



BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-FY-1072; Docket No. CDC-2018-0020]

**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 proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on the proposed revision of the information collection titled "The Enhanced STD surveillance Network (SSuN)," which is the only source for enhanced and sentinel sexually transmitted disease (STD) surveillance data in the United States that: (1) serves to strengthen national and local surveillance capacity; (2) collects information on populations at risk for STDs attending healthcare facilities; and (3) provides more accurate estimates of the burden of disease,

incidence of disease, trends and impact of STDs at the population level.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0020 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments 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 Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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; and

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.

5. Assess information collection costs.

Proposed Project

The Enhanced STD surveillance Network (SSuN)- Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention seeks to request a three-year revision approval of the information collection project entitled, *The Enhanced STD surveillance Network (SSuN)*. Revisions to this submission include, removal of facility-based surveillance in family planning clinics, the addition of seven interview questions to the gonorrhea population component and eight new data elements to the facility component, and the addition of an enhanced surveillance activity to monitor adverse health outcomes of early syphilis cases with neurologic and/or ocular syphilis manifestations. The estimate of annualized burden hours will

increase from 3,052 hours to 3,479 hours as a result of the revision.

The purpose of this project is to: (1) provide supplemental information on case reports of notifiable STDs that enhances the ability of public health authorities to interpret trends in reported case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD treatment and selected adverse health outcomes of STDs; and (2) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in at-risk populations seeking STD services in specific clinical settings.

While routine STD surveillance activities are ongoing in all US states and jurisdictions, through the *National Notifiable Disease Surveillance System*, these data are often missing critical patient demographics and are of limited scope with respect to risk behavior, provider and clinical information, treatment and partner characteristics needed to direct disease control activities. *Enhanced SSuN* is the only infrastructure providing information about diagnosed and reported STD cases with respect to patient and partner characteristics, clinical presentation, screening and uptake of HIV testing, treatment patterns or provider compliance with treatment recommendations for patients receiving STD-related care.

The precursor to *Enhanced SSuN* was the *STD Surveillance Network (SSuN)*, established in 2005 as a network of collaborating state and local public health agencies to provide more comprehensive STD case-level and clinical facility information. In 2008, *SSuN* was expanded to 12 awardees to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. Activities of the previously funded *SSuN* were subsumed under the network's scope in establishing enhanced *SSuN* in 2013.

The current project comprises 10 US local/state health departments. These facilities include Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

Since the initial OMB approval in 2015, *Enhanced SSuN* has provided ongoing data addressing CDC/Division of Sexually Transmitted Disease and Prevention priorities (DSTDPP), including contributing to CDC's annual STD surveillance report, CDC's quarterly progress indicators, and informed policy discussions on expedited partner therapy, pre-exposure prophylaxis to

prevent HIV infection (PrEP), documentation of critical clinical services provided by categorical STD clinics, and on the proportion of cases treated with appropriate antimicrobial regimens, which is an essential indicator of compliance with CDC treatment recommendations.

The two major data collection components of the *Enhanced SSuN* project are grouped into two primary categories, reflecting sentinel and enhanced population-based surveillance activities. The first component includes sentinel surveillance in participating STD clinics, which monitors patient care, screening and diagnostic practices, treatment and STD-related services delivered. Participating local/state health departments have implemented common protocols to collect demographic, clinical, risk behaviors on patients presenting for care in selected facilities. Data for this activity is abstracted from existing electronic medical records at participating STD clinics, leveraging information routinely collected in the provision of clinical care. All records are fully de-identified by collaborating health departments and transmitted to CDC through secure file transport mechanisms six times annually (every 2 months). The estimated time for the clinic data managers to abstract data is 3 hours every 2 months.

The second population-focused component is comprised of two activities, including enhanced surveillance on a random sample

of persons diagnosed with gonorrhea, and enhanced surveillance on person diagnosed and reported with early syphilis with ocular/neurologic manifestations. For the first activity a random sample of all gonorrhea cases diagnosed and reported to health departments among persons residing within the participating jurisdictions are selected for enhanced interview. The second population of interest are persons diagnosed with primary, secondary, and early latent syphilis. Cases determined to have neurologic/ocular manifestations will be selected for enhanced interview/investigation. In both these activities, jurisdictions follow consensus protocols to collect uniform data on demographic characteristics, behavioral risk factors, and health care seeking behaviors.

In 2016, there were 129,434 persons diagnosed and reported with gonorrhea across the 10 participating *Enhanced SSuN* jurisdictions. Approximately 10%, or 12,943 cases were randomly sampled for enhanced investigation. Many cases were lost to follow-up because of limited contact information. Hence, the response rate for gonorrhea patient interviews in the first three years of *Enhanced SSuN* data collection was 39.3%, with approximately 5,086 respondents interviewed.

In 2016, there were 25,253 early syphilis cases reported across the 10 participating *SSuN* jurisdictions. Studies estimate that 2% of all early syphilis cases will report neurologic

and/or ocular manifestations, corresponding to 507 cases requiring additional investigation. CDC expects to interview 80% of 507 patients or 406 respondents. The 5,492 patient interviews for both the gonorrhea and early syphilis are estimated to take 10 minutes to complete for an estimated annualized burden hours of 934.

CDC will conduct an early syphilis case follow-up evaluation with diagnosing or reporting providers to ascertain additional information about physical exam findings, laboratory tests results, including cerebrospinal fluid (CSF) results, and prescribed (type and duration) treatment not present in the original case or laboratory report. CDC will collect clinical information from the diagnosing healthcare facilities for those diagnosed with early syphilis who reported neurologic/ocular symptoms (406 early syphilis cases). These evaluations can be either by direct contact with providers (phone) or through other methods such as secure fax-back, mail or other means as long as privacy of patient information can be strictly maintained.

Collection of this information is estimated to take approximately 10 minutes to complete, for 69 burden hours.

For the syphilis cases with neurologic and/or ocular manifestations only, there will be a three-month follow up interview to document resolution of symptoms. Data collection for this three-month follow-up is expected to take about five

minutes per person and will be conducted through either telephone-administered or in-person interviews. With an estimated 50% follow-up success rate, the total burden hours is estimated at 16 hours.

Data managers at each of the 10 local/state health departments will be responsible for transmitting validated datasets to CDC every month, alternating between the facility and population-based activities in *Enhanced SSuN*. This reflects 2,280 burden hours for data management (10 respondents x 12 data transmissions x 19 hours).

The total estimated annual burden hours are 3,479 for *Enhanced SSuN*. Respondents from local/state health departments receive federal funds to participate in this project. Participation of patients and of facility staff are voluntary. There are no additional costs to respondents other than their time.

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)
Data manager at Sentinel STD clinics	Record Abstraction	10	6	3	180
General Public - Adults	Interview	5,492	1	10/60	934

(persons diagnosed with gonorrhea or early syphilis)					
Diagnosing Provider	Data for early syphilis cases	406	1	10/60	69
General Public - Adults (persons with early syphilis who have neurologic/ocular manifestations)	Follow up Interview	203	1	5/60	16
Data Managers: 10 local/state health department	Data cleaning/validation	10	12	19	2,280
Total					3,479

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Chief,

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