Prescription Drug Overdose Prevention for States (PfS) Program Assessment

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Purpose of the data collection:** To assess the implementation of the prescription drug overdose Prevention for States (PfS) program (CDC-RFA-CE15-1501) activities and identify the conditions under which these activities are effective and for whom. Objectives for the assessment are as follows:
    - Determine which activities each state implements and when,
    - Understand how states operationalized and implemented activities,
    - Identify barriers and facilitators to PfS implementation and to achieving outcomes, and
    - Assess short term (e.g., reduced barriers to PDMP registration) and intermediate (e.g., increased use of non-opioid therapies for pain) outcomes.
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- **Intended use of the resulting data:** The data will be used by CDC to:
    - Tailor technical assistance to awardees to specifically address their needs;
    - Obtain a valid program assessment about how states operationalized and implemented their activities;
    - Ensure a full understanding of the barriers and facilitators to PfS implementation; and
    - Understand successful implementation practices of PfS activities.

- **Methods to be used to collect data:** Telephone interviews will be conducted to collect information from respondents. If more than one respondent will participate, the telephone interviews will be conducted in a group setting with all respondents present.

- **The subpopulation to be studied:** Data will be collected from a respondent universe comprised of 87 respondents across all 29 PfS-funded states, including 58 PfS-funded state government staff (29 epidemiologists and 29 research assistants) and 29 respondents serving as delegates. Delegates include IT support staff external to the funded state government agency who directly support implementation of PfS activities.

  These individuals are considered delegates under the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879 generic mechanism for the following reasons:
    - As per 0920-0879 Generic ICR language, "delegates are governmental or non-governmental agents (agency, function, office or individual) acting for a principal or submitted by another to represent or act on STLT government behalf."
    - The task for CDC to reduce prescription drug overdoses through the CDC-funded program prescription drug overdose (PDO) PfS (CDC-RFA-CE15-1501) is part of Essential Public Health Services #5: Development of policies and plans that support individual and community health efforts
    - IT staff who support PfS activities are extensions of state health departments who may not have specialized technical staff to provide IT support for PfS activities related to implementing and maximizing Prescription Drug Monitoring Programs.

- **How data will be analyzed:** Data collected from this assessment will be analyzed using a hybrid multistep deductive-inductive coding process. Qualitative and quantitative analyses of narrative responses will be conducted.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from a respondent universe comprised of 87 respondents across all 29 PfS-funded states, including 58 PfS-funded state government staff (29 epidemiologists and 29 research assistants) and 29 respondents serving as delegates.

Delegates include IT support staff external to the funded state government agency who directly support implementation of PfS activities. These individuals are considered delegates under the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879 generic mechanism for the following reasons:

- As per 0920-0879 Generic ICR language, "delegates are governmental or non-governmental agents (agency, function, office or individual) acting for a principal or submitted by another to represent or act on STLT government behalf."
- The task for CDC to reduce prescription drug overdoses through the CDC-funded program PDO PfS (CDC-RFA-CE15-1501) is part of Essential Public Health Services #5: Development of policies and plans that support individual and community health efforts
- IT staff who support PfS activities are extensions of state health departments who may not have specialized technical staff to provide IT support for PfS activities related to implementing and maximizing Prescription Drug Monitoring Programs.

A complete listing of these respondents can be found in **Attachment A – List of PfS Awardees**.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of:

☐ 1. Monitoring health status to identify community health problems
☐ 2. Diagnosing and investigating health problems and health hazards in the community
☐ 3. Informing, educating, and empowering people about health issues
☐ 4. Mobilizing community partnerships to identify and solve health problems
☒ 5. Development of policies and plans that support individual and community health efforts
☐ 6. Enforcement of laws and regulations that protect health and ensure safety
☐ 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
☐ 8. Assuring a competent public health and personal health care workforce
☒ 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services

☐ 10. Research for new insights and innovative solutions to health problems [1]

Since 1999, the number of overdose deaths involving opioids has quadrupled[2]. As of 2013, nonmedical users of prescription drugs totaled an estimated 6.5 million[3]; in 2011, more than 1.4 million emergency department visits were related to pharmaceuticals. Although opioid poisoning deaths have stabilized, heroin use is rapidly increasing as a cheaper and more plentiful alternative to prescribed opioids[4]. Multiple federal agencies are working together collaboratively to address the opioid overdose epidemic. In its role as the nation's health protection agency, the U.S. Centers for Disease Control and Prevention (CDC) works with states to develop and implement evidence-based public health programming focused on prevention of opioid misuse, abuse, overdose, and death.

