DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-07–0573]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Adult and Pediatric HIV/AIDS Confidential Case Reports (OMB Control No. 0920–0573)—Revision-National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking a three-year OMB approval to continue data collection of the HIV/AIDS case reports with revision of currently approved data collection. Revisions include additional data elements on testing and treatment, specimen quality and sequence information for drug resistance and HIV–1 subtypes, and clinical and behavioral information on HIV-infected mothers and their infants.

The National Adult and Pediatric HIV/AIDS Confidential Case Reports are collected as part of the HIV/AIDS Surveillance System. CDC, in collaboration with health departments in 59 reporting areas (states, territories, possessions, and the District of Columbia), conducts national surveillance for cases of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS), the end-stage of disease caused by infection with HIV. HIV/AIDS surveillance data collection by CDC is authorized and protected under Section 306 of the Public Health Service Act (42 U.S.C. 242k).

Currently, all 59 areas mandate and collect AIDS surveillance data. In addition, 50 of the areas currently mandate and collect confidential name-based surveillance data on HIV cases which have not progressed to AIDS. The Adult HIV/AIDS Confidential Case Report form is used for patients ≥ 13 years of age. The Pediatric HIV/AIDS Confidential Case Report form is used for patients ≤ twelve years of age at the time of diagnosis. We anticipate that over the next three years all 59 areas will mandate collection of confidential name-based HIV surveillance data. Therefore, the estimated burden for the next three years is based on HIV case reporting in 59 areas.

The purpose of HIV/AIDS surveillance data is to monitor trends in HIV/AIDS and describe the characteristics of infected persons (e.g., demographics, risk behaviors, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease, and deaths due to AIDS). Because HIV infection results in untimely death and most often infects younger adults in the prime years of life, large amounts of Federal, State, and local government funding have been allocated to address all aspects of HIV infection, including prevention and treatment. HIV/AIDS surveillance data are the only nationally available data on persons reported with HIV and AIDS and 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.

HIV/AIDS case reports are sent to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers. Areas use a microcomputer system developed by CDC (the HIV/AIDS Reporting System, HARS) to store and analyze data, as well as transmit encrypted data to CDC. An improved HIV reporting system (eHARS) is currently in development and is scheduled to replace HARS during the period of this clearance.

We anticipate making a modification to the layout of both the Adult and the Pediatric HIV/AIDS confidential case report forms during this period which would include the addition of a blank space in the top portion and bottom portion of the forms. Areas could then have the option of using this space to assign a local form number. This form number would be for local use only and not be reported to CDC.

The burden estimate for this revision includes estimated burden for evaluations of HIV/AIDS surveillance and case report updates. In addition, the burden estimate also includes additional data on HIV testing and treatment history for the purpose of estimating HIV incidence. The availability of a serologic testing algorithm for recent HIV seroconversion (STARHS) allows surveillance systems to determine how many among a group of new diagnoses are from new infections. In order to derive a population-based estimate of HIV incidence based on data from those individuals who choose to have an HIV antibody test and who test positive (those reported to HIV surveillance systems), additional data are needed to assign statistical weights to individual STARHS results. These additional data include STARHS results, information on testing reason, frequency, location, dates tested, prior positive and negative tests, and use of HIV-related medicines.

The table also includes burden estimates of additional information requested on specimen quality and genotyping test results for drug resistance and HIV–1 subtypes as part of variant, atypical and resistant HIV surveillance (VARHS). These data will be reported to CDC by participating health departments for the purpose of calculating population-based estimates of prevalence of HIV drug resistance and HIV–1 subtypes among individuals with newly diagnosed HIV.

The burden estimate also includes enhanced data collection on HIV-infected mothers and their infants in 15 areas. Proposed data collection for enhanced perinatal surveillance (EPS) will supplement information collected on both the adult and pediatric case report form and include data on prenatal care, clinical history, testing, and antiretroviral therapy. These clinical and behavioral data will be used to better monitor the effects of HIV testing, prevention, and treatment guidelines and to maximally reduce perinatal HIV transmission.

No other Federal agency collects this type of national HIV/AIDS data. In addition to providing technical assistance for use of the case report forms, CDC also provides reporting areas with technical support for the HARS software. There is no cost to respondents. The total estimated annual burden hours are 57,774.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)
State Health Departments	Adult Case Report: AIDS	59	890	20/60
	Adult Case Report: HIV	59	932	20/60
State Health Departments	Peds Case Report: AIDS	59	3	20/60
	Peds Case Report: HIV	59	11	20/60
State Health Departments	Case Report Updates	59	85	5/60
State Health Departments	Incidence	30	2,833	10/60
State Health Departments	VARHS	24	2,917	5/60
State Health Departments	EPS	15	200	25/60

Dated: November 8, 2006.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30Day–07–0571]

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Proposed Project

Minimum Data Elements (MDEs)/ System for Technical Assistance Reporting (STAR) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)—(OMB Number 0920–0571)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The NBCCEDP was established in response to the Congressional Breast and Cervical Cancer Mortality Prevention Act of 1990. This Act mandates a program that will provide early detection, breast and cervical cancer screening services for under-served women.

CDC proposes to aggregate breast and cervical cancer screening, diagnostic and treatment data from NBCCEDP grantees at the State, territory and tribal level. These aggregated data will include demographic information about women served through funded programs. The proposed data collection will also include infrastructure data about grantee management, public education and outreach, professional education, and service delivery.

Breast cancer is a leading cause of cancer-related death among American women. The American Cancer Society (ACS) estimated that 211,240 new cases would be diagnosed among women in 2005, and 40,410 women would die of this disease. Mammography is extremely valuable as an early detection tool because it can detect breast cancer well before the woman can feel the lump, when it is still in an early and more treatable stage. Women older than age 40 that receive annual mammography screening reduce their probability of breast cancer mortality and increase their treatment options.

Although early detection efforts have greatly decreased the incidence of invasive cervical cancer in recent decades, ACS estimated that 10,370 new cases would be diagnosed in 2005 and 3,710 women would die of this disease. Papanicolaou (Pap) tests effectively detect precancerous lesions in addition to invasive cervical cancer. The detection and treatment of precancerous lesions can prevent nearly all cervical cancer-related deaths.

Because breast and cervical cancer screening, diagnostic and treatment data are already collected and aggregated at the State, territory and tribal level, the additional burden on the grantees will be small. Continuation of this program will require grantees to report a minimum data set (MDE) on screening and follow-up activities electronically to the CDC on a semi-annual basis. The program will require grantees to report infrastructure data (STAR) to the CDC annually using a web-based system. Information collected will be used to obtain more complete breast and cervical cancer data, promote public education of cancer incidence and risk, improve the availability of screening and diagnostic services for under-served women, ensure the quality of services provided to women, and develop outreach strategies for women that are never or rarely screened for breast and cervical cancer. Data collection will continue for the next three years.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,244.

ESTIMATED ANNUALIZED BURDEN HOURS

Reports	Number of respondents*	Number of responses per respondent	Average burden per response (in hours)
*Infrastructure Report (STAR)	68	1	25
*Screening and Follow-up (MDE)	68	2	4

* Respondents include State, territorial and tribal grantees.