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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[30Day-19-0573]

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 23rd, 2019 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

National HIV Surveillance System (NHSS) (OMB No. 0920-0573, Expiration 06/30/2019) - Revision - National Center for HIV/AIDS, 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, and to 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 stage 3 (AIDS), the end stage disease caused by

infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence, monitor patterns in HIV drug resistance and genetic diversity, identify and respond to clusters of recent and rapid transmission, as well as provide information on perinatal exposure to HIV 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 2018, CDC implemented activities under a new cooperative agreement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. The purpose of PS18-1802 is to implement a comprehensive HIV surveillance and prevention program to prevent new HIV infections and achieve viral suppression among persons living with HIV. These goals are in accordance with the CDC's and national prevention goals, including the President's new initiative to End the HIV Epidemic in America. This information collection request revision includes activities to continue national surveillance program activities and align with program priorities under the new cooperative agreement (PS18-1802).

The revisions requested in this extension include minor modifications to currently collected data elements and forms (including the Adult Case Report Form (ACRF) and the Pediatric Case Report Form (PCRF)), modifications to data system variables used to summarize geocoded address data collected as part of the geocoding and data linkage activities, addition of new cluster report forms for health departments to report on progress for HIV cluster response activities and addition of investigation reporting and evaluation activities to account for additional data reported as part of these activities. No changes are being requested to data elements collected on the Perinatal HIV Exposure Reporting (PHER) form, but the number of jurisdictions (respondents) completing the form has been reduced. Minor changes to the information collected in the standards evaluation report form (SER) are also requested to align with changes in program activities under PS18-1802. Finally, we have updated our burden estimates to more accurately reflect current data collection practices that are summarized in the table below.

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 adult and pediatric case reports. CDC estimates that on average,

approximately 854 adult HIV case reports and three pediatric case reports are processed by each health department annually.

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). CDC estimates that on average approximately 86 evaluations of case reports, 2353 updates to case reports and 9410 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. In addition, all 59 health departments will conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow-up on 2741 reports as part of deduplication activities 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.

When necessary additional information may be reported by health departments for monitoring and evaluation of health department investigations including activities identifying

persons who are not in HIV medical care and linking them to HIV medical care (e.g., Data-to-Care activities) and other services and identifying and responding to clusters. CDC estimates health departments will on average process 901 responses related to investigation reporting and monitoring annually.

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to interrupt ongoing transmission and prevent further HIV infections. Health departments may detect clusters through multiple means, including through routine analyses of Surveillance data and other data reported to the NHSS. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. These summary data will be collected through quarterly cluster report forms that will be completed by health departments for clusters that they have identified and for which they are actively conducting response activities. Health departments 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. Completion of forms

will be determined by the number of clusters detected. Health departments that do not identify recent and rapid clusters of HIV transmission will not complete any cluster report forms, while some jurisdictions will detect multiple recent and rapid clusters of HIV transmission, necessitating the completion of multiple cluster report forms. CDC estimates on average health departments will provide information for 2.5 initial cluster reports, five Cluster Follow-up reports, and 2.5 Cluster Close-out reports annually.

Perinatal HIV surveillance and prevention activities with HIV exposure reporting and perinatal services coordination is an integrated approach to advancing the progress toward perinatal HIV elimination goals. A subset of 16 health departments in the most affected jurisdictions will be reporting using the Perinatal Exposure Reporting (PHER) form to monitor and evaluate perinatal HIV prevention efforts. An estimated 197 reports containing perinatal exposure data elements will be processed on average annually by each of the 16 health departments reporting data collected as part of PHER. These supplemental data are also reported monthly to CDC.

The 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 that will be reported one time a year by each 59 health departments. The total estimated annual burden hours are 58,131.

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	59	854	20/60
Health Departments	Pediatric HIV Case Report	59	3	20/60
Health Departments	Case Report Evaluations	59	86	20/60
Health Departments	Case Report Updates	59	2,353	2/60
Health Departments	Laboratory Updates	59	9,410	0.5/60
Health Departments	Deduplication Activities	59	2,741	10/60
Health Departments	Investigation Reporting and Evaluation	59	901	1/60
Health Departments	Initial Cluster Report Form	59	2.5	1
Health Departments	Cluster Follow-up Form	59	5	30/60
Health Departments	Cluster Close-out Form	59	2.5	1
Health Departments	Perinatal HIV Exposure Reporting (PHER)	16	197	30/60
Health Departments	Annual Reporting: Standards Evaluation Report (SER)	59	1	8

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