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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

Clinical Laboratory Improvement Advisory Committee

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 number of webcast lines available. Time will be available for public comment.

DATES: The meeting will be held on November 9, 2022, from 11:00 a.m. to 6:00 p.m., EST, and November 10, 2022, from 11:00 a.m. to 6:00 p.m., EST.

ADDRESSES: This is a virtual meeting. Meeting times are tentative and subject to change. The confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at *https://www.cdc.gov/cliac.* Check the website on the day of the meeting for the web conference link.

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, Deputy Chief, Quality and Safety Systems Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology, and Laboratory Services, Deputy Director for Public Health Science and Surveillance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4027; Telephone: (404) 498–2769; Email: *HStang@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare & Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve quality, 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 CLIAC discussions will focus on the clinical and public health response to the monkeypox outbreak, efforts to address public health and clinical laboratory workforce challenges, and reports from two CLIAC workgroups: the CLIA Regulations Assessment Workgroup and the CLIA Certificate of Waiver and Provider-performed Microscopy Procedures Workgroup. Agenda items are subject to change as priorities dictate.

Public Participation

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items.

Oral Public Comment: 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 present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email *CLIAC@cdc.gov* or notify the contact person above (see **FOR FURTHER INFORMATION CONTACT**) at least five business days prior to the meeting date.

Written Public Comment: 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 submitted by email to *CLIAC@cdc.gov* or to the contact person above. All written comments will be included in the meeting minutes posted on the CLIAC website.

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

[30-Day–22–0573]

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 ''National HIV Surveillance System (NHSS)'' 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 April 1, 2022, to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. No changes were made to the information collection plan. 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. 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

National HIV Surveillance System (NHSS) (OMB Control No. 0920–0573, Exp. 11/30/2022)—Revision—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Collected with authorization under Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k), the National HIV Surveillance System (NHSS) data are the primary data used to monitor the extent and characteristics of the HIV burden in the United States. HIV surveillance data are used to describe trends in HIV incidence, prevalence and characteristics of infected persons and used widely at the federal, state, and local levels for planning and evaluating prevention programs and healthcare services, to allocate funding for prevention and care, and to monitor progress toward achieving national prevention goals of the Ending the HIV Epidemic in the U.S initiative.

The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data reported across the spectrum of HIV disease stages from HIV diagnosis to death. NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC Funding Opportunity Announcements PS18–1802: Integrated HIV Surveillance and Prevention Programs for Health Departments; PS20–2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States; PS18–1801: Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STDs, and TB in the U.S.—Affiliated Pacific Islands; and PS23–2302: Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S. Affiliated Pacific Islands.

The systematic data collection in NHSS provides the essential data used to calculate population-based HIV incidence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of recent and rapid transmission, and monitor perinatal exposures. NHSS data are also used locally to identify persons with HIV who are not in medical care and linking them to care and needed services. Describing geographic distribution allows CDC to assess social determinants of health in the context of HIV which allows identification health inequities, and guides steps to address and monitor the health equity over time moving forward. NHSS data continue to be collected, maintained, and reported using standard case definitions, report forms and software. The system is periodically updated to keep pace with changes in testing technology and advances in HIV care and treatment, as well as changing prevention program monitoring and evaluation needs.

The changes requested in this Revision include program-initiated modifications to currently collected data elements and forms including changes to the Adult Case Report Form (ACRF), the Pediatric Case Report Form (PCRF), the Perinatal HIV Exposure Reporting (PHER)form, and the Standards Evaluation Report (SER). We request approval to continue data collection using our currently approved data collection instruments through December 2022 and implement the proposed form changes starting in January 2023.

Changes include minor modifications to dates and time periods in the SER to align with information needs and assess program performance the next report cycle in 2023. Changes made to both the ACRF and PCRF include addition of two variables to collect sexual orientation information and updated gender identity response options. Modification of the gender identity response options and collection of a new variable on sexual orientation proposed in this revision will allow CDC to better address prevention needs of sexual minority populations (*e.g.,* including lesbian, gay, bisexual and transgender (LGBT) populations). In addition, to better reflect the most recent changes in testing technology in the data collection, two new HIV test types have been added and two new response options related to self-testing have been added. Finally, three new HIV testing history variables to summarize self-testing activities have been added to the ACRF (only) and formatting changes have been made to improve usability of both forms.

