ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	EQUIP Data Submission Form	240	3	10/60
IRATB Lead and Multielement Proficiency (LAMP) Testing Program				
Public Health Labs	LAMP Enrollment Form	226	1	10/60
	LAMP Data Submission Form	226	4	10/60
NSMBB Newborn Screening and Quality Assurance Program (NSQAP)				
Domestic NBS Labs	NSQAP Enrollment Form	3	1	10/60
	NSQAP Data Submission Portal Quality Control (QC)	78	2	45/60
	NSQAP Data Submission Portal Biochemical (Proficiency Testing) PT.	78	3	45/60
	NSQAP Data Submission Portal Molecular PT	78	3	45/60
International NBS Labs	NSQAP Enrollment Form	44	1	10/60
	NSQAP Data Submission Portal QC	568	2	45/60
	NSQAP Data Submission Portal Biochemical PT	568	3	45/60
	NSQAP Data Submission Portal Molecular PT	568	3	45/60
NBS Test Manufacturers	NSQAP Enrollment Form	3	1	10/60
	NSQAP Data Submission Portal QC	18	2	45/60
	NSQAP Data Submission Portal Biochemical PT	18	3	45/60
	NSQAP Data Submission Portal Molecular PT	4	3	45/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–26–0573]

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 ''National HIV Surveillance System (NHSS)'' 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 September 30, 2025 to obtain comments from the public and affected agencies. CDC received 83 comments in response 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

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 diagnoses, incidence, prevalence and characteristics of persons living with diagnosed 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, and reducing health-related disparities by using quality, timely, and complete surveillance, and program data to guide HIV prevention efforts toward reducing new HIV infections and ending HIV 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 virus 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, five 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 once a year by each of the 59 health departments.

There are no revisions to data collection or changes in burden requested in this Extension. CDC requests OMB approval for an estimated 60,731 annualized burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED 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 (ACRF)	59	789	20/60
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF).	59	57	35/60
Health Departments	Case Report Evaluations	59	85	20/60
Health Departments	Case Report Updates	59	2519	2/60
Health Departments	Laboratory Updates	59	10130	0.5/60
Health Departments	Deduplication Activities	59	3032	10/60
Health Departments	Investigation Reporting and Evaluation	59	929	1/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	Initial Cluster Report Form	59	2.5	1
Health Departments	Follow-up Cluster Report Form	59	5.0	30/60
Health Departments	Annual/Closeout Cluster Report Form	59	2.5	1
Health Departments	Annual Reporting: Standards Evaluation Report (SER)	59	1.0	8

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1857–NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area (High Point Regional Health)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from a hospital that has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated organ procurement organization (OPO). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by April 20, 2026.

ADDRESSES: In commenting, refer to file code CMS–1857–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1857–NC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1857–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lindsay Pulliam, (410) 786–8674.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, under section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must establish protocols which require the hospital to notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

Section 1138(a)(2)(A) of the Act provides that a hospital may submit a request to the Secretary of the Department of Health and Human Services (the Secretary) for a waiver of the above requirements. If the requested waiver meets certain conditions specified in section 1138(a)(2)(A) of the Act, the Secretary shall grant the waiver and allow the hospital to have an agreement with an OPO other than the one designated by CMS. The Secretary may consider factors described in section 1138(a)(2)(B) of the Act when determining whether to grant the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that the Secretary shall grant a waiver if he determines that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider factors that include but are not limited to: (1) cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions