PS22-2208 Component 2 (Strengthening Syringe Services Programs)Program Evaluation

OMB Control Number: 0920-XXXX
New

Supporting Statement A

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Table of Contents

Section

EXHIBITS

List of Attachments

Attachment number	Document description
1	Authorizing Legislation
2	NASTAD Baseline Survey Invitation
3	NASTAD Quarter 1 Survey Invitation
4	NASTAD's Strengthening SSPs Baseline Survey
5	NASTAD's Strengthening SSPs Quarterly Survey
6	Screenshots of Program Evaluation for PS22-2208 Component 2 Baseline Survey
7	Screenshots of Program Evaluation for PS22-2208 Component 2 Quarterly Survey
8	60-Day Federal Register Notice
9	Public Comments in Response to 60-Day FRN
10	Privacy Act Determination/Privacy Impact Assessment
11	Project Determination
12	Sample analysis tables

Goals of the study: PS22-2208 Component 2 serves as a coordinated and accountable mechanism for funding syringe services programs (SSPs) to support implementation and expansion of services in areas disproportionately affected by infectious disease consequences of injection drug use. This project will collect monitoring and evaluation data from funded SSPs for program evaluation as well as to report annual project performance reports and stratified aggregate data to CDC.

Intended Use: The primary purpose of this information collection is to monitor and evaluate the PS22-2208 Component 2 funding opportunity's overall goal of supporting SSP subrecipients in meeting the needs of people who use drugs (PWUD) and reducing infectious disease and other harms related to drug use.

Methods to be used to collect data: SSPs funded by NASTAD through component 2 of PS22-2208 will be sent a 25-minute baseline program evaluation survey at the start of project implementation, and a 15-minute quarterly program evaluation survey in the following three quarters of the project period. For Years 2-5, newly funded SSPs will be sent the baseline survey at the start of project implementation, and all existing funded SSPs will receive the quarterly program evaluation survey in the following three quarters of the project period. Funded SSPs will primarily complete the survey online in REDCap, with options to complete via telephone or videoconferencing modalities.

The subpopulation to be studied: The survey will be sent to SSPs funded through PS22-2208 and will evaluate program implementation and service delivery supporting people who use drugs.

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 by the recipient of PS22-2208 Component 2 (using SAS software or other appropriate statistical packages) and aggregate data will be reported annually to CDC.

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 Viral Hepatitis (DVH) requests a NEW 3-year approval for data collection for the evaluation of Component 2 under Notice of Funding Opportunity, PS22-2208 “Strengthening Syringe Services Programs”. The primary purpose of this information collection is to evaluate the overall goal of the PS22-2208 Component 2 syringe services programs (SSPs) funding opportunity, which is to support SSP subrecipients in meeting the needs of people who use drugs (PWUD) and reducing infectious disease and other harms related to drug use.

PS22-2208 Component 2 serves as a coordinated and accountable mechanism for distribution of funding to SSPs to support implementation and expansion of services in areas of the United States, Territories, and Tribal Nations disproportionately affected by infectious disease consequences of injection drug use. Project activities will directly contribute to establishing and expanding a national SSP infrastructure and prevention of infectious disease consequences of drug use. CDC has funded the National Alliance of State and Territorial AIDs Directors (NASTAD) to implement this project. NASTAD, in partnership with University of Washington, will collect evaluation data from funded SSPs through their internal mechanisms, both for their internal evaluation as well as semiannual and annual project performance reports and stratified aggregate data to CDC.

The survey will include questions on operational and programmatic characteristics, and quantity of prevention and treatment services provided during the specified evaluation period.

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…” and full text can be found in attachment 1 (Authorizing Legislation).

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 also been shown to be cost-effective in preventing HIV infection (8). In order for these programs to be most effective, sustained and flexible funding must be made available to promote continuous and expanded service provision (9). 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 (10). Due to an increase in HCV and HIV related to IDU (11,12), it is imperative to support and strengthen SSPs in the United States, Territories and affiliated states, and tribal nations through the provision of funding. The proposed evaluation will evaluate PS22-2208 Component 2 with the overall goal of identifying progress made by SSP subrecipients towards PS22-2208 Component 2 goals and identified outcomes.