CDC advances the mission of reducing prescription drug overdoses by supporting the dissemination of promising practices and funding research to develop the evidence base. In response to the opioid epidemic, CDC funded the Prescription Drug Overdose Prevention for States Program (PfS) to support state-level interventions for preventing prescription drug overuse, misuse, abuse, and overdose (CDC-RFA-CE15-1501). The program makes awards to state health departments and associated agencies to reverse the epidemic of overdoses, morbidity, and mortality associated with prescription drug use in the United States. In the first cohort of awardees, 16 states received funding under PfS. Beginning March 2016, the Centers for Disease Control and Prevention (CDC) funded a second cohort of 13 states. PfS funding supports the implementation of programs in four priority areas expressed as strategies—two required, two optional. For a full list of PfS strategies and activities, please (see **Attachment B – PfS Strategies and Activities).**
The two required strategies are to

- enhance and maximize a state Prescription Drug Monitoring Program (PDMP[1]) (strategy 1), and
- implement community or insurer/health system interventions to prevent prescription drug overdose and abuse (strategy 2).

The two optional strategies are to

- conduct policy evaluations (strategy 3) and
- develop and implement rapid response projects (strategy 4).

The purpose of this data collection is to assess the implementation of the PfS program activities by states related to the two required strategies: (1) enhancing and maximizing a state PDMP and (2) implementing community interventions to prevent prescription drug overdose and abuse. Data collected will also identify the conditions under which these activities are effective and for whom. Specifically, this data collection will focus on determining which activities each state implements and when, understanding how states operationalized and implemented those activities, identifying barriers and facilitators to PfS implementation and qualitatively assessing perceived progress

[1] PDMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. (http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq)

related to short-(e.g., reduced barriers to PDMP registration) and intermediate-term (e.g., increased use of non-opioid therapies for pain) outcomes.

Data collection will be conducted in partnership between CDC, Research Triangle Institute International (RTI), and the Injury Prevention Research Center at the University of North Carolina at Chapel Hill (UNC). RTI and UNC are being used to support development of the assessment tool and conduct the data collection and data analysis activities. CDC will oversee the data collection and state support teams will be available to answer questions for respondents.

The data collected will be used by the CDC to:

- tailor technical assistance to awardees to specifically address their needs;
- obtain a valid program assessment about how states operationalized and implemented their activities;
- ensure a full understanding of the barriers and facilitators to PfS implementation;
- and understand successful implementation practices of PfS activities.

Overview of the Information Collection System

Data will be collected via telephone interviews conducted by RTI and UNC. Using a standard interview guide (**Attachment C – Instrument: Telephone Interview Guide**), data will be collected from respondents regarding PfS strategies (e.g., expanding and improving proactive reporting, conducting public health surveillance with PDMP, and providing technical assistance to high burden communities). For each state, if more than one respondent will participate, the telephone interviews will be conducted in a group setting with all respondents present.

Interviews will be recorded to capture the conversation accurately. Verbal permission to be recorded will be obtained from the participant(s) prior to the beginning of the interview.

The interview guide was pilot tested by 3 public health professionals. Feedback from these individuals was used to refine questions as needed and establish the estimated time required to complete the interview guide.

Items of Information to be Collected

The data collection instrument (see **Attachment C – Telephone Interview Guide**) consists of 4 sections (detailed below) and includes a total of 40 main questions and 91 sub-questions. Respondents will answer all 'Core Questions' and up to 2 optional modules depending on time. Modules will be strategically selected to fill knowledge gaps where the most information is needed. To minimize response burden, the instrument was designed with particular focus on streamlining questions to allow for skipping questions based on responses to previous questions. To further reduce burden on respondents, interviewers will eliminate questions that have been sufficient answered by prior review of state annual progress reports (OMB No. 0920-1155), websites, and data dashboards.

The instrument will collect data on the following:

Core Questions (13 main questions, 17 sub-questions). Core questions occur at the beginning and end of the interview; 9 main questions and 13 sub-questions appear at the beginning of the interview. Four main questions and 4 sub-questions appear at the end.

