



<NOTICE>

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0573]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly S. Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

National HIV Surveillance System (NHSS) (OMB No. 0920-0573, Expiration 01/31/2013)-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. These national HIV surveillance data collected by CDC are the primary source of information used to monitor the extent and characteristics of the HIV burden in the U.S.

The purpose of HIV surveillance is to monitor trends in HIV and describe the characteristics of infected persons (e.g., demographics, modes of exposure to HIV, clinical and laboratory

markers of HIV disease, manifestations of severe HIV disease, and deaths among persons with HIV). HIV surveillance data are widely used at all government levels to assess the impact of HIV infection on morbidity and mortality, to allocate medical care resources and services, and to guide prevention and disease control activities.

As science, technology, and our understanding of HIV have evolved, the NHSS has been updated periodically to meet the nation's needs for information. CDC, in collaboration with health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conduct national surveillance for cases of HIV infection. National surveillance includes tracking 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 viral resistance and HIV-1 subtypes, as well as provide information on perinatal exposures in the U.S.

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 2008, the surveillance case definitions for adults and children for HIV and AIDS were revised. Since that time, the enhanced HIV/AIDS reporting system (eHARS) was fully deployed (2010) and forms have been updated to reflect those changes (2011). In 2012, CDC convened an expert consultation to consider revisions of various aspects of the case definition including criteria for reporting a potential case, criteria for a reporting a confirmed case, and case classification (disease staging system). Recommendations for revisions in the case definition were adopted in a position statement by the Council of State and Territorial Epidemiologists in June 2012 and the final case definition revision is planned for 2012.

The revisions requested include modifications to currently collected data elements and forms to align with anticipated changes in the case definitions for HIV surveillance to be published in 2012 and continuation of HIV surveillance activities funded under the new funding opportunity announcement CDC-RFA-PS13-1302 National HIV Surveillance System (NHSS). These include minor modifications of testing categories to accommodate new testing algorithms and modifications to staging criteria and non-substantial editorial changes aimed at improving the format and usability of the forms such as improved wording of terms and changes in the format of some response options. In addition, the

number of data elements from the former enhanced perinatal surveillance (EPS) was reduced and the form modified for continuation in 2013 as Perinatal HIV Exposure Reporting (PHER). Surveillance data collection on variant and atypical strains (formerly variant, atypical and resistant HIV surveillance (VARHS)) will be continued as Molecular HIV Surveillance (MHS) with a reduced number of data elements previously approved under VARHS.

CDC provides funding for 59 jurisdictions to conduct adult and pediatric HIV case surveillance. Health department staffs compile information from laboratories, physicians, hospitals, clinics and other health care providers in order to complete the HIV and pediatric case reports. CDC estimates that approximately 1,260 adult HIV case reports and 6 pediatric case reports are processed by each health department annually.

These data are recorded on standard case report forms, processed by either paper or electronic format and entered into eHARS. Updates to case reports are also entered into eHARS by health departments, as additional information may be received from laboratories, vital statistics offices, or additional providers. CDC estimates approximately 1,469 updates to case reports will be processed by each of the 59 health departments annually. Additionally, 5,876 updates of laboratory test data will be processed, primarily through electronic laboratory

reporting, by each of the 59 health departments annually. Health departments will de-identify compiled case report information and forward to CDC on a monthly basis for inclusion in the national HIV surveillance database. Evaluations are also conducted by health departments on a subset of case reports (e.g. including re-abstraction/validation activities and routine interstate de-duplication). CDC estimates approximately 127 evaluations of case reports will be processed by each of the jurisdictions annually.

Supplemental surveillance data are collected in a subset of areas to provide additional information necessary to estimate HIV incidence, to better describe the extent of HIV viral resistance and quantify HIV subtypes 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 care providers, and medical records. CDC estimates that 2,729 reports containing HIV Incidence Surveillance (HIS) data elements will be processed on average by each of the 25 health departments funded to collect incidence data annually. Additionally, an estimated 718 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 reporting MHS data annually. 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 PHER.

There are no costs to respondents except their time.

Estimate of Annualized Burden Table

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	Adult HIV Case Report	59	1,260	20/60	24,780
Health Departments	Pediatric HIV Case Report	59	6	20/60	118
Health Departments	Case Report Evaluations	59	127	20/60	2,498
Health Departments	Case Report Updates	59	1,469	2/60	2,889
Health Departments	Laboratory Updates	59	5,876	1/60	5,778
Health Departments	HIV Incidence Surveillance (HIS)	25	2,729	10/60	11,371
Health Departments	Molecular HIV Surveillance (MHS)	53	967	5/60	4,271
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60	1,995
Total					53,700

Kimberly Lane, M.B.A
Deputy Director
Office of Scientific Integrity
Centers for Disease Control and Prevention

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