

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Neurologist	Key Informant Interview	16	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office,
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

[60Day-15-0920-0573; Docket No. CDC-
2015-0054]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and
Prevention (CDC), Department of Health
and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease
Control and Prevention (CDC), as part of
its continuing efforts to reduce public
burden and maximize the utility of
government information, invites the
general public and other Federal
agencies to take this opportunity to
comment on proposed and/or
continuing information collections, as
required by the Paperwork Reduction
Act of 1995. This notice invites
comment on a proposed revisions of the
National HIV Surveillance System
(NHSS) information collection. This
data collection provides the primary
population-based data used to describe
the epidemiology of HIV in the United
States.

DATES: Written comments must be
received on or before September 11,
2015.

ADDRESSES: You may submit comments,
identified by Docket No. CDC-2015-
0054 by any of the following methods:

- *Federal eRulemaking Portal:*
Regulation.gov. Follow the instructions
for submitting comments.

- *Mail:* Leroy A. Richardson,
Information Collection Review Office,
Centers for Disease Control and
Prevention, 1600 Clifton Road NE., MS-
D74, Atlanta, Georgia 30329.

Instructions: All submissions received
must include the agency name and

Docket Number. All relevant comments
received will be posted without change
to *Regulations.gov*, including any
personal information provided. For
access to the docket to read background
documents or comments received, go to
Regulations.gov.

Please note: All public comment should be
submitted through the Federal eRulemaking
portal (*Regulations.gov*) or by U.S. mail to the
address listed above.

FOR FURTHER INFORMATION CONTACT: To
request more information on the
proposed project or to obtain a copy of
the information collection plan and
instruments, contact the Information
Collection Review Office, Centers for
Disease Control and Prevention, 1600
Clifton Road NE., MS-D74, Atlanta,
Georgia 30329; phone: 404-639-7570;
Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the
Paperwork Reduction Act of 1995 (PRA)
(44 U.S.C. 3501-3520), Federal agencies
must obtain approval from the Office of
Management and Budget (OMB) for each
collection of information they conduct
or sponsor. In addition, the PRA also
requires Federal agencies to provide a
60-day notice in the **Federal Register**
concerning each proposed collection of
information, including each new
proposed collection, each proposed
extension of existing collection of
information, and each reinstatement of
previously approved information
collection before submitting the
collection to OMB for approval. To
comply with this requirement, we are
publishing this notice of a proposed
data collection as described below.

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; (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; and (e) estimates of capital
or start-up costs and costs of operation,
maintenance, and purchase of services

to provide information. Burden means
the total time, effort, or financial
resources expended by persons to
generate, maintain, retain, disclose or
provide information to or for a Federal
agency. This includes the time needed
to review instructions; to develop,
acquire, install and utilize technology
and systems for the purpose of
collecting, validating and verifying
information, processing and
maintaining information, and disclosing
and providing information; to train
personnel and to be able to respond to
a collection of information, to search
data sources, to complete and review
the collection of information; and to
transmit or otherwise disclose the
information.

Proposed Project

National HIV Surveillance System
(NHSS) (OMB Control No. 0920-0573,
Expiration 02/29/2016)—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 U.S.C. 242b and 242k) to collect
information on cases of human
immunodeficiency virus (HIV) and
indicators of HIV disease and HIV
disease progression including AIDS.
Data collected as part of the National
HIV Surveillance System (NHSS) 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 and prevalence and
characteristics of infected persons. HIV
surveillance data are used widely at the
federal, state, and local levels for
planning and evaluating prevention
programs and health-care services, and
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 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 HIV drug resistance and genetic diversity, as well as provide information on perinatal exposures 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 2014, following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multitest algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Clinical (nonlaboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition.

Modifications to data elements to accommodate the 2014 HIV Case

Surveillance definition were approved in the last renewal of this information collection. The updates requested in this revision request include modifications to currently collected data elements and forms to accommodate new testing technologies as well as clinical practice guidelines. Specifically, the *HIV Testing and Antiretroviral Use History* section will be revised on the adult/adolescent and pediatric case report forms to include new laboratory tests, additional information on use of antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child-transmission among HIV infected women during pregnancy, and hepatitis B virus (HBV) treatment. Other changes include addition of dates to the address and patient identification fields to better track residence information and minor formatting changes to the form used for Perinatal HIV Exposure Reporting (PHER).

