 0923–0047; expiration date 01/31/2022). To continue this collection, the CDC is currently requesting a three-year PRA clearance for a new information collection request (ICR) under the same title.

CDC is currently distributing a product line of TOM Kits\*. Examples of products in this line include the: (1) Opioid Certified Reference Material Kit (Opioid CRM Kit); and (2) Fentanyl Analog Screening Kit (FAS Kit). Respondent laboratories requesting the TOM Kits\* can be from any sector (academic, public, or private), must be located in the U.S., must have a verifiable business address, must have a

current DEA registration, must comply with respective state and local regulations, and must submit requests directly to the respective vendor.

As the number of laboratories requesting TOM Kits\* is high, the information collection will be used to prioritize which laboratories will receive kits when quantities are limited. The brief six-minute web-based survey will allow the CDC to (1) determine what service the recipient laboratory performs and the volume of samples the laboratory processes, and to (2) equitably distribute TOM Kits\* based on the analysis techniques, matrix, and sample size used by the recipient laboratory.

The annual number of respondents (n=1,200) was based on the number of 2019 requests. The total time burden requested is 120 hours per year. There is no burden on the respondents other than their time.

\*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Federal Laboratories .....	TOM Kits* Questions ....	400	1	6/60	40
State, Local, and Tribal Government Laboratories.	TOM Kits* Questions ....	400	1	6/60	40
Private or Not-for-Profit Institutions .....	TOM Kits* Questions ....	400	1	6/60	40
Total .....	.....	.....	.....	.....	120

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA-CE-20-001, Evaluating Practiced-based Programs, Policies, and Practices from CDC’s Rape Prevention Education Program.

Date: April 29–30, 2020.

Time: 8:30 a.m.–5:30 p.m., EDT.

Place: Embassy Suites Buckhead, 3285 Peachtree Road NE, Atlanta, Georgia 30305.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Kimberly Leeks, Ph.D., M.P.H., Scientific Review Official, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Building 106, MS S106-9, Atlanta, Georgia 30341, Telephone (770) 488-6562, KLeeks@cdc.gov.

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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**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](http://www.cdc.gov/cliac).

**DATES:** The meeting will be held on April 16, 2020, 8:30 a.m. to 5:00 p.m., EDT and April 17, 2020, 8:30 a.m. to 11:30 a.m., EDT.

**ADDRESSES:** Food and Drug Administration (FDA), White Oak Campus, 10903 New Hampshire Avenue, Building 31, Great Room, Silver Spring, Maryland 20993 and via webcast at [www.cdc.gov/cliac](http://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](mailto: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 10 business days in advance for international registrants. Register at: [www.cdc.gov/cliac](http://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 8, 2020, for U.S. registrants and April 1, 2020, 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 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](http://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 on CLIAC recommendations; an update on the Genetic Testing Reference Materials Coordination Program (GeT-RM); an update of the December 2019 CDC's Board of Scientific Counselors, Deputy Director for Infectious Diseases meeting; a report from the Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology Advisory Committee; the laboratory response to the COVID-19 coronavirus disease outbreak; and technological advances in digital imaging. 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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-20-0493; Docket No. CDC-2020-0015]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

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

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the