

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Territorial Health Department Tobacco Control Program Staff.	Evaluation Reporting Template for National and State Tobacco Control Program.	53	1	8	424
Total	424

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-0573; Docket No. CDC-2025-0519]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National HIV Surveillance System (NHSS). The NHSS collects comprehensive population-based data on persons living with HIV in the U.S. and its territories, utilizing standard reporting from laboratories and healthcare providers to monitor trends, estimate incidence and prevalence, analyze drug resistance, detect and monitor clusters, and inform public health planning and resource allocation at federal, state and local levels and by HIV prevention and care partners.

DATES: CDC must receive written comments on or before December 1, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0519 by either of the following methods:

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

- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920-0573, Exp. 2/28/2026)—Extension—National Center for HIV, 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, prevalence and characteristics of persons diagnosed with HIV infection and used widely at the federal, state, and local levels for planning and evaluating prevention programs and health-care services, allocating funding for prevention and care, and monitoring progress toward achieving national prevention goals. NHSS data collection activities are currently supported through cooperative agreements with health departments

under CDC Notice of Funding Opportunity PS24—0047: High-Impact HIV Prevention and Surveillance Programs for Health Departments CDC—RFA—PS—24—0047 and Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S. Affiliated Pacific Islands CDC—RFA—PS23—2302. The activities funded under these announcements promote and support improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, by using quality, timely, and complete surveillance, and program data to guide HIV prevention efforts toward reducing new HIV infections and ending the HIV epidemic in the United States.

The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. territories and freely associated states, conducts national surveillance for cases of HIV infection that includes critical data reported across the spectrum of HIV disease stages from HIV diagnosis to death. The systematic data collection provides the essential data used to calculate population-based HIV case counts, HIV incidence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of recent and rapid transmission, and monitor perinatal exposures. NHSS data are also used locally to identify persons with HIV who are not in medical care and linking them to care and needed services. NHSS data continue to be collected, maintained, and reported using standard case definitions, report forms and software. The system is periodically updated as needed to keep pace with changes in testing technology and advances in HIV care and treatment, as well as changing prevention program monitoring and evaluation needs.

CDC receives adult and pediatric HIV case reports from 59 areas. Additional information on perinatal exposures is also reported in a subset of jurisdictions when reportable using the same pediatric case report form used to monitor progress toward perinatal HIV elimination goals. Health department staff compile information from laboratories, physicians, hospitals, clinics, and other health care providers to complete the HIV adult and pediatric case reports. CDC estimates that approximately 789 adult HIV case reports and 57 perinatal exposure and pediatric case reports are processed by each health department annually.

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-abstraction, validation). CDC estimates that on average approximately 85 evaluations of case reports, 2519 updates to case reports and 10130 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. In addition, 59 health departments will conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow up on 3032 reports as part of deduplication activities annually. Case report information compiled over time by health departments is then de-identified and forwarded to CDC monthly to become part of the national HIV surveillance database.

Additional information will be reported by health departments for monitoring and evaluation of health department investigations including activities identifying persons who are not in HIV medical care and linking

them to HIV medical care (e.g., Data-to-Care activities) and other services and identifying and responding to clusters. CDC estimates health departments will on average process 929 responses related to investigation reporting and monitoring annually.

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed to intervene and interrupt ongoing transmission and prevent future HIV infections. Health departments may detect clusters through multiple means, including through routine analyses of Surveillance data and other data reported to the NHSS. Summary data on clusters of recent and rapid HIV transmission in the United States are collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. Health departments complete an Initial Cluster Report Form when a cluster is first identified, a Follow-up Cluster Report Form each quarter when response activities are ongoing, and an Annual/Closeout Cluster Report Form depending on the state of cluster response. CDC estimates on average health departments will provide information for 2.5 Initial Cluster Report Forms, 5 Follow-up Cluster Report Forms, and 2.5 Annual/Closeout Cluster Report Forms annually.

The Standards Evaluation Report (SER) is used by CDC and Health Departments to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The information collected for the SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data that will be reported one time a year by each of the 59 health departments.

There are no revisions to data collection or changes in burden requested in this Extension. The total estimated annualized burden is 60,731 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health Departments	Adult HIV Case Report (ACRF)	59	789	20/60	15,517
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF).	59	57	35/60	1,962
Health Departments	Case Report Evaluations	59	85	20/60	1,672
Health Departments	Case Report Updates	59	2519	2/60	4,954
Health Departments	Laboratory Updates	59	10130	0.5/60	4,981
Health Departments	Deduplication Activities	59	3032	10/60	29,815
Health Departments	Investigation Reporting and Evaluation	59	929	1/60	914

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health Departments	Initial Cluster Report Form	59	2.5	1	148
Health Departments	Follow-up Cluster Report Form	59	5.0	0.5	148
Health Departments	Annual/Closeout Cluster Report Form ..	59	2.5	1	148
Health Departments	Annual Reporting: Standards Evaluation Report (SER).	59	1.0	8	472
Total	60,731

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-25-1011]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Emergency Epidemic Investigation (EEI)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 16, 2025 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Emergency Epidemic Investigations (EEI) (OMB Control No. 0920-1011, Exp. 12/31/2025)—Extension—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC previously conducted Emergency Epidemic Investigations (EEIs) under Office of Management and Budget (OMB) Control Number 0920-0008. In 2013, CDC received OMB approval (OMB Control No. 0920-1011) for a New Generic Clearance to collect vital information during EEIs in response to outbreaks or other urgent public health events (i.e., natural, biological,

chemical, nuclear, radiological) characterized by undetermined agents, undetermined sources, undetermined transmission, or undetermined risk factors. This Generic Clearance has been approved for a number of Extensions since 2013 and expires on 12/31/2025. CDC seeks OMB approval for an additional Extension of this Generic Clearance for another three-year period.

Supporting effective EEIs is one of the most important ways that CDC protects the health of the public. CDC is frequently called upon to conduct EEIs at the request of local, state, or international health authorities seeking support to respond to outbreaks or urgent public health events. In response to external partner requests, CDC provides the necessary epidemiologic support to identify the agents, sources, modes of transmission, or risk factors to effectively implement rapid prevention and control measures to protect the public’s health. Data collection is a critical component of the epidemiologic support provided by CDC; data are analyzed to determine the agents, sources, modes of transmission, or risk factors so that effective prevention and control measures can be implemented. During an unanticipated outbreak or urgent public health event, immediate action by CDC is necessary to minimize or prevent public harm. The legal justification for EEIs is found in the Public Health Service Act (42 U.S.C. 301 [241] (a).

Successful investigations are dependent on rapid and flexible data collection that evolves during the investigation and is customized to the unique circumstances of each outbreak or urgent public health event. Data collection elements will be those necessary to identify the agents, sources, mode of transmission, or risk factors. Examples of potential data collection methods include telephone or face-to-face interviews; email, web, or other types of electronic questionnaires; paper-and-pencil questionnaires; focus groups; medical record review and abstraction; laboratory record review