Of note, The National Survey of Syringe Services Programs (NSSSP) (0920-1359), which is funded under PS22-2208 Component 1, aims to assess, analyze, and disseminate findings related to SSP operational characteristics using a publicly available directory of known SSPs. The NSSSP is a voluntary survey that goes out to all SSPs regardless of whether they are funded by Component 2 or not. While one data element from the NSSSP may be used to determine impacts of Component 2 funding on SSP program outcomes, SSPs funded through Component 2 may not necessarily complete the NSSSP and the NSSSP will not provide complete program evaluation on SSPs funded through Component 2.

2. Purpose and Use of Information Collection

The primary purpose of the project is to evaluate the PS22-2208 Component 2 funding opportunity, which is to support SSP subrecipients in meeting the needs of people who use drugs (PWUD) and reducing infectious disease and other harms related to drug use. The Component 2 recipient, NASTAD, uses an innovative model for funding SSPs intended to reduce the burdens related to receiving federal funding to community-based organizations, like

SSPs. This information collection will be used by NASTAD to demonstrate to CDC how funding SSPs can help better serve people who use drugs and reduce infectious disease consequences of drug use. Without this data collection, NASTAD will have significant gaps in understanding the impact of Component 2 on SSP implementation efforts in support of reducing infectious disease and overdose among people who use drugs.

The project will include all PS22-2208 SSP subrecipients (up to 200 programs). Subrecipients will receive an e-mail invitation to complete a baseline REDCap survey at funding start as found in attachment 2 (NASTAD Baseline Survey Invitation) and an e-mail invitation to complete a quarterly survey at the end of each funded quarter as found in attachment 3(NASTAD Quarter 1 Survey Invitation). Informal reminders may take place during standing meetings (i.e., videoconferences and calls) with NASTAD. If the survey is not completed after one month, NASTAD will collaborate with the subrecipient to determine an alternate method of survey completion. The baseline survey can be found in attachment 4 (NASTAD's Strengthening SSPs Baseline Survey) and the quarterly survey can be found in attachment 5 (NASTAD's Strengthening SSPs Quarterly Survey).

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 PWUD and their communities. Additionally, the project will help CDC understand how the provision of funding to SSPs contributes to sustaining and enhancing programmatic capacity. As SSPs continue to offer and expand services over time, additional prevention and treatment resources will become available for PWUD and their communities. Fully evaluating SSP service provision and utilization will help CDC identify programmatic successes, needs, and gaps in services for future support.

3. 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, REDCap. Screenshots of the baseline survey can be found in attachment 6 (Screenshots of Program Evaluation for PS22-2208 Component 2 Baseline Survey) and screenshots of the quarterly survey can be found in attachment 7 (Screenshots of Program Evaluation for PS22-2208 Component 2 Baseline Survey). 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.

4. Efforts to Identify Duplication and Use of Similar Information

Significant effort has been made by NASTAD, in collaboration with CDC, to ensure that the program evaluation for Component 2 only collects data that cannot be acquired from other sources. The CDC project team is aware of other data collection efforts that have some similarities, but this data collection is uniquely designed to evaluate NASTAD's SSP subrecipients in order to report outcomes and progress related to Component 2.

Strengthening Syringe Services Programs (PS22-2208), Component 1 administers an annual survey (the National Syringe Services Program Evaluation survey, OMB #: 0920-1359) to SSPs nationwide to understand the breadth of services and operational characteristics provided at SSPs on an annual basis. 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 component 2 program evaluation survey seeks to specifically evaluate the SSP subrecipients funded through Component 2 and collects information beyond what is captured through the two previously mentioned efforts (operational characteristics SSPs and substance use treatment centers. Quantitative data on the number of prevention and treatment services provided in-person, through tele-health, and through referral to off-site care, during the specified evaluation period will be collected. This information collection request also differs from the previously mentioned efforts by using quarterly evaluation surveys to capture timely changes in operational and program characteristics in order to improve program planning and identify unmet needs of SSP subrecipients.

In addition, the "Injection Drug Use Surveillance Project," (OMB 0920-21KH) is focused on drug use patterns of *participants* of SSPs. In this case, quantitative data on SSP services provided will be collected, which will allow the CDC and the 2208 Component 2 implementing partner, NASTAD, in partnership with University of Washington, to monitor 22-2208 SSP subrecipient

programs throughout the course of the funding period.

5. Impact on Small Businesses or Other Small Entities

Data will be collected from 2208 Component 2 SSP subrecipients, which are predominantly 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 questionnaire at a time that is convenient for them through the method of their choosing (e.g., online or by scheduling a telephone interview).

6. Consequences of Collecting the Information Less Frequently

Data collection activities under the current funding period are expected to occur quarterly, as funding and timelines allow. It is expected that these program evaluation activities will continue during the duration of the funding period. Program evaluation data need to be collected on a quarterly basis to inform program planning, identifying unmet needs, and to detect changes in SSP service provision and operational capacity resulting from this funding.

SSPs are an important component of community-level public health interventions addressing the negative sequelae associated with injection and non-injection drug use. 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 from SSP subrecipients include inadequate program monitoring and evaluation, inability to make future informed decisions regarding program funding and implementation strategy planning, and inability to properly support programs to address these gaps and better serve their participants.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. 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 August 25, 2023, Volume 88, Number 165, Pages 58278-58280 and can be found in Attachment 8 (60-Day Federal Registry Notice). There were 3 public comments received that can be found in attachment 9 (Public Comments in Response to 60-Day FRN). None of the comments received were related to this project and were not deemed substantive.

NASTAD, as the recipient and implementer of PS22-2208 Component 2, led the planning and design of this survey to evaluate their progress and responsiveness to the CDC performance measures outlined in the PS22-2208 Notice of Funding Opportunity. NASTAD received funding for Component, in part, because of their deep expertise surrounding SSPs and their ability to collaborate and consult with external partners to ensure feasibility and minimized burden of any program evaluation efforts.

9. Explanation of any Payment or Gift to Respondents

No payment will be given to survey respondents for survey completion, as this activity serves as the primary mechanism for program evaluation.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CIO's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. Activities do not involve the collection of individually identifiable information as outlined in attachment 10 (10_Privacy Act Determination/Privacy Impact Assessment). The information collection pertains to organizations (i.e. SSPs), not individuals or households.

No potentially identifying information about SSP participants 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 by a survey identification number. CDC will only receive survey data in aggregate.

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

IRB Approval

The intent of the activity is to collect data for program evaluation purposes, there is no intent to engage in research and the data collection activities do not constitute human subjects research in accordance with 45 CFR 46 requiring review and approval by an institutional review board.

This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l)and can be found in attachment 11 (Project Determination).

Sensitive Questions

Respondents are managers/administrators of Syringe Services Programs who will provide monitoring and evaluation data. Personally identifiable information is not being collected; data for evaluation and performance monitoring are not sensitive.

12. Estimates of Annualized Burden Hours and Costs

The annualized estimates of respondent burden for each data collection instrument is provided below. While it is difficult to project funding availability and thus the total number of SSP subrecipients in future years of this activity, we estimate 65-200 SSP subrecipients will be requested to participate in the baseline and quarterly surveys.

We estimate that it will take an average of 70 minutes to complete the baseline survey and three quarterly surveys, regardless of how the respondent chooses to complete it (i.e., self-administered online or interviewer-administered by phone or videoconferencing). This accounts for the amount of time SSPs take collecting requested data.

NASTAD will reach out via e-mail or phone to coordinate an alternate method of completion for SSPs that do not respond to the initial survey invitation.