Critical perinatal exposure information has been consolidated across the PHER and PCRF to one revised PCRF form to reduce redundancy and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities. In all, 10 variables in the PHER form will no longer be collected; 7 variables from the PHER form were combined with existing variables on the PCRF; 13 variables were moved from the PHER form to the new PCRF; 5 new variables were added to the PCRF including 4 related to breastfeeding/chestfeeding and premastication risk behaviors and one variable related to documentation of laboratory results in a person's labor and delivery record; response options for the existing delivery method variable were revised on the PCRF to align with current medical practices.

Health departments will use the revised PCRF form to report both perinatal exposures and pediatric case reports. The number of jurisdictions that will submit pediatric case reports is 59 and a subset will also report perinatal exposure information using the revised PCRF form. The estimated burden per response for the PCRF has been revised from an average of 20 minutes to 35 minutes per response to account for these changes and increased reporting of perinatal exposure data elements.

Burden estimates have been revised to reflect program changes when needed. HIV Incidence data collection is being discontinued as a separate activity and removed from the ICR. HIV incidence continues to be estimated by CDC via statistical methods. Burden estimates have been updated to reflect the

discontinuation of incidence data collection, discontinued use of the PHER form for perinatal exposure reporting, and the revised PCRF. Additionally, the revised burden estimate includes small increases in burden for case and laboratory updates, deduplication activities and increased case investigations due to the increase in the number of persons living with HIV, requiring additional laboratory and case information reporting and linkage to care activities. Small decreases were made to the burden estimates for case reports to account for decreases in adult and pediatric HIV diagnoses reported.

Health department staff compile information from laboratories, physicians, hospitals, clinics, and other health care providers to complete the HIV adult and pediatric case and perinatal exposure reports. These data are recorded using standard report forms either on paper or electronically and entered in the electronic reporting system. CDC estimates that approximately 789 adult HIV case reports and 57 perinatal exposure and pediatric case reports are processed by each health department annually.

Updates to case reports are also entered into the reporting system by health departments if additional information is received from laboratories, vital statistics, or additional providers. Health departments also conduct evaluations on a subset of case reports (*e.g.,* re-abstraction, validation). CDC estimates that on average approximately 85 evaluations of case reports, 2,519 updates to case reports and 10,130 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. All 59 health departments will also conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow-up on 3,032 reports as part of deduplication activities annually. Case report information is compiled over time by health departments, de-identified and forwarded to CDC on monthly basis for inclusion in the national HIV surveillance database.

Additional information will be reported by health departments for monitoring and evaluation of health department investigations, including activities to identify persons who are not in HIV medical care, linking them to HIV medical care (*e.g.,* Data-to-Care activities) and other services and for identifying and responding to clusters. CDC estimates health departments will on average process 929 responses related to investigation reporting and monitoring annually.

Health departments actively review HIV surveillance and other data to detect clusters that include groups of persons with HIV related by recent and rapid transmission. Data on clusters will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. Health departments with detected clusters will complete an initial cluster report form when a cluster is first identified, a cluster follow-up form for each quarter in which the cluster response remains active and a cluster close-out form when cluster response activities are closed or at annual intervals while a cluster response remains active. CDC estimates on average health departments will provide information for 2.5 initial cluster reports, five Cluster Follow-up Form reports, and 2.5 Cluster Close-out Form reports annually.

The annual Standards Evaluation Report (SER) is used by CDC and health departments to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The information collected for the SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data.

OMB approval is requested for three years. The total estimated annualized burden in hours is 60,731. There are no costs to the respondents other than time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	Adult HIV Case Report (ACRF)	59	789	20/60
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF).	59	57	35/60
Health Departments	Case Report Evaluations	59	85	20/60
Health Departments	Case Report Updates	59	2,519	2/60
Health Departments	Laboratory Updates	59	10,130	0.5/60
Health Departments	Deduplication Activities	59	3,032	10/60
Health Departments	Investigation Reporting and Evaluation	59	929	1/60
Health Departments	Initial Cluster Report Form	59	2.5	1
Health Departments	Cluster Follow-up Form	59	5	0.5
Health Departments	Cluster Close-out Form	59	2.5	1
Health Departments	Annual Reporting: Standards Evaluation Report (SER).	59	1	8

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