- state context related to opioid misuse,
- state experience and history in implementing efforts to address the opioid epidemic,
- internal and external state capacity for addressing the opioid epidemic (e.g., internal department capacity and resources; partnerships),
- other external factors that affect or may affect implementation
- unexpected successes or challenges
- lessons learned

Optional Module 1: Expand and improve proactive reporting (12 main questions, 23 sub-questions)

- types of proactive reporting (e.g., internal and external notifications)
- parameters used to generate internal and external notifications
- stakeholder groups who receive internal and external notifications
- protocol for information sharing with licensing boards
- lessons learned

Optional Module 2: Conduct public health surveillance using PDMP data (8 main questions, 28 sub-questions)

- use of PfS resources
- types of PDMP surveillance activities supported by PfS resources
- data dashboard development and maintenance
- dissemination of public health surveillance products
- technical assistance offered using public health surveillance products
- lessons learned

Optional Module 3: Identify and provide technical assistance (TA) to high-burden communities (7 main questions, 23 sub-questions)

- how TA topics provided to high burden communities
- selection process for organizations providing TA
- utilization of coalitions or advisory groups to provide TA
- evaluation of TA provided

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess the implementation of the PfS program activities related to the two required strategies: (1) enhancing and maximizing a state PDMP and (2) implementing community interventions to prevent prescription drug overdose and abuse. Data collected will also identify the conditions under which these activities are effective and for whom.

Specifically, this data collection will focus on determining which activities each state implements and when, understanding how states operationalized and implemented those activities, identifying barriers and facilitators to PfS implementation and to achieving outcomes, and assessing short-term (e.g., reduced barriers to PDMP registration) and intermediate-term (e.g., increased use of non-opioid therapies for pain) outcomes.

Data collected from this assessment will be used by the CDC to tailor technical assistance to awardees to specifically address their needs; obtain a valid program assessment about how states operationalized and implemented their activities; ensure a full understanding of the barriers and facilitators to PfS implementation; and understand successful implementation practices of PfS activities.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via telephone interviews (**see Attachment C – Telephone Interview Guide**). For each state, if more than one respondent will participate, the telephone interviews will be conducted in a group setting with all respondents present. While online questionnaires are quick, effective methods for collecting quantitative data from many respondents, telephone interviews can solicit rich qualitative data, which better aligns with the purpose of this data collection.

Collecting data via telephone interviews will also help to minimize the burden on RTI and UNC staff by reducing the time required for follow-up. RTI and UNC can verify responses and request clarification in real time as needed during the information collection process. Embedded within the interview guide are skip patterns which will customize the interview to respondent answers and help minimize overall burden to the respondent. To further reduce burden on respondents, interviewers will eliminate questions on a case-by-case basis that were addressed by prior review of each state's annual progress reports, websites, and data dashboards.

4. Efforts to Identify Duplication and Use of Similar Information

Data collected through this assessment is not available from other data sources or through other means nor does it duplicate any information currently being collected on the PfS program.

This assessment will be the first of its kind to collect data regarding PfS strategies (e.g., expanding and improving proactive reporting, conducting public health surveillance with PDMP, and providing technical assistance to high burden communities) and will focus on determining which activities each state implements and when, understanding how states operationalized and implemented those activities, identifying barriers and facilitators to PfS implementation and to achieving outcomes, and assessing short-term (e.g., reduced barriers to PDMP registration) and intermediate-term (e.g., increased use of non-opioid therapies for pain) outcomes.

Efforts were made to identify duplication and use of similar information, including a review of state annual progress reports to ensure the interview guide does not collect information previously provided. Rather, the telephone interview guide will capture information regarding external factors that may have hindered implementation of activities, understanding the capacity of the funded agency, and identifying effective partnerships that may have facilitated PfS efforts.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection. There are no legal obstacles to reduce the burden.

If no data are collected, CDC will be unable to:

- Obtain a valid program assessment about how states operationalized and implemented their PfS activities
- Ensure a full understanding of the barriers and facilitators to PfS implementation
- Understand successful implementation practices of PfS activities
- Tailor technical assistance to awardees to specifically address their needs

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on May 16, 2014, Vol. 79, No. 95; pp. 28513. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this information collection. State governmental staff will be speaking from their official roles. Although RTI and UNC will be collecting some individually identifiable information (IIF), including the respondents' official role, organization, state, and date of interview, all information will be kept on secure, password protected RTI and UNC servers accessible only to project team members. RTI and UNC will remove all potential identifiers and share only the de-identified data with CDC. No IIF will be distributed.