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 and pediatric case reports. CDC estimates that, annually, approximately 1,061 adult HIV case reports and 5 pediatric case reports are processed by each health department.

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-abstractation, validation, de-duplication). CDC estimates that on average approximately 107 evaluations of case reports, 1,576 updates to case reports and 6,303 updates of laboratory test data 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 to become part of the national HIV surveillance database.

Supplemental surveillance data are collected in a subset of areas to provide additional information necessary to estimate HIV incidence, the extent of HIV drug resistance and HIV genetic diversity 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 on average 2,288 reports containing incidence data elements will be processed annually by each of the 25 health departments funded to collect incidence data; 829 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 conducting Molecular HIV Surveillance (MHS) and 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 Perinatal HIV Exposure Reporting (PHER). These supplemental data are also reported monthly to CDC.

The total estimated time burden is 52,204 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Health Departments	Adult HIV Case Report	59	1,061	20/60	20,866
Health Departments	Pediatric HIV Case Report	59	5	20/60	98
Health Departments	Case Report Evaluations	59	107	20/60	2,104
Health Departments	Case Report Updates	59	1,576	5/60	7,749
Health Departments	Laboratory Updates	59	6,303	1/60	6,198
Health Departments	HIV Incidence Surveillance	25	2,288	10/60	9,533
Health Departments	Molecular HIV Surveillance (MHS)	53	829	5/60	3,661
Health Departments	Perinatal HIV Exposure Reporting (PHER).	35	114	30/60	1,995
Total					52,204

Leroy A. Richardson,

Chief, Information Collection Review Office,
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 Medicare & Medicaid
Services**

[Document Identifier: CMS-10464]

**Agency Information Collection
Activities: Submission for OMB
Review; Comment Request**

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 12, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges; *Use:* The CMS collects personally identifiable information from agents/brokers to register them with the FFM and permit them to assist individuals and employers in enrolling in the FFM. We use this collection of information to ensure agents/brokers possess the basic knowledge required to enroll individuals and SHOP employers/employees through the Marketplaces. Agents/brokers will use CMS or third-party systems to enter identifying information and register with the FFM. As a component of registration, agents/brokers are required to complete online training courses through a CMS or third-party Learning Management System

(LMS). Upon completion of their applications and training requirements, agents/brokers will be required to attest to their agreement to adhere to FFM standards and requirements through a CMS or third-party LMS. *Form Number:* CMS-10464 (OMB control number: 0938-1204); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 19,474; *Total Annual Responses:* 32,929,239; *Total Annual Hours:* 2,786,198. (For policy questions regarding this collection contact Daniel Brown at 301-492-5146.)

Dated: July 8, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office
of Strategic Operations and Regulatory
Affairs.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
**Administration for Children and
Families**
**Submission for OMB Review;
Comment Request**

Title: LIHEAP Quarterly Allocation
Estimates, Form ACF-535.

OMB No.: 0970-0037.

Description: The LIHEAP Quarterly Allocation Estimates, ACF Form-535 is a one-page form that is sent to 50 State grantees and to the District of Columbia. It is also sent to Tribal Government grantees that receive over \$1 million annually for the Low Income Home Energy Assistance Program (LIHEAP). Grantees are asked to complete and submit the form in the 4th quarter of each year. The data collected on the form are grantees' estimates of obligations they expect to make each quarter for the upcoming fiscal year for the LIHEAP program. This is the only method used to request anticipated distributions of the grantees' LIHEAP funds. The information is used to develop apportionment requests to OMB and to make grant awards based on grantees' anticipated needs. Information collected on this form is not available through any other Federal source. Submission of the form is voluntary.

Respondents: State Governments, and Tribal Governments that receive over \$1 million annually, and the District of Columbia.