Attachment 2

Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance OMB No. 0920-0573

60 Day Federal Register Notice

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-0920-0573]

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 404-639-5960 or send comments to Maryam Daneshvar, CDC Reports Clearance Officer, 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

Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance 0920-0573 expiration 02/28/2010 - revisions - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

<u>Background and Brief Description</u>

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) infection and acquired immunodeficiency syndrome (AIDS). These national HIV/AIDS surveillance data collected by CDC are the primary source of information used to monitor the extent and characteristics of the HIV epidemic in the U.S.

As science, technology, and our understanding of the epidemic have evolved, the national surveillance system 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, 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 viral resistance and HIV-1 subtypes in the U.S.

Since 1993, these data have been maintained and reported through the HIV/AIDS reporting system (HARS) software. In 2010, the new enhanced electronic HIV/AIDS reporting system (eHARS) will be fully deployed. The revisions requested include additional data elements for eHARS that will allow better tracking of documents and flow of previously approved currently collected surveillance data. In addition, CDC is requesting approval of a revised data collection form for enhanced perinatal surveillance (EPS) that includes non-substantial editorial changes aimed at improving the format and usability of the EPS form. Revisions include improved wording of terms and changes in the format of some response options.

The purpose of HIV/AIDS surveillance data is to monitor trends in HIV/AIDS 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/AIDS). HIV/AIDS 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.

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 in order to complete the HIV and pediatric case reports. CDC estimates that 1839 adult HIV case reports and 8 pediatric case reports are processed by each health department annually.

These data are recorded on standard paper case report forms and entered into the eHARS reporting system. Updates to case reports are also entered into the eHARS system by health departments as additional information may be received from laboratories, vital statistics, or additional providers. CDC estimates approximately 97 updates to case reports 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 (twelve times a year) for inclusion in the national HIV surveillance database.

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 providers, and medical records. CDC estimates that 2,437 reports containing incidence data elements will be processed on average by each of the 25 health departments funded to collect incidence data annually. Additionally, an estimated 2,019 reports containing additional viral resistance data elements will be processed on average by each of the 11 health departments conducting variant and resistant HIV surveillance (VARHS) annually. An estimated 167 reports containing perinatal surveillance data elements will be processed on average annually by each of the 15 health departments reporting data collected as part of enhanced perinatal surveillance (EPS). Data collected for these 3 supplemental data collections are also reported monthly to CDC.

Estimate of Annualized Burden Table

Form	Type of Respondent	No. of Respondents	No. of Responses per Responden t	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Adult HIV/AIDS Case Reports	Health Departments	59	1,839	20/60	36,167
Peds HIV/AIDS Case Reports	Health Departments	59	8	20/60	157
Case Report Updates	Health Departments	59	97	5/60	477
Incidence	Health Departments	25	2,437	10/60	10,154

VARHS	Health Departments	11	2,019	5/60	1,851
EPS	Health Departments	15	167	1	2,505
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