SUPPORTING STATEMENT: PART A

OMB# XXX

July 18, 2016

MONITORING AND REPORTING SYSTEM FOR THE PRESCRIPTION DRUG OVERDOSE PREVENTION FOR STATES COOPERATIVE AGREEMENT

Supported by:

Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Injury Prevention and Control
Division of Unintentional Injury Prevention

Point of Contact: Sarah Bacon
Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

4770 Buford Highway NE MS F-64
Atlanta, GA 30341-3724
phone: 770-488-0520
fax: 770-488-8305
email: jfy5@cdc.gov

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SUMMARY TABLE

- The goal of this ICR is to collect, from awardees, information needed to monitor cooperative agreement programs funded under Prescription Drug Overdose Prevention for States (CDC-RFA-CE15-1501).
- Information to be collected will provide crucial data for program performance monitoring and budget tracking, and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources.
- Awardees will report progress and activity information to CDC on an annual schedule using an Excel-based fillable electronic templates, pre-populated to the extent possible by CDC staff, and submitted via Grant Solutions. No research design or human subjects involved.
- 100% of population, no sampling.

  The data will be analyzed using descriptive and summary statistics, qualitative summary.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) seeks OMB approval to collect information from awardees funded under Prescription Drug Overdose (PDO) Prevention for States (CDC-RFA-CE15-1501). This program is a new initiative. OMB approval is requested for the first three years of the four year funding period. An extension will be sought to cover the fourth year. Awardees will report progress and activity information to CDC on an annual schedule using an Excel-based ***Annual Progress Report Tool*** composed of performance measures for monitoring program implementation and impact, as well as a work plan tool that links activities and tasks to outcomes. In addition, awardees will develop and report assessment progress using a writable MS Word ***Plan Tool.*** Information to be collected will provide crucial data for program performance monitoring. Information to be collected will improve real-time CDC-awardee communications, and strengthen CDC's ability to monitor awardee progress.

Background

Drug overdose is the leading cause of injury death in the United States.[1,2] Opioid-prescribing behaviors are associated with an increased risk for morbidity and mortality. While opioid pain relievers can play an important role in the management of some types of pain, the

overprescribing of these powerful drugs has fueled a national epidemic of prescription drug abuse and overdose. To reverse this complex epidemic and prevent future overdose, abuse, and misuse, CDC emphasizes improving surveillance, providing support to states, and changing health system practices. Improving the way opioids are prescribed can promote safer, more effective treatment while reducing opioid-related abuse, misuse, and overdose.

The Public Health Service Act (PHS Act) provides the legislative means for states to advance public health across the lifespan and to reduce health disparities. Section 301(a) of the PHS Act 42 U.S.C. 241(a), authorizes grants to aid other "other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." (**Attachment 1**).

The new PDO Prevention for States program is a collaborative effort involving National Center for Injury Prevention and Control's (NCIPC) Division of Unintentional Injury Prevention (DUIP) and the Division of Analysis, Research, and Practice Integration (DARPI). Collectively, these units have a rich history of working with State Health Departments (SHDs) to (i) increase their ability to implement evidence-based strategies and activities aimed at reducing risk factors associated with preventing or reducing prescription drug misuse, abuse, or overdose, and (ii) assist SHDs in building capacity for implementing and evaluating PDO strategies.

Funded awardees will monitor and report progress on their work plan objectives, activities, and performance measures. The Annual Progress Report Tool will capture this information through the use of performance measures (indicators that signify progress towards an objective) and development of a work plan that links activities and tasks to desired outcomes (**Attachment 3a**). In addition, each awardee will develop an assement plan and report relevant information using the Plan Tool (**Attachment 3b**). Information will be transmitted to CDC electronically through Grant Solutions and through emails from awardees to their Project Officers.

CDC plans to begin using the proposed performance monitoring tools immediately upon receipt of OMB approval. CDC is authorized to collect information for public health purposes by Section 301(a) of the Public Health Service Act (**Attachment 1**).

A.2. Purpose and Use of Information Collection

The information collection will enable the accurate, reliable, uniform, and timely submission to CDC of each awardee's work plans and progress reports, including strategies and performance measures. The information collection and reporting requirements have been carefully designed to align with and support the specific goals and outcomes outlined in the PDO Prevention for States cooperative agreement. The information collection plan will enable collection and reporting of the information in an efficient, standardized, and user-friendly manner that will generate a variety of routine and customizable reports. Local level reports will allow each awardee to summarize activities and progress towards meeting work plan strategies and performance measure targets. CDC will also have the capacity to generate reports that describe activities across multiple awardees. CDC will also use the information collection to respond to

inquiries from the HHS, the White House, Congress and other stakeholder inquiries about program activities and their impact.

