National Syringe Services Program (SSP) Evaluation

OMB Control Number: 0920-New

Supporting Statement A

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**Goals of the study:** The primary goal of this project is to: 1) assess and monitor Syringe Services Programs (SSP) operational characteristics and services, client characteristics and drug use patterns, funding resources, community relations, and key operational and programmatic successes and challenges, and 2) support timely analysis and dissemination of national program evaluation survey findings.

**Intended Use:** Data from this project will be used to inform planning and evaluation of prevention programs that aim to reduce injection-related adverse health outcomes among people who inject drugs. The data collected will establish a system for ongoing program evaluation and improvement and help ensure quality service delivery at SSPs nationwide.

**Methods to be used to collect data:** The survey will be administered annually using the most updated national directory of SSPs during each survey administration. SSPs listed in the directory will be contacted via email and invited to complete a 35-minute program survey. Participants will have options to complete the survey online and via telephone or videoconferencing modalities.

**The subpopulation to be studied:** During each annual survey administration, all SSPs registered in the publicly available North American Syringe Exchange Network (NASEN) directory of SSPs in the United States will be contacted and invited to participate in the survey, with a goal of 80% of all SSPs in the United States completing the survey.

**Issues considered during COVID-19 pandemic:** Since this survey will be administered remotely (either online or via remote interview), participation will not involve any face-to-face interaction with an interviewer or other project staff. Participation in the survey is not expected to affect SSP operations.

**How data will be analyzed:** Data will be analyzed using SAS software or other appropriate statistical packages. Univariate and bivariate statistics and multivariable regression methods will be used to address the objectives of the project.

A. Justification

1. **Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for new data collection under the “National Harm Reduction Technical Assistance and Syringe Services Program (SSP) Monitoring and Evaluation” Notice of Funding Opportunity, PS19-1909. This project aims to improve the ability of CDC and local and state partners to monitor syringe services programs (SSPs) nationally, with the overall goal of supporting, sustaining, and improving SSPs nationwide. Over the course of three years, an annual program survey will be conducted with support of key partners through a cooperative agreement, in order to help build a stable foundation for ongoing SSP monitoring, establish a system for program improvement, and ensure quality service delivery at SSPs nationwide. The partners include the University of Washington (UW)(the awardee), Don Des Jarlais from New York University, and the North American Syringe Exchange Network (NASEN). Don Des Jarlais and NASEN have historically conducted the survey, but have not been able to conduct it consistently since 2013. The two main goals of the project are to 1) assess and monitor SSP operational characteristics and services, client characteristics and drug use patterns, funding resources, community relations, and key operational and programmatic successes and challenges, and 2) support timely analysis and dissemination of national program evaluation survey findings.

Background, Need and Circumstances Motivating the Request

The opioid crisis in the United States has led to steep increases in overdose (1), hepatitis C virus (HCV) incidence (2) and HIV clusters and outbreaks among people who inject drugs (PWID)(3-6). These alarming trends indicate an urgent need to strengthen interventions to prevent morbidity and mortality and transmission of infectious disease among PWID. SSPs are evidence-based, highly effective programs that prevent the spread of infectious disease (e.g., HIV and HCV) related to injection drug use (IDU) at the community level (7). SSPs have expanded in many areas in the United States to respond to the increasing need to provide HIV and HCV prevention and other health and social services to PWID and their communities. The Dave Purchase Memorial Survey of SSPs has been previously implemented through a collaboration between New York University (NYU) and the North American Syringe Exchange Network (NASEN) but has not been consistently conducted since 2013 (8). Due to an increase in HCV and HIV related to IDU (9,10), it is imperative to understand the operational structures and services provided for the prevention of these infectious diseases and other injection-related harms. The proposed evaluation program will strengthen and improve the capacity of SSPs to conduct regular monitoring and evaluation to ensure their program goals and objectives are met.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) to “…cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…” **(Attachment 1).**