This information collection is not research involving human subjects.

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

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the data collection instrument by 3 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 93 minutes (range: 70 –120) for the core questions and 2 optional modules (the maximum number of optional modules a state could receive). For the purposes of estimating burden hours, the upper limit of this range (i.e., 120 minutes, or 2 hours) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for Epidemiologists, Social Science Research Assistants (Analyst), and Computer and Information Analysts. http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of $34.05 is estimated for 29 Epidemiologist (State PfS), $20.76 for 29 Social Science Research Assistants (State PfS), and $42.29 for 29 Computer and Information Analyst (delegates). Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Information collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
PfS Telephone Interview Guide PfS Telephone Interview Guide	State PfS Epidemiologists	29	1	2	58	$34.05	$1975
	State PfS Social Science Research Assistants (Analyst)	29	1	2	58	$20.76	$1,204
	Delegates: Computer and Information Analysts	29	1	2	58	$42.29	$2453
	TOTALS	**87**	**1**		**174**		**$5632**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff, RTI, and UNC contractors. Contractors are being used to support development of the assessment tool, data collection, and data analysis. CDC will oversee the data collection and state support teams will be available to answer questions for respondents. The total estimated cost to the federal government is **$68,129.90.** Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Behavioral Scientist GS-[13], Step [1]; Oversee and provide guidance on evaluation, data collection, and deliverables	40	$43.14	$1725.60
Behavioral Scientist and Evaluation Officer GS-[13], Step [3]; Provide guidance on evaluation, data collection, and deliverables	10	$46.01	$460.10
Behavioral Scientist GS-[13], Step [6];	10	$50.32	$503.20

Provide guidance on evaluation, data collection, and deliverables			
Project Director, RTI Oversee and provide guidance on evaluation, data collection, and deliverables	40	Contractor Sub-total: $65,440	
Associate Project Director, RTI Oversee and provide guidance on evaluation and data collection	70		
RTI Interviewer	70		
Project Manager, RTI Manage evaluation tasks, coordinate data collection	60		
Analyst, RTI Code data, contribute to deliverables	40		
Associate Project Director, University of North Carolina – Chapel Hill provide guidance on evaluation, data collection	70		
Research Associate, University of North Carolina – Chapel Hill Conduct interviews, code data, contribute to deliverables	110		
Total Estimated Cost of Information Collection			**$68,129.90**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Following the competition of all telephone interviews, RTI and UNC will transcribe audio recordings using Rev.com and import into NVivo 11.0 qualitative analysis software. The qualitative data will then be coded and analyzed thematically and used to identify key themes that emerged across interviews.

Although RTI and UNC will be collecting some individually identifiable information (IIF), including the respondents' official role, organization, state, and date of interview, all information will be kept on secure, password protected RTI and UNC servers accessible only to project team members. RTI and UNC will remove all potential identifiers and share only the de-identified data with CDC. No IIF will be distributed. Once transcription is completed all audio files will be deleted.

Once data analysis in complete, a summary report will be produced to share findings from this data collection. Additionally, there is the potential to publish findings in peer-reviewed journals and/or present findings at relevant conferences and meetings.

Project Time Schedule

- ✓ Design instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ❑ OMB approval ..... (TBD)
- ❑ Conduct data collection ..... (Open 6-8 weeks)
- ❑ Code data, conduct quality control, and analyze data..... (8 weeks)
- ❑ Prepare summary report(s) ..... (6 weeks)
- ❑ Disseminate results/reports ..... (8 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

A. Attachment A – List of PfS Awardees
B. Attachment B – PfS Strategies and Activities
C. Attachment C – Instrument: Telephone Interview Guide

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at http://www.cdc.gov/nphpsp/essentialservices.html. Accessed on 8/14/14.

2. Centers for Disease Control and Prevention. (n.d.). CDC WONDER. About compressed mortality, 1999–2015. Retrieved from https://wonder.cdc.gov/cmf-icd10.html.

3. Frieden T. Preventing Prescription Drug Overdose: New Challenges, New Opportunities. Paper presented at: Prescription Drug Abuse Summit 2015; Atlanta, GA.

4. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. (2016). Retrieved from https://www.cdc.gov/drugoverdose/epidemic/index.html

5. Office of National Drug Control Policy. (2011). *Epidemic: Responding to America's prescription drug abuse crisis*. Washington, DC: Executive Office of the President of the United States.