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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-1072; Docket No. CDC-2019-0091]

**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 comment on a proposed information collection project titled "*The Enhanced STD surveillance Network (SSuN)*", which is the only source for enhanced and sentinel STD surveillance data in the United States that serves to strengthen national and local surveillance capacity, collects information on populations

at risk for STDs attending healthcare facilities, and 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-2019-0091 by any of the following methods:

- Federal eRulemaking Portal: 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, 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 Jeffrey M. Zirger, 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), (OMB Control No. 0920-1072, Exp. 09/30/2021) - 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 is requesting revision of the information

collection entitled "Enhanced STD Surveillance Network (SSuN)". Revisions to this submission include adding reported adult syphilis cases to enhanced case-based surveillance records, addition of 87 new data elements, removal of 115 data elements associated with a discontinued neurosyphilis surveillance activity, and revision of methods to include Health Department surveillance HIV registry matching activities for patients presenting for care in STD clinical facilities. This revision also includes changes to the number and identity of collaborating jurisdictions from 10 to 11 sites as a result of a recent notice of funding opportunity. The estimate of annualized burden hours for this data collection increases modestly from 3,479 hours to 6,303 hours for the revised project as a result of revisions and expanding the project from 10 to 11 awardees for the current data collection cycle.

The purpose of this project is to enhance capacity for STD surveillance and better meet CDC's disease surveillance mandate by; (1) providing more comprehensive information on reported cases of notifiable STDs to enhance the ability of public health authorities to interpret trends in 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) monitoring STD and HIV co-infection, screening, uptake of high-impact HIV prevention

and health care access trends among patients seeking care and those diagnosed with STDs in specific clinical settings.

Routine STD surveillance activities are ongoing in all US states and jurisdictions, and cases are reported to CDC through the National Notifiable Disease Surveillance System (NNDSS). However, case reports are often missing critical patient demographics and are of limited scope with respect to risk behavior, provider and clinical information, treatment, co-infection and partner characteristics - data that are needed to appropriately direct disease control activities. Enhanced SSuN is the only current surveillance infrastructure providing information on patient and partner characteristics, clinical presentation, screening and uptake of HIV testing, treatment patterns, provider compliance with treatment recommendations, HIV co-infection among persons diagnosed with STDs and use of high impact STD-related HIV prevention interventions such as pre-exposure prophylaxis.

The precursor to Enhanced SSuN was the STD Surveillance Network (SSuN), which was established in 2005 as a network of six collaborating state and local public health agencies providing 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, which funded 10 awardees to conduct core data collection activities.

The revised project, SSuN - Cycle 4, comprises 11 US local/state health departments, including Baltimore City Health Department, California Department of Public Health, City of Columbus Public Health Department, Florida Department of Health, Indiana Department of Public Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, Utah Department of Public Health and Washington State Department of Health.

Subsequent to reinstatement of OMB approval in 2018, enhanced SSuN continues to provide ongoing data addressing CDC's Division of Sexually Transmitted Disease and Prevention priorities (DSTDP), including contributing to CDC's annual STD surveillance report, CDC's quarterly and annual progress indicators, and has informed policy discussions on expedited partner therapy, pre-exposure prophylaxis to prevent HIV infection (PrEP), documented critical clinical services provided by categorical STD clinics, and provided information on the proportion of cases treated with appropriate antimicrobial regimens, which is an essential indicator of compliance with CDC

treatment recommendations and critical for addressing the emergence of antimicrobial resistance. The major data collection components of the network are grouped into two primary strategies, reflecting different sentinel and enhanced population-based surveillance methods.

The first, Strategy A, includes sentinel surveillance in STD clinics to monitor patient care, screening and diagnostic practices, HIV co-infection, treatment and assess the delivery of high impact, STD-related HIV prevention services. Participating local/state health departments are implementing common protocols to abstract demographic, clinical, risk behaviors from existing health records for patients presenting for care in 15 selected local STD Clinics. Data for this strategy is abstracted from existing electronic medical records at the participating STD clinics, leveraging information that is routinely collected in the provision of clinical care. A brief 10-item de-identified survey will be administered at registration to 350 patients presenting consecutively to the clinics once annually to assess demographics not collected in the course of routine patient care. All survey and medical records are fully de-identified by collaborating health departments and transmitted to CDC through secure file transport mechanisms six times annually (every two months). The estimated time for the STD clinic data managers to abstract data from

electronic health records and process patient surveys is four hours every two months.

The second surveillance activity in SSuN - Cycle 4, Strategy B, includes abstraction of all reported gonorrhea and adult syphilis cases from the jurisdiction's routine STD surveillance data management system, recoding case data to conform with common protocols and performance of a registry match with the jurisdictions HIV case surveillance system. A random sample of gonorrhea cases is selected, and enhanced investigations conducted on the gonorrhea cases selected in the random sample. Enhanced investigations include clinical data collection from reporting providers, searching existing health department disease and laboratory registries for additional diagnostic and laboratory data, and attempting to obtain brief patient behavioral and demographic interviews on patients selected in the random sample. Estimated time for patients to complete these interviews is 10 minutes or less depending on skip patterns. For these activities, jurisdictions follow consensus protocols for all data collection to provide uniformly coded data on demographic characteristics, behavioral risk factors, clinical care, laboratory data and health care seeking behaviors.

There were 164,177 cases of gonorrhea diagnosed and reported across the 10 participating enhanced SSuN jurisdictions

funded in 2018. Approximately 10.6%, or 17,512 cases were randomly sampled for enhanced investigation and full enhanced investigations were completed for 7,132 (40.7%). The remaining cases were lost to follow-up due to insufficient contact information, or the patient failed to respond to multiple contact attempts. Similar performance is anticipated in the revised project, which includes eleven jurisdictions which reported 173,605 gonorrhea cases in 2017. Approximately 17,360 cases will be sampled and 7,380 completed patient investigations are anticipated.

Data managers at each of the 11 local/state health departments are responsible for transmitting validated datasets to CDC every month, alternating between strategies A and B each month. This reflects 3,168 burden hours for data management (11 respondents x 12 data transmissions x 24 hours). Data managers will also be responsible for conducting HIV registry matching bimonthly; registry matches are estimated to take 20 hours for matching, cleaning and recoding records into approved data formats. Across all 11 jurisdictions, this represents an additional data management burden of 1,320 hours (11 sites x 6 annual matches x 20 hours).

The estimated annual burden hours for data management staff in funded jurisdiction is 4,488 hours (3,168 + 1,320) for the revised information collection. Respondents from local/state

health departments receive federal funds to participate in this project. Participation of patients and of facility staff is voluntary. The total estimated annual burden hours for which CDC seeks approval is 6,303. 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 managers at sentinel STD clinics	Electronic Clinical Record Abstraction	11	6	4	264
General Public - Adults (persons diagnosed with gonorrhea)	Patient interviews for a random sample of gonorrhea cases	7,380	1	10/60	1,230
Data Managers: 11 local/state health department	Data cleaning/validation, HIV registry matching and data transmission for Strategy A and Strategy B	11	12	44	4,488
General Public - Adults (persons visiting STD clinics and	Clinic Survey	3850	1	5/60	321

participating in the clinic survey)					
Total		11,274			6,303

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