1. **Purpose and Use of Information Collection**

The primary purpose of the project is to strengthen and improve the capacity of SSPs to conduct regular monitoring to ensure that comprehensive prevention services are provided and meets the needs of PW. The project will include all SSPs that are listed in a publicly available directory of all known SSPs in the United States, maintained by the North American Syringe Exchange Network (NASEN; <https://nasen.org>). SSPs will be sent a letter of invitation (Attachment 3) to participate in an approximately 35-minute program survey(Attachments 7, 8). The Dave Purchase Memorial Survey was a national survey of syringe services programs (SSPs) that collected data on program operations and outcomes. For continuity purposes, and because community partners and SSPs are familiar with this survey and its purpose, the CDC will retain the survey name, “The Dave Purchase Memorial Survey”. The letter of invitation will include options and instructions for completing the survey via different modalities to enhance feasibility and comfort in completing the survey. For example, the survey will be offered online via the Research Electronic Data Capture (REDCap)or a similarly secure web-based application (Attachments 10, 11). Other modalities for survey administration will include a coordinated telephone or videoconferencing interview with NSSPE project staff. SSPs will be sent reminder letters (Attachment 4) during the approximate 3-month data collection period. SSPs that do not respond to prior reminders, will be sent one final reminder (Attachment 5), and if the SSPs still do not participate, one question on why the SSPs did not complete the survey will be collected to improve subsequent implementation of the survey (Attachment 6).

This project will help develop partnerships with SSPs to collect information to strengthen SSP effectiveness in reducing infectious disease related to IDU and to inform other prevention efforts for PWID and their communities. As SSPs continue to expand services and build local partnerships, these programs could be ideal long-term partners for national and local surveillance and to inform HIV and HCV elimination efforts.

1. **Use of Improved Information Technology and Burden Reduction**

Data will be collected electronically to minimize burden to respondents. The survey will be offered online using a secure web-based application, like REDCap. This self-administered survey modality will include programmed logic checks, skip patterns, and range values, thereby improving the quality of the data and reducing burden for respondents. Respondents who do not wish to complete the survey online via secure web-based application will be given other options including to schedule a telephone or videoconference interview with a study interviewer. All data, regardless of survey modality used, will be entered into a secure web-based application, like REDCap. The burden to respondents will remain the same regardless of mode of administration.

1. **Efforts to Identify Duplication and Use of Similar Information**

CDC has established relationships with other federal stakeholders and consultants during the conception and development of this project. Consultations have been held with state and local health departments, the National Institutes of Health (NIH), and other agencies. To promote collection of data that can be used by multiple agencies, ongoing communications with these federal, state, and local partners will continue for the duration of this project. Other surveys may have obtained data related to topics covered in this proposed information collection, but most were more limited in the questions they ask, the populations they represent, the geographic areas covered, or all of these factors.

The Substance Abuse and Mental Health Services Administration (SAMHSA) collects annual national data on substance use services through the National Survey of Substance Abuse Treatment Services (N-SSATS) (OMB #: 0930-0106) and on characteristics of persons in substance use treatment through the Treatment Episode Data Set (TEDS). However, the current program survey seeks to understand the breadth of services and operational characteristics provided at SSPS on an annual basis, beyond substance use treatment centers. Moreover, there is currently no systematic, ongoing data collection system for monitoring a range of SSP services and aggregating characteristics of SSP clients. In addition, the “Injection Drug Use Surveillance Project,” (OMB 0920-21KH) is focused on drug use patterns of *clients* of SSPs. Data from the current information collection request is different and will provide a program perspective which will allow the CDC and its state and local partners to monitor prevention services provided by SSPs nationwide. Data will also help build the capacity of SSPs to conduct monitoring and evaluation and inform prevention planning among national, state, and local partners.

NIH has recently funded two research projects that involve collecting information from SSPs in the US. However, each of these surveys differ in focus and scope from the proposed information collection, and both are time-limited, research projects. One survey focuses on medical models of care, while the other focuses on recent impacts of COVID-19 on SSPs. The proposed information collection intends to establish an ongoing, annual evaluation system of SSPs and primarily seeks to monitor provision of evidence-based services to identify program gaps and needs. Senior leaders from CDC and NIH, as well as principal investigators of the various surveys, have communicated throughout the development of this project and will continue to coordinate activities, avoid duplication, and ensure that objectives are met throughout the duration of the project.

1. **Impact on Small Businesses or Other Small Entities**

Data will be collected from SSPs, which are typically small, not-for-profit entities. The questionnaire has been held to the absolute minimum required for the intended use of the data. Program directors or designated staff will be able to complete the brief questionnaire at a time that is convenient for them through the method of their choosing (e.g., online or by scheduling a telephone interview).

1. **Consequences of Collecting the Information Less Frequently**

Data collection activities under the current funding period are expected to occur annually, as funding and timelines allow. It is expected that if successful, these activities will continue beyond this initial funding period to establish a routine activity to support continuous program monitoring and improvement. Data for prevention and resource planning need to be collected on an annual basis to meet reporting requirements of CDC and to inform program planning and funding.

SSPs are an important component of community-level public health interventions addressing the negative sequelae associated with IDU. Although these programs have operated in the United States for over 30 years, there is a lack of standardized and systematic information about how they are implemented, what services they offer, and who uses them. The consequences of not routinely collecting this information include inadequate program monitoring and evaluation, lack of understanding of national program gaps and needs, and inability to properly support programs to address these gaps and better serve their clients.

There are no legal obstacles to reduce the burden.

1. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the guidelines of 5 CFR 1320.5.

1. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A 60-day Federal Register Notice to solicit public comments was published in the *Federal Register* on 02/25/2021, Volume 86, Number 36, Pages 11532-11533 (**Attachment 2**). There were no substantive comments.

1. **Explanation of any Payment or Gift to Respondents**

Payments will be given to programs to increase participation and response rates. An NIH-funded survey of SSPs conducted by Cornell University provided a $75 token of appreciation for completing the survey and was only able to achieve a 60% response rate, despite strong efforts of project staff in reaching out to programs and providing multiple ways to complete the survey. While the low response rate may be in part due to the COVID-19 pandemic, based on the experiences with collecting information from SSPs in these previous surveys, a token of approximately $125 is an appropriate amount to encourage participation in the proposed NSSPE project, and it will help achieve a high response rate. Specifically, a response rate below 80% may lead to response biases that will affect our ability to make conclusions based on the data. In addition, a  2018-2019 qualitative study conducted by CDC’s Division of HIV/AIDS Prevention to assess HIV, viral hepatitis, substance use treatment, and overdose prevention services offered by SSPs, provided each SSP an incentive as high as $3000 to conduct 20 interviews or $150 per interview. The proposed NSSPE project seeks to collect data from all known SSPs in the United States to ensure accurate program data to inform prevention interventions and CDC’s HIV and HCV elimination efforts.

With increased response rates, the reliability of the data will be improved as the sample of participating SSPs will be more representative of the underlying population of all known SSPs in the United States.

1. **Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The information collection pertains to organizations (i.e. SSPs), not individuals or households. Some limited information will be collected about SSP clients (e.g., the estimated distribution of SSP clients by gender and race/ethnicity), but these data will be collected in aggregate from responding SSPs rather than individual clients. No individual-level information or potentially identifying information about SSP clients or any other individuals will be collected. Any SSP staff member(s) can complete the survey on behalf of the SSP. No information that could be used to identify the staff member(s) completing the survey will be collected. Data collected from responding SSPs will be stored and accessed locally and at CDC by a survey identification number.

The PRA Coordinator in the National Center for HIV/AIDS, Viral Hepatitis, STDs, and Tuberculosis (NCHHSTP)at CDC has determined that the privacy act does not apply.

Participation in the survey is optional. SSPs can abstain from participating by simply not accessing the survey, not submitting survey responses, or not scheduling a telephone interview. All participants will be informed that data about their programs will be kept private and secure and that the data will be reported only in aggregate format. Interviewer-administered surveys over the phone or a videoconferencing platform will be conducted by trained staff in a private location where the questions and responses cannot be overheard by others.

Data for this project will be collected using a web-based application like REDCap, a secure web-based data collection program. For respondents who choose to complete the online survey, data entered by respondents will be transmitted directly to the secure web-based application server rather than stored locally. Respondents who choose to complete the survey for example, via telephone or videoconferencing will provide verbal responses to be entered into REDCap by the interviewer at the time of interview. The award recipient will routinely download and clean the data files and will provide routine recruitment monitoring reports to CDC. At the conclusion of data collection, the award recipient will process all data collected and produce a clean, final data set for use by CDC. This dataset will be sent via a secure network to CDC.

Data from the proposed information collection will be transmitted to CDC using the internet-based system that is used to transmit HIV/AIDS surveillance data to CDC. This system is referred to as the Secure Data Network (SDN). Databases submitted through the SDN must be encrypted before being sent to CDC. Encryption security for all data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES).

1. **Institutional Review Board (IRB) and Justification for Sensitive Questions**

IRB Approval

The approved Project Determination Form (Attachment 9) indicates that because the project is a program evaluation activity, the protocol will not be reviewed by CDC’s IRB.

Sensitive Questions

This information collection will ask responding SSPs a variety of questions about program services, operational characteristics, and challenges. Some of this information could be viewed as sensitive, as it involves providing harm reduction services to people who inject drugs. Furthermore, some SSPs may be reluctant to divulge information about program operations or unmet client needs. However, collection of this information will improve understanding of national gaps in services for people who inject drugs and support program enhancement to reduce infectious disease transmission and other harms related to IDU.

The context in which questions are asked help to overcome their potential sensitivity. Several steps will be taken to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

* + Respondents will receive clear information about privacy and confidentiality of survey responses and how and by whom the information will be used.
  + Respondents will be made aware that the survey is sponsored by CDC and the award recipient, and phone numbers will be provided if respondents have questions about the survey.
  + The program survey is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy of the data are reiterated.
  + Most questions allow for responses of “don’t know” or “refuse to answer.”
  + The provision of a token of appreciation indicates clearly to the respondent that the information is important to the survey sponsors.

1. **Estimates of Annualized Burden Hours and Costs**

The annualized estimates of respondent burden for each data collection instrument is provided below. We intend to invite all SSPs listed in the publicly available NASEN directory to participate in the survey (approximately 400 to 600 SSPs over the next few years. To be eligible to complete the survey, SSPs must have provided at least some services during the recall period of the respective administration of the survey (e.g., previous calendar year). SSPs can agree or decline to participate in the survey. We anticipate that approximately 20% of 600 SSPs will decline to complete the survey, yielding approximately 480 completed surveys per year. However, given that this is the first survey of SSPs funded by CDC during the COVID-19 pandemic, it makes it challenging to predict response rates.

We estimate that it will take an average of 35 minutes to complete the survey, regardless of how the respondent chooses to complete it (i.e., self-administered online or interviewer-administered by phone or videoconferencing). In addition, in the first year of survey administration, a short module to capture key metrics for calendar year 2020 will be added to the main survey to establish baseline measures (Attachment 7); however, this brief 2020 module will be dropped from the survey in subsequent years (Attachment 8). The addition of the module in year 1 adds a couple of minutes to the burden and has been incorporated into the overall estimated burden of 35 minutes for survey completion, thus we have one burden line for the survey, regardless of year of administration.

SSPs that do not respond to the initial survey invitation will be sent reminders to complete the survey over the duration of the survey implementation period. The final reminder will include a link to a single question for SSPs that choose not to complete the survey about why they declined to complete the survey. Given the uncertainties in response rates described above, we are requesting enough burden hours to allow at least 80% of SSPs to respond to this question. We also estimate that it will take 2 minutes to respond to non-response survey item (Attachment 6).

Burden estimates were informed by mock interviews with staff from CDC, award recipient, and a few SSPs.

The estimates in the table below cover the time that each respondent will spend communicating with the project staff to answer survey questions.

**Exhibit 12 A: Estimates of Annualized Burden Hours (Based on maximum number of participating SSPs (n=480)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Respondent | Form | No. of Respondents | No. of Responses per Respondent | Average Burden per Response  (hours) | Total Burden(in hours) |
| All participating SSPs | Survey  (Att 7,8) | 480 | 1 | 35/60 | 280 |
| Non-responding SSPs | Non-Response Survey Item  (Att 6) | 480 | 1 | 2/60 | 16 |
| Total Annualized Burden |  |  |  |  | 296 |

**B. Estimated Annualized Cost to Participants**

Note: The hourly rate was determined by using data obtained from the U.S. Department of Labor, Bureau of Labor Statistics

(<http://www.bls.gov/cps/cpsaat39.htm>). The 2019 rate for “social and community service managers” was used.

**Exhibit 12 B: Annualized Cost to Respondents**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | No. of Participants | No. of Responses per Respondent | Total Burden Hours | Hourly wage rate | Total Respondent Cost |
| All participating SSPs | 480 | 1 | 280 | $31.08 | $8,702 |
|
|
| Non-responding SSPs | 480 | 1 | 16 | $31.08 | $497 |
| Total Annualized Cost |  |  |  |  | $9,199 |
|

1. **Estimates of Other Total Annual Cost Burden to Participants or Record Keepers**

There are no other costs to participants associated with this proposed collection of information.

1. **Annualized Cost to the Federal Government**

The annualized cost to the government for one year is $278,996 and for the three years is estimated to be $836,988. The annualized cost is summarized in Exhibit 14.A.

**Exhibit 14.A. NSSPE Annualized Cost to the Federal Government**

|  |  |  |
| --- | --- | --- |
| Expense Type | Expense Explanation | Annual Costs  (dollars) |
| Direct Costs to the Federal Government | Personnel | $153,996 |
| Epidemiologist-14 1 15% $19,309 |
| Epidemiologist-13 1 15% $16,341 |
| Epidemiologist-13 1 75% $81,701 |
| Epidemiologist-12 2 15% $13,742 |
| Epidemiologist-12 1 25% $22,903 |
|  | Cooperative agreement funds | $125,000 |
|  | TOTAL COST TO THE GOVERNMENT | $278,996 |

\*Salary estimates were obtained from the U.S. Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/.

The personnel related to the NSSPE data collection include project officers (epidemiologists) at the GS-12, 13, and 14 levels, and a cooperative agreement. Travel is related to conducting site visits.

The information collection described in this request will be funded through cooperative agreements with state and local health departments through fiscal year 2021. CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments.

1. **Explanation for Program Changes or Adjustments**

This is a new data/information collection.

|  |  |
| --- | --- |
| **Annual Survey Activities** | **Estimated Time Schedule**  **Based on Expected OMB Approval** |
| Begin Data Collection: Year 1 | 3 months after OMB approval |
| End Data Collection and Clean Data: Year 1 | 7 months after OMB approval |
| Complete Analysis of Data: Year 1 | 12 months after OMB approval |
| Publication of Data: Year 1 | No more than 14 months after OMB approval |
| Begin Data Collection: Year 2 | 15 months after OMB approval |
| End Data Collection and Clean Data: Year 2 | 18 months after OMB approval |
| Complete Analysis of Data: Year 2 | 23 months after OMB approval |
| Publication of Data: Year 2 | No more than 25 months after OMB approval |
| Begin Data Collection: Year 3 | 26 months after OMB approval |
| End Data Collection and Clean Data: Year 3 | 29 months after OMB approval |
| Complete Analysis of Data: Year 3 | 33 months after OMB approval |
| Publication of Data: Year 3 | No more than 36 months after OMB approval |

1. **Plans for Tabulation and Publication and Project Time Schedule**

The survey will be administered up to three times during this approval period; approval is requested for 3 years. The following is a brief overview of the project timeline.

Data from the NSSPE will inform prevention programs services and increase existing knowledge about drug-related behaviors and risk. See Attachment 12 for sample analysis tables.

Most of the results are expected to be useful at the local level, while other results will be more meaningful aggregated regionally or nationally. CDC, in collaboration with the award recipient University of Washington, has primary responsibility for the release of data aggregated from all participating SSPs. These data will be distributed to agencies, researchers, policy makers, and other interested parties through presentations at local, national, and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars.

Furthermore, CDC will regularly publish an SSP surveillance report using data collected annually. Depending on publication schedules, these reports will be published within 12-18 months of the end of data collection.

National data results will be released through national publications and presentations at conferences. Epidemiologic profile reports, and presentations to local SSPs and at local conferences and workshops.

1. **Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is not inappropriate.

1. **Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

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