There are significant advantages to collecting information with these reporting tools:

- The data structures will help awardees formulate performance measures that are specific, measurable, achievable, relevant, and time-framed (SMART). This formulation is intended to facilitate successful achievement of performance measures and is integral to CDC's program evaluation strategy for the program.
- The information being collected provides crucial information about each awardee's work plan, activities, partnerships, and progress over the award period.
- Capturing the required information uniformly will allow CDC to formulate ad hoc analyses and reports.

CDC will use the information collected to monitor each awardee's progress and to identify facilitators and barriers to program implementation and achievement of outcomes. Monitoring allows CDC to determine whether an awardee is meeting performance and budget goals and to make adjustments in the type and level of technical assistance provided to them, as needed, to support attainment of their performance measures. Program monitoring and evaluation activities also allow CDC to identify and disseminate information about successful prevention and control strategies implemented by awardees. These functions are central to the NCIPC's broad mission of protecting Americans from violence and injury threats. The information collection will allow CDC to monitor the increased emphasis on strategies that affect health outcomes and impact, and is expected to reduce duplication of effort, enhance program impact and maximize the use of federal funds.

Working with CDC staff, program awardees will use the information collected to manage and coordinate their activities and to improve their efforts to prevent and control prescription drug misuse, abuse, and overdose. The tools will allow awardees to fulfill their annual reporting obligations under the funding opportunity announcement in an efficient manner by employing user-friendly instruments to collect necessary information for both progress reports and continuation applications including work plans. This approach, which enables awardees to save pertinent information from one reporting period to the next, will reduce the administrative burden on the yearly continuation application and the progress review process. Awardee program staff will be able to review the completeness of data needed to generate required reports, enter basic summary data for reports at least annually, and finalize and save required reports for upload into other reporting systems as required.

Although program evaluation is an essential public health function, limitations of this type of data collection are the generalizability of results and the certainty of causation. The conclusions drawn from awarded states may not generalize to the entire country due to differences in demographics, policies, and implementing agencies. In addition, because this is not a research cooperative agreement, states are not required to implement rigorous research designs that have strong internal validity and produce generalizable knowledge. As such, the information we gather may make a strong inference of correlation, but causation cannot be inferred.

A.3. Use of Improved Information Technology and Burden Reduction

The CDC contractor, has developed the Annual Progress Report Tool using the Excel platform. Additionally, a Plan Tool has been developed using MS Word. Since the use of Excel, Word, and similar Microsoft products is common, these user-friendly interfaces will be easier and more intuitive for awardees to use than special-purpose tools or software. Use of Excel and Word will require very little training and awardees will use the tools provided to record and update cooperative agreement information. Awardees will upload completed Word documents and Excel spreadsheets tailored for their specific work plans, to the Grant Solutions website to satisfy FOA reporting requirements. Awardees will also send completed Excel and Word documents to their assigned Project Officer for technical review. Once the technical review is complete, the Project Officer will send the completed workbooks to the contractor to be input into NCIPC's internal Monitoring and Evaluation Tool database for examination and reporting.

These tools improve information quality by minimizing errors and redundancy. Having all of the information collected in the same place in the same manner will reduce the level of burden attributable to redundancy and reduce the workload to enter and maintain the data. Programs will have data self-populated from one year to another, which minimizes data re-entry, burden, and potential errors.

With the tools, the use of a standard set of data elements, definitions and specifications at all levels will help to improve the quality and comparability of performance information that is received by CDC for multiple awardees and multiple award types. Further, standardization will enhance the consistency of plans and reports, enable examination of cross-program performance and strategies, and will facilitate a higher degree of reliability by ensuring that the same information is collected on all strategies and performance measures with slightly different areas of emphasis, depending on strategies chosen by the awardee. Finally, the report generation capabilities of the system will reduce the respondent burden associated with paper-based reports. Without the reporting tools and the integrated approach to information collection and reporting, awardees and CDC would need to continue to use time consuming, labor intensive procedures for information collection and reporting.

