

reducing the burden of cardiovascular disease risk factors among women who utilize program services. CDC uses the information submitted through progress reports to assess each grantee's progress

toward meeting stated program objectives. Participation in the information collection is required under the terms of the WISEWOMAN cooperative agreement.

OMB approval is requested for one year. The total estimated annualized burden hours are 1,680.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
WISEWOMAN Grantees	Screening and Assessment MDE	21	2	16
	Lifestyle Intervention MDE	21	2	8
	Progress Report	21	2	16

Dated: December 18, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0573]

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 (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The 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). This title is being changed from the previously approved title *Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance* in 2009.

Background and Brief Description

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.

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 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 reporting a confirmed case, and case classification (disease staging system). Recommendations for revisions in the case definition were adopted by the Council of State and Territorial Epidemiologists in June 2012 and the final case definition revision is planned for implementation in 2013 after publication.

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. Updates to case reports are also entered into enhanced HIV/AIDS Reporting system (eHARS) by health departments, as additional information may be received from laboratories, vital statistics offices, or additional providers. 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) in all jurisdictions.

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 25 health departments will be reporting data elements containing HIV Incidence Surveillance (HIS) data, 53 health departments will report additional data

elements on HIV nucleotide sequences as part of MHS, and 35 areas will be reporting data as part of PHER annually. The total estimated annual burden hours are 53,700.

Estimated Annualized Burden Hours

EXHIBIT 12.A ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average Burden per response (in hours)
Health Departments	Adult HIV Case Report	59	1,260	20/60
Health Departments	Pediatric HIV Case Report	59	6	20/60
Health Departments	Case Report Evaluations	59	127	20/60
Health Departments	Case Report Updates	59	1,469	2/60
Health Departments	Laboratory Updates	59	5,876	1/60
Health Departments	HIV Incidence Surveillance (HIS)	25	2,729	10/60
Health Departments	Molecular HIV Surveillance (MHS)	53	967	5/60
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60

Kimberly S. Lane,
Deputy Director, Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director, Centers for Disease
Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 3:00 p.m.—4:10 p.m., EDT, January 23, 2013.

Place: Teleconference.

Status: Open to the public, limited only by the availability of telephone ports. The public is welcome to participate during the public comment period. A public comment period is tentatively scheduled from 4:00 p.m. to 4:05 p.m. To participate in the teleconference, please dial (877) 953-5019 and enter code 5280655.

Purpose: The subcommittee will provide advice to the CDC Director through the ACD on strategic and other broad issues facing CDC.

Matters To Be Discussed: Agenda items will include the following: review of draft recommendations for health equity at CDC.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, HDS, ACD, CDC, 1600 Clifton Road NE., M/S E-67, Atlanta, Georgia 30333, telephone (404) 498-2320, email: LEL1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 18, 2012.

Elaine L. Baker,
Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0176]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 25, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title, “Experimental Study: Examination of Corrective Direct-to-Consumer Television Advertising.” Also include