DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-0920-0573]; [Docket No. CDC-2015-0054]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revisions of the National HIV Surveillance System (NHSS) information collection. This data collection provides the primary population-based data used to describe the epidemiology of HIV in the United States.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0054 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920-0573, Expiration 02/29/2016) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression including AIDS. Data collected as part of the National HIV Surveillance System (NHSS) 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 and prevalence and characteristics of infected persons. HIV surveillance data are used widely at the federal, state, and local levels for planning and evaluating prevention programs and health-care services, and allocate funding for prevention and care.

As science, technology, and our understanding of HIV have evolved, the NHSS has been updated periodically. CDC, in collaboration with health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to AIDS, the end-stage disease caused by infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence and monitor patterns in HIV drug resistance and genetic diversity, as well as provide information on perinatal exposures in the United States.

The CDC surveillance case definition has been modified periodically to accurately monitor disease in adults, adolescents and children and reflect use of new testing technologies and changes in HIV treatment. Information is then

updated in the case report forms and reporting software as needed.

In 2014, following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multitest algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Clinical (nonlaboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition.

Modifications to data elements to accommodate the 2014 HIV Case Surveillance definition were approved in the last renewal

of this information collection. The updates requested in this revision request include modifications to currently collected data elements and forms to accommodate new testing technologies as well as clinical practice guidelines. Specifically, the *HIV Testing and Antiretroviral Use History* section will be revised on the adult/adolescent and pediatric case report forms to include new laboratory tests, additional information on use of antiretrioviral (ARV) medications for pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child-transmission among HIV infected women during pregnancy, and hepatitis B virus (HBV) treatment. Other changes include addition of dates to the address and patient identification fields to better track residence information and minor formatting changes to the form used for Perinatal HIV Exposure Reporting (PHER).

CDC provides funding for 59 jurisdictions to provide adult and pediatric HIV case reports. Health department staff compile information from laboratories, physicians, hospitals, clinics and other health care providers to complete the HIV and pediatric case reports. CDC estimates that, annually, approximately 1,061 adult HIV case reports and 5 pediatric case reports are processed by each health department.

These data are recorded using standard case report forms either on paper or electronically and entered into the electronic reporting system. Updates to case reports are also entered into the reporting system by health departments as additional information may be received from laboratories, vital statistics, or additional providers. Evaluations are also conducted by health departments on a subset of case reports (e.g. re-abstraction, validation, de-duplication). CDC estimates that on average approximately 107 evaluations of case reports, 1,576 updates to case reports and 6,303 updates of laboratory test data will be processed by each of the 59 health departments annually. Case report information compiled over time by health departments is then de-identified and forwarded to CDC on a monthly basis to become part of the national HIV surveillance database.

Supplemental surveillance data are collected in a subset of areas to provide additional information necessary to estimate HIV incidence, the extent of HIV drug resistance and HIV genetic diversity among persons infected with HIV and to monitor and evaluate perinatal HIV prevention efforts. Health departments funded for these supplemental data collections obtain this information from laboratories, health providers, and medical records. CDC estimates that on average 2,288 reports containing

incidence data elements will be processed annually by each of the 25 health departments funded to collect incidence data; 829 reports containing additional data elements on HIV nucleotide sequences from genotype test results will be processed on average by each of the 53 health departments conducting Molecular HIV Surveillance (MHS) and an estimated 114 reports containing perinatal exposure data elements will be processed on average annually by each of the 35 health departments reporting data collected as part of Perinatal HIV Exposure Reporting (PHER). These supplemental data are also reported monthly to CDC.

The total estimated time burden is 52,204 hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden Hours)
Health Departments	Adult HIV Case Report	59	1,061	20/60	20,866
Health Departments	Pediatric HIV Case Report	59	5	20/60	98

Health Departments	Case Report Evaluations	59	107	20/60	2,104
Health Departments	Case Report Updates	59	1,576	5/60	7,749
Health Departments	Laboratory Updates	59	6,303	1/60	6,198
Health Departments	HIV Incidence Surveillance	25	2,288	10/60	9,533
Health Departments	Molecular HIV Surveillance (MHS)	53	829	5/60	3,661
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60	1,995
Total					52,204

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