A.4. Efforts to Identify Duplication and Use of Similar Information

The information collected from awardees is not available from other sources. The information is specific to the PDO Prevention for States Program. The collection of this information is part of a federal reporting requirement for funds received by awardees. The tools will consolidate information necessary for both continuation applications and progress reports so that information entered once can be used to generate multiple types of reports without having to duplicate efforts. As one of CDC's primary PDO prevention initiatives, Prevention for States occupies a unique niche within the larger scope of Health and Human Services' (HHS) opioid priority initiative. The Substance Abuse and Mental Health Services Administration (SAMHSA) is also engaged in opioid overdose work, but their role is specific to naloxone availability and use, and medically-assisted substance use treatment. As such, their efforts are complementary rather than redundant, and the data/information they collect are specific to different outcomes of interest and would not serve to inform CDC's efforts.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

Reports will be collected annually. The annual progress report is due 120 days before the end of the budget period and serves as a non-competing continuation application. Less frequent reporting would undermine accountability efforts at all levels and negatively impact monitoring awardee progress. The annual reporting schedule ensures that CDC responses to inquiries from HHS, the White House, Congress and other stakeholders are based on timely and up-to-date information. . Typical inquiries involve requests for specific details on what types of activities states and communities are implementing, how those activities are being implemented, what the grantees' objectives are, and what successes have been achieved by grantees.

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

The request fully complies with the regulation 5 CFR 1320.5.

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

A.8.a) Federal Register Notice
A 60-day Federal Register Notice was published in the Federal Register on July 28, 2015 vol. 80 No. 144, pp. 44965- 44966 (Attachment 2). No public comments were received.

A.8.b) Efforts to Consult Outside the Agency
The data collection instruments were designed collaboratively by CDC staff and the contractor. Consultation will continue throughout the implementation process.

A.9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts for providing information.

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

The CIO has determined that the Privacy Act does not apply for this information collection request. Respondents are cooperative agreement awardees. No personal contact information will be collected. All data will be reported in aggregate form, with no identifying information included. Key program staff will provide information related to programmatic improvement and they will be notified that their responses on the electronic information system will be treated in a secure manner. Staff identifiers will not be used in any progress reports. The information collection does not require consent from individuals. All procedures have been developed, in

accordance with federal, state, and local guidelines, to ensure that the rights and privacy of key awardees' program staff (e.g. program director) will be protected and maintained.

While consent is not required to report aggregate data, awardee approval will be obtained if specific state data is used for publications, reports, or other publicly disseminated information. Respondents are state governmental agencies. Although contact information is obtained for each awardee, the contact person provides information about the organization, not personal information. No system of records will be created under the Privacy Act. Submission and access to state data will be controlled by a password-protected login to the secure Monitoring and Evaluation Tool site. Access levels vary from read-only to read-write, based on the user's role and needs. CDC staff, and evaluation contractors will have varying levels of access to the system with role-appropriate security training, based on the requirements of their position(s). Aggregated information will be stored on an internal CDC Access server subject to CDC's information security guidelines.

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

IRB Approval

The CDC National Center for Injury Prevention and Control's OMB and human subject's liaison has determined that IRB approval is not needed. No personal information will be collected and human participants will not be used (Attachment 4)

Sensitive Questions

The proposed tools do not collect sensitive information.

A.12. Estimates of Annualized Burden Hours and Costs

Respondents will be the 29 awardees for the PDO Prevention for States cooperative agreement. Respondents will report information to CDC about their activities and performance measures, and evaluation progress based upon selected strategies. Two information collection tools will be used: an Excel-based Annual Progress Report Tool (**Attachment 3a**) and a Word-based Plan Tool (**Attachment 3b**). Annual reporting is applicable to Year 1, Year 2, and Year 3. An OMB extension will be requested for Year 4. A supplemental allocation for initial start-up burden will occur one time only in Year 1 for completion of the Annual Progress Report Tool.

The same instruments will be used for all information collection and reporting. However, burden estimates for the Annual Progress Report will vary according to the reporting year (Year 1, vs. Year 2, and Year 3of the OMB approval period, with plans for a fourth year extension request). The time commitments for data collection, entry, and training will be greatest during the first year and the efficiencies of the Annual Progress Report Tool will be realized in subsequent reporting years, when burden is limited to entering changes, progress information, and new activities. That is, the first round of reporting (in Year 1) will take the longest and therefore have the highest burden. In subsequent years, respondents can simply revise the tools they have used

for Year 1 and therefore the process will be faster, with fewer burden hours. For all respondents, the burden per response is estimated to be 20 hours for initial population of the tool. The routine annual burden per response is estimated at 4 hours.
Awardees submitted a draft evaluation plan as part of their application for the funding opportunity, and therefore have already completed much of the work that will be reported in the Plan Tool. Therefore, reporting burden for completing the Plan Tool will remain the same throughout the OMB approval period, as awardees will simply update what was submitted in their original application. The routine annual burden per response is estimated at 4 hours (see **Attachment 3b**).