Burden estimates were informed by mock interviews with staff NASTAD.

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=200)

Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden (in hours)
All subrecipients	NASTAD Strengthening SSPs Evaluation: Baseline survey	200	1	25/60	83
All subrecipients	NASTAD Strengthening SSPs Evaluation: Quarterly survey	200	3	15/60	150
Total Annualized Burden					233

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 2022 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	200	4	233	$34.55	$8,050.15
Total Annualized Cost					$8,050.15

13. 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.

14. Annualized Cost to the Federal Government

The annualized cost to the government for one year is $365,174 and for the three years is estimated to be $1,095,522. 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 Epidemiologist-14 1 15% $18,436 Epidemiologist-13 1 25% $26,002 Epidemiologist-13 1 50% $52,004 Epidemiologist-12 1 25% $21,866 Epidemiologist-12 1 25% $21,866	$140,174
	Cooperative agreement funds	$225,000
	TOTAL COST TO THE GOVERNMENT	$365,174

*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/2023/general-schedule/.

The annualized cost to the federal government includes personnel related to the PS22-2208 Component 2 data collection, including project officers (epidemiologists) at the GS-12, 13, and 14 levels, and cooperative agreement funds.

The information collection described in this request will be funded through the cooperative agreement “Strengthening Syringe Services Programs” (PS22-2208) with NASTAD. This cooperative agreement ends 7/31/2027 and we expect to collect data from PS22-2208 Component 2 annually until the end of the cooperative agreement.

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The baseline survey or quarterly survey will be administered up to 12 times during this approval period; approval is requested

for 3 years. The following is a brief overview of the project timeline.

Data from the Program Evaluation for PS22-2208 Component 2 will inform PS22-2208 Component 2 program evaluation efforts and planning. See Attachment 12 (Sample Analysis Tables) for sample analysis tables.

Findings from this data will be useful at the program level and will inform program evaluation. CDC will receive semi-annual and annual reports from the NASTAD team. The NASTAD team will seek opportunities for further dissemination of project findings through success stories, webinars, and other resources and opportunities. Accomplishments and lessons learned will be disseminated to wider public health networks on an annual basis through white paper publications and relevant presentations and will inform ongoing organizational capacity development across other CDC and HRSA cooperative agreements where relevant.

Quarterly Survey Activities	**Estimated Time Schedule Based on Expected OMB Approval**
Begin Data Collection: Year 1, Quarter 3	0 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis of Data: Year 1, Quarter 3	3 months after OMB approval
Begin Data Collection: Year 1, Quarter 4	3 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data : Year 1, All Quarters	6 months after OMB approval
Begin Data Collection: Year 2, Quarter 1	6 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data: Year 2, Quarter 1	9 months after OMB approval
Begin Data Collection: Year 2, Quarter 2	9 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data : Year 1, All Quarters	12 months after OMB approval
Begin Data Collection: Year	12 months after OMB approval

2, Quarter 3	
End Data Collection, Clean Data, and Complete Analysis and Report of Data: Year 2, Quarter 3	15 months after OMB approval
Begin Data Collection: Year 2, Quarter 4	15 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data : Year 1, All Quarters	18 months after OMB approval
Begin Data Collection: Year 3, Quarter 1	18 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data: Year 3, Quarter 1	21 months after OMB approval
Begin Data Collection: Year 3, Quarter 2	21 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data : Year 3, All Quarters	24 months after OMB approval
Begin Data Collection: Year 3, Quarter 3	24 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data: Year 3, Quarter 3	27 months after OMB approval
Begin Data Collection: Year 3, Quarter 4	30 months after OMB approval
End Data Collection, Clean Data, and Complete Analysis and Report of Data : Year 3, All Quarters	30 months after OMB approval
Complete Analysis of Data: Year 3	33 months after OMB approval
Complete Analysis and Report of All Data: Year 3	No more than 38 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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