## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–26–1072]**

### 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 ''STI Surveillance Network (SSuN)'' 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 December 5, 2025, to obtain comments from the public and affected agencies. CDC received three public 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**

The STI Surveillance Network (SSuN) (OMB Control No. 0920–1072, Exp. 09/30/2026)—Revision—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention (CDC) is requesting a Revision of a currently approved information collection request (ICR) titled The STI Surveillance Network (SSuN) and approval for an additional period of three years. The Revision submitted for this ICR reflects changes to: (1) the title of the currently approved ICR; (2) the inclusion of Doxycycline Post-exposure Prophylaxis (Doxy PEP) data elements; (3) the deletion of multiple data elements no longer required; and (4) an updated anonymous patient clinic survey. The estimated burden hours for this revised collection decreases from the previously approved 7,510 to 7,237 due to decreases in the number of participating clinical sites and expected number of interviews conducted by funded jurisdictions, a result of declines in reported gonorrhea cases.

The purpose of the STI Surveillance Network (SSuN) is to enhance national capacity for STI surveillance. While U.S. jurisdictions voluntarily report STI cases to the CDC via the National Notifiable Diseases Surveillance System (NNDSS), these reports often lack essential patient demographics and detailed information on risk behaviors, treatment, co-infections, preventive services, and sexual networks.

SSuN enhances CDC's STI surveillance efforts by:

1. Providing comprehensive behavioral and demographic data on STI cases not available from standard case-based surveillance;

2. Monitoring trends in STI and HIV co-infection, screening, prevention interventions, and healthcare access among patients with gonorrhea or other STIs;

3. Providing an additional sentinel monitoring system for emerging health threats like mpox;

These data help public health authorities better understand STI trends, assess disease burden inequalities, and monitor treatment outcomes and adverse health effects among STI patients. Data will be transmitted through CDC's Secure Access Management System (SAMS) by the 15 state and local health jurisdictions (eight jurisdictions funded for both Strategy A and B, four Strategy A only jurisdictions, and three Strategy B only jurisdictions) funded to conduct SSuN activities. The revised project, SSuN Cycle 5 (2024–2029), comprises 15 US local/state health departments. SSuN recipients are funded to conduct either or both of the two core SSuN Strategies: Sentinel surveillance in specialty sexual health clinics (Strategy A) and enhanced population-based surveillance for persons diagnosed with gonorrhea and adult syphilis (Strategy B).

In Strategy A, data is abstracted from existing electronic medical records at 16 participating STI clinics across 12 funded jurisdictions (several sites utilize >1 clinical facility), utilizing information already collected during routine clinical care. This reflects a total of 384 burden hours (16 STI clinic respondents across 12 funded jurisdictions × six data transmissions × four hours per data transmission). These data are sent to the 12 funded health jurisdictions, where they are formatted and deduplicated by data managers into standardized formats. Records are also matched with the jurisdiction's HIV surveillance registry, providing data on HIV co-infection not available from other multi-jurisdictional sources. All patient records are fully de-identified and securely transmitted to the CDC six times a year. Data managers at each of the 16 clinical facilities across 12 jurisdictions receiving funding are responsible for transmitting validated datasets for these activities to CDC every other month. This reflects 2,880 burden hours for Strategy A health department data management (12 health jurisdiction respondents × six data transmissions × 40 hours per data transmission). Participating Strategy A clinics are also required to administer a one-time brief (~five minute) clinic patient survey between years 2–5 of the cycle. Clinic patient surveys will be conducted with approximately 3,000 patients across all funded sites for a total of five minutes each, resulting in 250 burden hours.

The second core data collection activity, Strategy B, includes: (1) abstraction, recoding, and reporting of all gonorrhea and syphilis cases in the collaborating jurisdiction; (2) enhanced investigations of a random sample of diagnosed individuals; and (3) health

department abstraction and registry matching for a complete census of reported cases. Enhanced investigations include clinical data abstraction from providers, registry matching, and brief demographic and behavioral interviews. SSuN recipients implement data collection protocols that provide uniformly coded data on demographics, risk factors, clinical care, laboratory data, and healthcare-seeking behaviors, which are compiled into a national dataset after quality assurance at the CDC. For Activity 1, data managers at participating health jurisdictions are responsible for transmitting validated datasets case datasets to CDC every other month, resulting in 2,640 burden hours (11 jurisdictions × six data transmissions × 40 hours per data transmission). In 2023, there were 187,833 cases of gonorrhea diagnosed and reported across the 11 Strategy B SSuN jurisdictions. Approximately 7%, or 13,148 gonorrhea cases were randomly sampled for enhanced investigation. Over past cycles, approximately 50% of patients contacted for investigation responded; we estimate this will result in 1,083 burden hours for patients with gonorrhea.

The total estimated annual burden hours are 7,237. Respondents will not receive federal funds to participate in this project. There are no additional costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average hours per response |
|---|---|---|---|---|
| Data managers at sentinel STI clinics | Electronic Clinical Record Abstraction | 16 | 6 | 4 |
| General Public—Adults (persons diagnosed with gonorrhea). | Patient interviews for a random sample of gonorrhea cases. | 6,500 | 1 | 10/60 |
| Data Managers: local/state health departments (Strategy A). | Data cleaning/validation, HIV registry matching and data transmissions for all activity components. | 12 | 6 | 40 |
| Data Managers: local/state health departments (Strategy B). | Data cleaning/validation, HIV registry matching and data transmissions for all activity components. | 11 | 6 | 40 |
| General Public—Adults (persons presenting for care in STI Clinics). | Clinic patient surveys | 3,000 | 1 | 5/60 |

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–D–9429]**

### Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs); Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs).'' FDA is issuing this draft guidance for submitters of certain PMAs to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those submitters to the current publicly available resources and associated content developed to support electronic submissions of certain PMAs and PMA supplements to FDA. This draft guidance, when finalized, is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by November 17, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2026–D–9429 for ''Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.