All respondents will complete the Excel-based Annual Progress Report Tool (**Attachment 3a**, due each year before the end of the budget period.

Over the three-year period of this information collection request, the total estimated burden for the 29 awardees is 812 hours, as summarized in Table A.12-A.

Table A.12-A. 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)
	Initial population - Annual reporting - Progress Report Tool (Attachment 3a)	29	1	20	580
State and Territorial Health Department Program Awardees	Annual reporting - Progress Report Tool (Attachment 3a)	29	1	4	116
	Annual reporting - Plan Tool (Attachment 3b)	29	1	4	116
				Total	812

Methodology Used:

- Annual Progress Report: Estimates for burden were developed based on beta-testing and feedback sessions with fewer than 10 respondents from a small cooperative agreement

program, Prescription Drug Overdose: Boost for State Prevention (funding opportunity announcement CE14-1404; referred to as "Boost"). All data was pre-populated and awardees only update the data for the indicators and work plan portion. It is assumed this would take substantially less time from the initial work plan. The estimate for the initial Annual Progress Report includes the time for reviewing instructions, searching existing data sources, data collection, and completion of the Tool.

  - Indicators: 1 hour
  - Work plan update: 3 hours

- Annual Plan Tool: Estimates for burden were developed based on beta-testing and feedback sessions with fewer than 10 respondents from the Boost program referenced above. Each section of the Evaluation Plan Tool took between 30 minutes and 45 minutes to collect and enter data. This was multiplied by each section of the Tool (6):
  - Annual evaluation plan: 4 hours

A.12.b) Annual burden cost

A program manager will prepare the progress reports for each area. The average hourly wage for a program manager is $30.65. The hourly wage rates for program managers are based on wages for similar mid-to-high level positions in the public sector. The total estimated cost over three years annualized is $24,888 as summarized in Table A.12-B.

Table A.12-B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Average Hourly Wage Rate (in dollars)	Total Cost
FOA CE15-1501 Program Awardees	Initial Collection Annual Progress Report Tool	580	$30.65	$17,777
	Annual reporting – Progress Report Tool	116	$30.65	$3555
	Annual reporting – Plan Tool	116	$30.65	$3555
			Total	$24,888

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

No capital or maintenance costs are expected. Additionally, there are no start-up, hardware, or software costs.

A.14. Annualized Cost to the Government

Table A.14. Estimated Annualized Cost to the Government

Type of Cost	Description of Services	Annual Cost
CDC Personnel	• 100% GS-12@$71,901/year = $71,901 • 50% GS-13 @ $85,500/year = $42,500 • 25% GS-14 @ $101,035/year = 25,258 Subtotal, CDC Personnel	$139,659
Contractor	Data Collection Contractor	$100,000
	Total Annual Estimated Costs	$239,659

A.15. Explanation for Program Changes or Adjustments

This is a new collection.

A.16. Plans for Tabulation and Publication, and Project Time Schedule

A. Time schedule for the entire project
The cooperative agreement cycle is four years. OMB approval is being requested for the first three years of the four year funding period. An extension will be sought for the fourth year. Reports will be generated by the awardees per the FOA requirements once a year due 120 days before the end of the budget period. Data collection began with the awarding of the cooperative agreements and will continue throughout the funding cycle.

B. Publication plan
Information collected by the awardees will be reported in internal CDC documents and shared with state-based programs.

C. Analysis plan
CDC will not use complex statistical methods for analyzing information. Most statistical analyses will be descriptive. Statistical modeling may be included to examine predictors of specified outcomes. For example, the difference between baseline rates and achieved rates on indicators will be documented and analyzed. In addition, the percent of objective met versus proposed will also be documented and analyzed. Furthermore, the information in the work plan will allow for CDC staff to monitor program activities and implementation and provide technical assistance to awardees after an internal qualitative review has been completed.

Table Project Time Schedule

Activity Time Schedule	

Notification of Tool Availability	Immediately upon OMB approval
User Training	Immediately upon OMB approval and ongoing through expiration date
Data Collection	1-36 months after OMB approval
Data Publication	Once annually
Data Analysis	1-36 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

1. Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. (2014) Available from URL: http://www.cdc.gov/injury/wisqars/fatal.html.
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3. Substance Abuse and Mental Health Services Administration. Highlights of the 2011 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. The DAWN Report. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2013. Available from URL: http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm