HHS/CDC/NCIPC
SUPPORTING STATEMENT FOR
OMB INFORMATION COLLECTION REQUEST

Part A

Date: November 4, 2013

Evaluation of the SAMHSA PDMP Electronic Health Record (EHR) Integration and Interoperability Expansion Program

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

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SUPPORTING STATEMENT A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

Proposed Project

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control, is requesting approval of a new information collection request for a period of 24 months to conduct a qualitative evaluation of the *Prescription Drug Monitoring Program (PDMP) Electronic Health Record (EHR) Integration and Interoperability Expansion (PEHRIIE)* program. This program is a collection of state initiatives funded by 2012 Prevention and Public Health Funds (PPHF-2012) cooperative agreements through the Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration (SAMHSA). CDC is conducting a qualitative evaluation of this program in order to understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with Health Information Technology (HIT) systems and interoperability of PDMP systems across states. This information collection will also capture the experiences of clinical end users with the systems being upgraded under the PEHRIIE program as well as their recommendations for how the goals of the PEHRIIE program could have been better accomplished.

This qualitative information collection is a part of CDC's larger evaluation of the PEHRIIE program, as stipulated by the cooperative agreements between the funded states and SAMHSA. The purpose of this multi-faceted evaluation is to determine if successful completion of the two primary goals of this program (i.e., improved accessibility of PDMP data via integration with existing HIT and increased PDMP data availability via interstate interoperability) resulted in changed provider behavior and impacted prescription drug related health outcomes in these states. In addition, this evaluation will identify cross-cutting barriers to and facilitators of successful implementation of the HIT integration and interstate interoperability projects funded through the PEHRIIE program. To address these evaluation questions, CDC will combine the results of the qualitative information collection described herein with the results of a detailed quantitative analysis of PDMP data from the PEHRIIE-funded states and data from SAMHSA's and CDC's national health outcomes datasets.

Background

In 2009, drug overdose deaths became the leading cause of injury death in the United States (U.S.), exceeding motor vehicle traffic crash deaths for the first time, a trend that continued in 2010.[1] Prescription drugs, particularly opioid pain relievers, have been identified as the main driver of this increase. The number of overdose deaths per year involving opioid pain relievers increased more than four-fold from 1999 to 2010 (from 4,030 to 16,651), outnumbering overdose deaths involving all illicit drugs combined.[2] Morbidity associated with opioid pain reliever abuse increased in parallel. The rate of emergency department visits associated with the misuse or abuse use of pharmaceuticals increased 153% from 2004 to 2011, while rates for illicit drugs remained largely stable.[3]

Concurrent to this rise in overdose death rates, sales of opioid pain relievers have increased four-fold since 1999.[4] According to the National Survey of Drug Use and Health, the primary source of prescription

drugs for non-medical use is from prescribed and dispensed prescriptions; more than 70% of those who reported non-medical use of pain relievers said they obtained the pain reliever they most recently used from a friend or relative.[5] Moreover, multiple studies have found an association between increased opioid prescribing – in the amount prescribed per prescription, the total days' supply, and the number of prescriptions per patient – and increased morbidity and mortality in the U.S. over the last 10 to 15 years.[6, 7, 8, 9]

Prescription Drug Monitoring Programs (PDMPs) are now recognized as a key tool in federal, state, and local efforts to address prescription drug abuse and misuse.[10] PDMPs are state databases to which pharmacies and other dispensers report dispensed outpatient controlled substance prescription information. Forty-nine states have passed legislation authorizing a PDMP, and 46 states currently have an operational program. In the vast majority of these programs, prescribers and pharmacists (herein referred to collectively as providers) can register to become an authorized user of the PDMP. Following authorization, users can then conduct online queries to obtain prescription histories for their patients, a process that may take up to several minutes. For many providers, accessing patient prescription histories offers critical input that can inform their clinical decision-making. This process has shown promise in preventing prescribing to patients who appear to be abusing prescription medications or obtaining controlled substance prescriptions from multiple providers without the knowledge of the other prescriptions (referred as doctor shopping) while enabling appropriate prescribing and dispensing for legitimate patients, especially for pain medication.[11, 12]

However, for many providers, even the few minutes required to log on to the PDMP and query a patient's prescription history presents a barrier to regular use. Moreover, gaps in patients' prescription histories due to limited interstate sharing of PDMP data has contributed to relatively slow rates of provider registration with and use of PDMPs. An evaluation of PDMP reports show that it often takes four or more years following the implementation of online PDMP access for registration in the state to reach 50% of the prescribers who write controlled substance prescriptions,[13] thus limiting the potential impact of these programs. Various strategies have been proposed to increase provider use of PDMPs. For example, several states have recently passed legislation mandating provider registration with and use of the PDMP under certain circumstances. Many states have also initiated efforts to enroll providers in educational training programs about the value of using PDMP data to counteract the prescription drug overdose epidemic. The project described below takes a different approach to increasing provider use of PDMPs.

In an effort to increase provider utilization of PDMPs and to effectively reduce prescription drug abuse and overdose, the Substance Abuse and Mental Health Services Administration (SAMHSA) funded projects in nine states beginning in fiscal year (FY) 2012 and lasting for a period of two years through its PDMP Electronic Health Records (EHRs) Integration and Interoperability Expansion (PEHRIIE) cooperative agreement program. The goals of this program are to:

1) Increase provider utilization of their state's PDMP by improving real-time access to PDMPs via the integration of PDMP data and/or access thereof within health information technologies (HIT) such as health information exchanges (HIEs), EHR systems, and/or pharmacy dispensing software (PDS). Ultimately, when a prescriber accesses a patient's EHR, s/he will have automatic access to that patient's up-to-date prescription history within the course of their normal clinical

workflow, thereby obviating the time and effort otherwise needed to access the PDMP and obtain this information separately from the patient's medical record. Similarly, when a pharmacist calls up patient information via the PDS, the patient's prescription history from the PDMP will be automatically compiled, allowing for expedited access and review prior to dispensing.

2) Increase provider utilization of PDMP data by increasing the comprehensiveness and quality of PDMP data by increasing the interoperability of state PDMPs across state lines. When a provider accesses a patient's prescription history from his or her state PDMP (either directly or via the systems described above), data from other state PDMPs with which the home state PDMP is interoperable will be automatically included. By providing a more complete prescription history, PDMP data is expected to have greater utility in clinical decision-making, thus offering an inducement for providers to access and utilize PDMP data more frequently.

Both of these goals are expected to contribute to improving prescribing and dispensing practices, resulting in decreased prescription drug abuse and misuse and related health consequences such as fatal and non-fatal overdoses as well as lead to improvements in care.

State efforts to integrate PDMP data and/or PDMP access into HIEs, EHRs, and PDS systems and to expand interstate PDMP data sharing are just beginning. Prior to this SAMHSA program, six three-month pilot projects were conducted in five states, primarily to establish the technical feasibility of completing this type of work in a limited period of time. However, due to the short-term nature and limited scope of the pilot projects, only minimal conclusions could be drawn about the most effective ways to implement systemic upgrades of this nature to PDMPs in different state settings, the costs associated with implementation of these projects, and any unanticipated consequences resulting from such work. Moreover, evaluations of the outcomes of these pilot projects, including effects on providers' use of PDMP data and the ultimate impact on prescription drug abuse and misuse, were not conducted. As a result, while integration and interoperability of PDMP data appears promising as a way to increase provider utilization of these important public health tools, information regarding the utility and cost-effectiveness of this approach is lacking. Therefore, robust evaluations of the PEHRIIE program and the state projects funded by it are of critical importance.

Under the cooperative agreements issued by SAMHSA, the Centers for Disease Control and Prevention (CDC) is responsible for conducting a comprehensive process and outcomes evaluation of the above described PEHRIIE program. The evaluation team consists of health scientists on the Prescription Drug Overdose team within the Division of Unintentional Injury Prevention, National Center for Injury Control and Prevention at CDC, and two subject matter experts at the PDMP Center of Excellence at Brandeis University working with CDC through Intergovernmental Personnel Act agreements. The primary goals of the qualitative evaluation component of this work are:

1) To understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with Health Information Technology (HIT) systems and interoperability of PDMP systems across states; and

2) To understand the experiences of clinical end users with the systems being upgraded under the PEHRIIE program and to capture their recommendations, if any, for how the goals of the PEHRIIE could have been better accomplished.

To achieve these evaluation goals, the CDC evaluation team will conduct qualitative interviews with those individuals involved in the planning and implementation of the PEHRIIE projects (i.e., key project staff and stakeholders) as well as with the clinical end users (i.e., prescribers and pharmacists) of the PDMPs in the states where these projects are taking place.

This evaluation is consistent with CDC's strategic goals of improving surveillance, informing policy, and improving clinical practice. CDC believes that the most effective interventions in combating the prescription drug overdose epidemic include those designed to identify and address high-risk patients at a stage when their risky behaviors can be most effectively addressed. Strong yet accessible PDMPs that promote proactive patient interventions are a critical component of this high-risk focused strategy. By enabling providers to identify high-risk patients at the point of care, via improved access to and use of PDMPs and improved comprehensiveness of PDMP data, providers can intervene with patients and address their high-risk behaviors, including providing or redirecting patients to substance abuse treatment as necessary. Through this evaluation, CDC, SAMHSA, and others will better understand the impact of PDMP integration and interoperability in the funded states.

Authority for the CDC to collect this data is granted by Section 301 of the Public Health Services Act (42 U.S.C. 241) (Attachment 1).

A.1.A. Privacy Impact Assessment

This qualitative evaluation is needed to capture firsthand accounts from project stakeholders of the processes, challenges, and successes in implementing and sustaining integration of PDMP data with HIT systems and interoperability of PDMP systems across states. This qualitative evaluation is also needed to capture the experiences of the clinical end users of these systems in order to provide important context for the results of the concurrent quantitative data analysis. Therefore, CDC will conduct a series of interviews with those key stakeholders involved in the planning and implementation of the PEHRIIE projects and the clinical end users of the PDMPs in the states where these projects are taking place.

Overview of the Data Collection System

During the course of a four-day in state visit to each PEHRIIE grantee state, the evaluation team will conduct in-person interviews at multiple sites with key project staff and stakeholders and with clinical end users, using pilot-tested semi-structured interview guides (Attachment 3 and 4, respectively). In person site visits will allow the evaluation team to ascertain in-depth information about the implementation and sustainability of each project, as well as descriptions and demonstrations of the usability and functionality of the PDMP project elements that are either newly in place or under construction. At least two evaluation team members will conduct each interview during the site visits, with additional note takers participating via conference call. Interviews with key project staff and stakeholders will take approximately 45 minutes and interviews with clinical end users will take approximately one hour.

For their convenience, interviewees will be given the option of doing their interviews in small groups instead of individually. In the event that in-person interviews cannot be scheduled during the planned site visits, interviews will be conducted via conference call with individual interviewees and the CDC evaluation team. These measures are intended as alternatives to the planned information collection in order to ensure that all of the information required to address the identified evaluation questions is collected in a timely manner. The CDC evaluation team anticipates that the vast majority of the planned interviews will be conducted in person in a one-on-one setting and have prepared these materials to reflect this.

Based on preliminary conversations with the primary project coordinators in each of the nine PEHRIIE grantee states, the evaluation team anticipates conducting interviews with an average of 10 key project staff members/stakeholders in each state (91 total interviews) as well as 14 individuals from vendors working with multiple PEHRIIE states for a total of 105 interviews. Individuals in the key project staff/stakeholder category include state officials and selected staff members involved in the operations and oversight of the state PDMP, including board officials of the agency where the PDMP is housed; other state officials involved in policy, technical, and legal support agencies as well as the state's substance abuse authority; PDMP software and data sharing hub vendors; and HIT systems' partners, including hospital staff responsible for EHR implementation at their site and their respective IT personnel. A detailed description of this respondent universe can be found in Section B1 of Supporting Statement B and in Attachment 5 (Tables 6, 7, and 8).

Additionally, the evaluation team will conduct interviews with three clinical end users of the upgraded PDMP systems at identified medical practice sites where access to the PDMP or PDMP data itself will be integrated into providers' EHRs and/or PDS systems (herein referred to as "implementation sites"). These interviews will be conducted at an average of four implementation sites per state (39 total sites) for a total of 117 clinical end user interviews. Individuals in the clinical end users category include prescribers, practice administrators, pharmacists, and other pharmacy stakeholders. A detailed description of this respondent universe can be found in Section B1 of Supporting Statement B and in Attachment 5 (Table 9).

Prior to the interviews, each stakeholder will be provided with a summary of the evaluation plan and a brief description of the interview purpose (Attachment 6), as well as a copy of the relevant interview guide via email (see Attachment 7 for email templates). Potential participants will be given the option to refuse to participate in the interviews. There may be questions that are potentially sensitive; however, respondents will have the right to refuse to answer any question he or she does not feel comfortable answering. Interviewees will be audibly apprised of their privacy rights and asked to give vocal confirmation of their agreement to participate prior to each interview. This information will also be included in the distributed pre-interview materials.

During the interviews, both the attending evaluation team members and those participating via conference call will take extensive notes using standard note-taking sheets in order to capture consistent data. With explicit permission from the interviewees, interviews will be audiotaped to use for reference and clarification in cases where the written notes are unclear. After each interview, all participating team members will compare their notes and compile a summary for that interview. All notes and audio-

recordings will be stored digitally on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access. Any hard copies will be kept in locked filing cabinets on secure CDC properties. Files will not be maintained by the name of the individual, but by assigned ID number. ID numbers will be 12 characters in length and will be generated from a combination of state and site identifiers as well as the date and time of each interview. An ID number code key will be kept in digital form in a unique location on hard drives behind the CDC firewall, separate from the collected notes and audiotapes. All files will be kept for six months following the completion of the evaluation in case any information is needed and then destroyed thereafter.

Following the completion of all interviews pertaining to a given PEHRIIE grantee state, the evaluators will conduct a thematic analysis of each finalized interview summary as well as within and across case qualitative analysis. The evaluation team will produce a summary report on each grantee state as well as an overall evaluation report highlighting cross cutting challenges encountered and successes achieved by the PEHRIIE projects. Draft reports for each PEHRIIE grantee state will be sent to the primary project coordinator in that state for review and correction of any factual inaccuracies or omissions.

Description of the Information to Be Collected

Semi-structured interviews will be used to collect information pertaining to the implementation, sustainability, and use of the PDMP systems upgraded through the PEHRIIE program. Interviews will be conducted with key project staff/stakeholders and clinical end users.

Topics to be covered in interviews with key project staff and stakeholders include:

- Background and project context:
    - Role of interviewee at their organization.
    - Role of interviewee and organization in development of project and current role in implementation and maintenance of project activities.
    - Experience of interviewee and organization in prior PDMP EHR integration or interoperability projects.
    - Role in and experience with other PDMP-related projects.
    - Factors that led to the development of this PDMP EHR integration or interoperability project.
- Activities and challenges:
    - Grant activities carried out so far.
    - Resources needed to carry out these activities.
    - Challenges encountered in interviewee's and organization's work on this project.
- Successes and outcomes:
    - Successes that have been achieved through the grant process.
    - Partnerships or collaborations created or strengthened as a result of this project.
    - Interviewee and organization methods for tracking successes and challenges on this project.
    - The most valuable activities or improvements made through this project, and the most valuable features of the PDMP.
- Future work and lessons learned:

    - Aspects of interviewee's or organization's work which are likely to be sustained after the grant ends.
    - Resources needed to sustain the interviewee's or organization's work relating to this project.
    - Next steps for interviewee and organization.
    - Recommendations to other states looking to conduct similar projects.

Topics to be covered in interviews with the clinical end users of the upgraded PDMP systems include:

- Background:
    - Current medical practice and prescribing/dispensing practices.
    - Experiences with the prescription drug overdose epidemic as a medical provider.
    - Knowledge of the changes to the PDMP under the SAMHSA cooperative agreement program.
- Current Use:
    - Description of how the interviewee is currently using the PDMP, including frequency and method of access and any training received.
    - Comparison of experiences with the enhanced PDMP system compared to experiences with the previous means of accessing the PDMP.
    - Challenges encountered in accessing the enhanced PDMP system.
    - Best and least useful features of the enhanced PDMP system.
- Clinical Impact:
    - Assessment of quality and comprehensiveness of PDMP data in the enhanced system.
    - Changes to prescribing/dispensing behaviors and/or patient management following PDMP enhancement.
    - Changes to interactions with other providers following PDMP enhancement.
    - Concerns about PDMP data security and privacy following PDMP enhancement.
- Recommendations for Future Improvements:
    - Recommended improvements to increase usability of the PDMP system.
    - Recommended improvements to make returned PDMP data or reports more user-friendly.

For this evaluation the following Information in Identifiable Form (IIF) will be collected for all interviewees:

- Name
- Mailing Address
- Phone Number
- Email Address
- Employment Status

The majority of this IIF will be collected solely for the purposes of logistical interview planning and follow-up for clarification. As part of the interview, information about the interviewees' employment status (i.e. their position, background, and expertise in their current field) will be collected in order to provide context for their perspectives on grantees' activities. There may be interview questions that the interviewees feel are potentially sensitive, including questions about relationships across the state and

between stakeholders and, for clinical end users, questions about their controlled substances prescribing or dispensing practices. Interviewees have the right to refuse to answer any question that they deem to be sensitive, and/or prefer not to discuss.

All written notes and audiotapes from interviews will be stored in locked filing cabinets on secure CDC properties. Files will not be maintained by the name of the individual, but by assigned ID number. Digital notes will be stored on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access. All materials will be kept in this secure manner for the duration of the evaluation project, and then destroyed thereafter.

A.2. Purpose and Use of Information Collection

As noted above, the primary goal of CDC's qualitative evaluation of the SAMHSA PEHRIIE cooperative agreement program and the projects funded thereby, is to understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with HIT systems and interoperability of PDMP systems across states. This information collection will also capture the experiences of clinical end users with the systems being upgraded under the PEHRIIE program as well as their recommendations, if any, for how the goals of the PEHRIIE program could have been better accomplished. To achieve these evaluation goals, the CDC evaluation team will conduct interviews with key project staff and stakeholders as well as with clinical end users using pilot-tested semi-structured interview guides (Attachments 3 and 4).

About the Key Project Staff/Stakeholder Interview Guide: The goal of these interviews is to solicit information that is not available through progress reports and reported quantitative data in order to gain qualitative perspectives on the PEHRIIE projects. Based on pilot-tests (described in more detail in Supporting Statement B, Section B4), these interviews will take approximately 45 minutes to complete. In addition to an introduction statement describing the purpose of the interview and soliciting informed consent, these interviews will consist of four domains:

1. Background and project context (e.g., interviewee role, related projects, project development activities);
2. Activities and challenges (e.g., progress on project activities, resources needed, challenges encountered);
3. Successes and outcomes (e.g., technical improvements and policy changes resulting; new partnerships formed; effect on other related work; and what monitoring is being done); and
4. Future recommendations and lessons learned (e.g., what products are sustainable with what resources; next steps; advice for future implementers; and any additional comments the interviewee wishes to add).

About the Clinical End User Interview Guide: Based on pilot-tests, these interviews will take approximately one hour to complete. In addition to an introduction statement describing the purpose of the interview and soliciting informed consent, these interviews will consist of four domains:

1. Background (e.g., interviewee role; controlled substance prescribing or dispensing practices; experiences with the prescription drug overdose epidemic as a medical provider; knowledge of the SAMHSA PEHRIIE project);
2. Current use (e.g., how often and by what method are they currently accessing PDMP data; training in use of the enhanced PDMP system; comparisons to the previous means of accessing the PDMP; most challenging aspects of current system; best and least useful features);
3. Clinical impact (e.g., perceived quality and comprehensiveness of PDMP data; changes in controlled substances prescribing or dispensing; changes in overall patient management; effect on interactions with other prescribers and pharmacists; security concerns); and
4. Recommendations for future improvements (e.g., what changes might be made in the future to improve accessibility to the PDMP system and usability of the PDMP data and/or reports; any additional comments).

The primary results of this qualitative data collection will be included in summary reports for each of the nine PEHRIIE state grantees and a final comprehensive report of the overall evaluation findings, which will be disseminated to the primary stakeholders in the SAMHSA PEHRIIE cooperative agreement program, including agency officials at SAMHSA and CDC, state PDMP administrators and health technology experts, colleagues at the PDMP Center of Excellence at Brandeis University, and other interested parties. Because this is the first evaluation of PDMP integration with HIT and interstate interoperability, the findings from the evaluation will likely inform future collaborations between government agencies, PDMP advisory groups, and state stakeholders as they pursue additional work focused on improving PDMP efficacy and reducing the epidemic of prescription drug misuse, abuse, and overdose.

Moreover, while the results of this evaluation are not explicitly generalizable beyond the specific projects being evaluated, it is anticipated that the findings of this work will serve as an informative guide for additional states looking to make similar upgrades to their PDMP and HIT systems. In particular, this work will provide important insights on commonly encountered challenges during the development, implementation, and maintenance of these types of systematic PDMP improvements as well as effective strategies to overcoming these challenges. Finally, it is anticipated that the reports resulting from this evaluation will be used by the nine PEHRIIE grantee states in order to continue to refine and expand the improvements made to their PDMPs and HIT systems beyond the funding period.

A.2.A. Privacy Impact Assessment

As stated in the previous section, beyond contact information used to coordinate interview scheduling, the only IIF that will be collected as a part of this information collection is that pertaining to the interviewee's current employment status (including job title, employer name, and tenure) in order to provide context for their involvement in the PEHRIIE grant projects. This evaluation will focus on identifying and analyzing universal successes achieved and common challenges encountered by the participating states as a group. Therefore, any and all reports that are produced from this evaluation will present the findings and conclusions in the aggregate. No specific interviewee names will be reported. Any specific observations deemed critical to include in the final reports will refer to interviewees' general roles in the project and their experience in implementation. All final interview notes will be referenced and filed by the

interviewee's project role and not their name or other IIF. Collected information will be stored digitally on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access or physically in locked filing cabinets on secure CDC properties. This information will not be shared outside of the evaluation team members and will be destroyed no more than six months following the completion of the evaluation project. Therefore, participation in this information collection is not expected to impact the privacy of respondents.

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

Interviews with key project staff and stakeholders are intended to elicit detailed information about interviewees' involvement in developing and implementing the project, and their views on project successes, challenges, and unanticipated consequences. Because the key project staff and stakeholders will likely have distinct perspectives on the project, and because their backgrounds and involvement in the project will differ, one-on-one interviews are planned with these stakeholders. The CDC evaluation team will conduct as many of these interviews in person as possible in order to facilitate interviewer observation of interviewee body language, enabling the interviewer to sense when further probe questions might elicit more detailed information and to allow for flexibility in wording, phrasing, and follow-up. Thus, the collection of information from key project staff and stakeholders does not involve the use of automated, electronic, mechanical, or other forms of information technology.

Interviews with clinical end users in each grantee state will also be conducted as in-person, one-on-one interviews to the greatest extent possible. In-person interviews with this respondent group will allow for clinical end users to openly describe their controlled substances prescribing or dispensing behaviors as well as their use or non-use of the PDMP in their clinical practice. Given the potentially sensitive nature of some of these questions, conducting these interviews in person will enable the interviewer to observe the respondents' non-verbal means of expression and to use these cues to determine when to withdraw or skip questions that may be uncomfortable for the respondent to address. In addition, in-person interviews mitigate potential technological issues that may arise when conducting interviews via conference call, including poor audio quality and lack of connectivity. Finally, conducting these interviews on site will allow the interviewees' to demonstrate aspects of the upgraded systems that may be difficult to describe or explain. Thus the collection of information from clinical end users does not involve the use of automated, electronic, mechanical, or other forms of information technology.

A list of key project staff and stakeholder interviewees will be developed in advance through evaluator conversations with each of the primary project coordinators for each grantee state. One-on-one interviews with key staff and stakeholders and with clinical end users will be scheduled over the course of one four-day in-state visit to each PEHRIIE grantee state.

At least two evaluation team members will be present during each interview to facilitate note taking. Additional evaluation team members may also participate as note takers via conference call. The interviewers will request the permission of all interviewees to audiotape the interview, which will only be referred to in the event of missing or unclear notes. The interviewers will use standard note-taking sheets, either electronically or in hard copy. Use of the standard note-taking form will facilitate interviewers' comparison and compiling of notes for each interview and across all interviews conducted at each site.

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

The SAMHSA PEHRIIE program is a new funding initiative that has not been previously evaluated. While individual states funded through this program may have informally evaluated their projects independently, this will be the first formal evaluation of the PEHRIIE program in totem with an explicit focus on understanding the processes, challenges, and successes in implementing and sustaining integration of PDMP data with HIT systems and interoperability of PDMP systems across states. Moreover, this will be the first evaluation to capture the experiences of clinical end users with the systems being upgraded under the PEHRIIE program as well as their recommendations for how the goals of the PEHRIIE program could have been better accomplished.

As noted above, the PEHRIIE program was preceded by six short-term EHR integration pilot projects that were funded by the Office of the National Coordinator for Health Information Technology (ONC) and managed under contract by the MITRE Corporation. Discussions with the principal coordinators of that earlier program indicated that the limited nature of those projects did not allow evaluators of those projects to draw any conclusions about the impact of HIT integration on prescribing behaviors or prescription drug-related health outcomes. Therefore, prior to issuing the request for applications for the PEHRIIE program, CDC and SAMHSA staff discussed the potential goals of this larger program, including the goals for an evaluation of the program. These same staff members had previously worked with MITRE and ONC on their pilot projects over the prior two years and were well aware of the evaluation limitations for these projects. As a result, the evaluations of those projects were hampered by the inability to conduct qualitative interviews with either the individuals responsible for implementing these projects or the clinical end users of these upgraded systems. Finally, a review of both the published and grey literature on PDMPs did not produce any prior evaluation work related to PDMP interoperability or EHR integration. Therefore, CDC and SAMHSA determined that the proposed PEHRIIE program was an opportunity to conduct a first-of-its-kind, cross-cutting evaluation to better understand the challenges, barriers, and successes for multiple states implementing PDMP EHR integration and interstate interoperability. The discussion between CDC and SAMHSA revolved around realistic evaluation outcomes, including both qualitative and quantitative measures, to be evaluated during the two-year funding period.

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

Key Project Staff/Stakeholder Interviews: The Key Project Staff/Stakeholders interview guide will be used to conduct interviews with individuals employed by small businesses that are/were involved in the development and implementation of projects funded through the PEHRIIE program or the maintenance of improvements made through these same projects. As the individuals to be interviewed as part of this group and that are employed by small businesses have received grant funding for their work on these projects through the PEHRIIE cooperative agreement program, there is an implicit personal benefit to those individuals and their employers in assessing the effectiveness of both the larger project in general and their work specifically. These interviews will take approximately 45 minutes to complete, thus minimizing the amount of burden on these individuals. However, all participants in the PEHRIIE projects will have the option of refusing to respond to all of or part of the interview guide if they feel it is particularly burdensome.

Clinical End User Interviews: The Clinical End Users interview guide will be used to conduct interviews with clinical end users of the PDMP systems that were upgraded through the PEHRIIE program. As many of these end users are either self-employed or work for a small medical practice, they are considered employees of small businesses for these purposes. These interviews will take approximately one hour to complete. While there is a large pool of potential clinical end user interviewees at each implementation site, the number of individual interviews to be conducted at each of these sites was selected to minimize the burden on any one medical practice setting while still enabling the evaluation team to capture of range of experiences with the newly upgraded PDMP systems. Finally, while the opportunity to provide feedback in order to improve these important public health systems is likely to be a motivating factor for taking part in these interviews, participation of the clinical end users in these interviews will be completely voluntary.

A.6. Consequences of Collecting the Information Less Frequently

Each interviewee will only be interviewed once, following either the Key Project Staff/Stakeholder or Clinical End User interview guide as appropriate for the individual's role in the project. There will be no further information collected from the interviewees covered in this request. The respondent universe for both the key project staff/stakeholder interviews has been restricted to only those personnel that are critical for achieving the objectives of the qualitative evaluation. The target number of clinical end user interviewees at each PEHRIIE project implementation site was chosen to ensure a variety of respondent experiences with using the upgraded PDMP systems while minimizing the burden at any one implementation site. In the absence of these interviews, the CDC will be unable to properly conduct an evaluation of the PEHRIIE program as stipulated in the cooperative agreements that were entered into with SAMHSA and the funded states.

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

This request fully complies with the regulations of 5 CFR 1320.5(d)2.

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

A. A notice for public comment on the proposed information collection was published in *The Federal Register* on July 19, 2013, vol. 78, No. 139, pp. 43206-43208 (see Attachment 2). No public comments have been received to date in response to this notice.

B. Members of the CDC evaluation team consulted with the following entities and persons in 2012 and 2013 regarding the overall design of this evaluation of SAMHSA's PEHRIIE program and the projects funded thereby as well as the specific components of the planned qualitative interviews:

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Documentation of consultation with CDR Lee from SAMHSA is included in Attachment 8.

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

Interviewees will not be offered payments, gifts, or other incentives to participate in or complete the planned interviews. Individuals involved in the recruitment of clinical end users for interviews will not be compensated for their time.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does not apply.

Although this evaluation is not covered by human research regulations because it was determined to be a non-research activity, interviews will still be conducted in a manner that is guided by the ethical principles of respect for persons, beneficence, and justice. Prior to each interview, the interviewee will be read a brief summary of the evaluation and interview purpose and will be allowed to ask any questions that they may have based on the evaluation summary disseminated prior to the interview date (Attachment 6). Interviewees will then be advised that their participation in the interview is voluntary and that they do not have to answer any question that they deem sensitive. Interviewees will be asked to verbally acknowledge that they understand and agree to continue with the interview. Finally, interviewees

will be asked to give verbal approval allowing for both note taking by the interviewers and audiotaping of the interview. This language can be found on the front page of both the Key Project Staff/Stakeholder interview guide (Attachment 3) and the Clinical End Users interview guide (Attachment 4), which will also be sent to the interviewees via email prior to the interview (see email templates in Attachment 7).

To ensure the security of information collected from the interviewees participating in this evaluation, the following procedures will be implemented:

Key Project Staff/Stakeholder Interviews: PEHRIIE project coordinators for each of the nine funded states will provide contact lists of individuals who are/were involved in the planning, implementing, and/or maintenance of their project activities. This contact information will be used to schedule interviews with each of the primary stakeholders that the evaluation team plans to interview. During the interviews, both the attending CDC evaluation team members and those participating via conference call will take extensive notes using standard note-taking sheets. With consent from each interviewee, each interview will be audiotaped to use for reference and clarification in cases where the written notes are unclear. All notes and audio-recordings will be stored digitally on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access. Any hard copies will be kept in locked filing cabinets on secure CDC properties. Files will not be maintained by the name of the interviewee, but by assigned ID number. ID numbers will be 12 characters in length and will be generated from a combination of state and site identifiers as well as the date and time of each interview. An ID number code key will be kept in digital form in a unique location on hard drives behind the CDC firewall, separate from the collected notes and audio recordings. Collected information will not be shared outside of the evaluation team members prior to the release of the final report(s). All files will be kept for six months following the completion of the evaluation in case any information is needed and then destroyed thereafter.

Clinical End User Group Interviews**:** PEHRIIE project coordinators for each of the nine funded states will provide a list of implementation sites where PDMP data that has been integrated with EHR, PDS, or other HIT systems is currently accessible to clinical end users, as well as contact information for individuals at each site that can help facilitate the identification of potential clinical end user interviewees (herein referred to as “recruiters”). Recruiters will provide the names and contact information to the CDC evaluation team at least one month prior to the planned visit to that state and implementation site. This information will be used to schedule interviews with three clinical end users at each identified user site. During the interviews, both the attending CDC evaluation team members and those participating via conference call will take extensive notes using standard note-taking sheets. With consent from each interviewee, each interview will be audiotaped to use for reference and clarification in cases where the written notes are unclear. All notes and audio-recordings will be stored digitally on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access. Any hard copies will be kept in locked filing cabinets on secure CDC properties. Files will not be maintained by the name of the interviewee, but by assigned ID number. ID numbers will be 12 characters in length and will be generated from a combination of state and site identifiers as well as the date and time of each interview. An ID number code key will be kept in digital form in a unique location on hard drives behind the CDC firewall, separate from the collected notes and audio recordings. Collected information will not be shared outside of the evaluation team members prior to the release of the final report(s). All files will be kept for

six months following the completion of the evaluation in case any information is needed and then destroyed thereafter.

All interviewees will be provided a description of these security procedures in the evaluation plan summary that will be disseminated via email prior to the interview date (Attachment 6) and will be given an opportunity to ask any questions that they may have in person, prior to the start of the interview.

IRB Approval

All protocols and methods associated with this project have been reviewed by the Associate Director for Science for the Division of Unintentional Injury Prevention (DUIP) and the Human Subjects Contact for the National Center for Injury Prevention and Control (NCIPC). Because this work is an evaluation, it was determined that this project is does not constitute research involving human subjects (Attachment 9). Therefore, CDC IRB approval is not required for this project.

A.10.A Privacy Impact Assessment

A. All individuals will be informed that participation in the planned interviews is voluntary. Interviewees will be asked via email to voluntarily participate in this evaluation, as well as in person immediately prior to the start of the interview. They will be notified at that time that they can refuse to respond to any question that they wish. This language can be found on the front page of both the Key Project Staff/Stakeholder interview guide (Attachment 3) and the Clinical End User interview guide (Attachment 4), as well as in the initial contact email (Attachment 7).

B. Because this work is an evaluation and not research, informed consent of the participants in this information collection is not required. However, out of respect for the ethical principles of respect for persons, beneficence, and justice, all interviewees will be read a statement prior to their interview informing them that their participation in the interview is voluntary as well as briefly describing the methods of note keeping and audiotaping that will be employed and the planned use of the collected information. Interviewees will be asked to verbally acknowledge that they understand and agree to these statements prior to beginning the interview. This language can be found on the cover sheet of both the Key Project Staff/Stakeholders and Clinical End User interview guides (Attachments 3 and 4, respectively). Interviewees will also be provided with this information in the initial contact email (Attachment 7).

C. As described above, all notes and audio-recordings will be stored digitally on hard drives that are behind the CDC firewall and require Smart Card and/or password clearance to access. Any hard copies will be kept in locked filing cabinets on secure CDC properties. Files will not be maintained by the name of the interviewee, but by assigned ID number. ID numbers will be 12 characters in length and will be generated from a combination of state and site identifiers as well as the date and time of each interview. An ID number code key will be kept in digital form in a unique location on hard drives behind the CDC firewall, separate from the collected notes and audio recordings. Collected information will not be shared outside of the evaluation team members prior to the release of the final report(s). All files will be kept for six months following the completion of the evaluation in case any information is needed and then destroyed thereafter.

D. A system of record will not be created under the Privacy Act.

A.11. Justification for Sensitive Questions

The interview questions for individuals involved in PEHRIIE project planning, implementation, and/or maintenance can be found in the Key Project Staff/Stakeholders interview guide in Attachment 3. The primary purpose of these interviews is to identify cross-cutting barriers to and facilitators of successful implementation of the HIT integration and interstate interoperability projects funded through the PEHRIIE program. Therefore, interviewees will be asked to express their opinions on the process of planning, implementing, and/or sustaining the PEHRIIE project that they are working on, which may be considered sensitive information by some interviewees. It is critical that such potentially sensitive questions are included so that the data may inform the possible subsequent expansion of the grant work within grantee states, and the work of other states looking to make similar improvements to their PDMPs. Interviewees will be notified prior to the start of the interview that they can refuse to respond to any question that they feel uncomfortable answering. No participant will be persuaded to answer any question that they determine to be sensitive in nature.

The planned interview questions for the clinical end users of the PDMP systems that are being upgraded through the PEHRIIE program project activities can be found in the Clinical End User interview guide in Attachment 4. The primary purpose of these interviews is to determine if the successful completion of the two primary goals of this program (i.e. improved accessibility of PDMP data via integration with existing health information technologies and increased PDMP data availability via interstate interoperability) resulted in changed provider behavior. Therefore, interviewees will be asked about their clinical practices, especially around the prescribing or dispensing of controlled substances, which may be considered sensitive information by some interviewees. It is critical that such potentially sensitive questions are included in order to capture the impact of the PEHRIIE projects on these behaviors which have been linked to the prescription drug overdose epidemic[6,7,8,9]. Interviewees will be notified prior to the start of the interview that they can refuse to respond to any question that they feel uncomfortable answering. No participant will be persuaded to answer any question that they determine to be sensitive in nature.

A.12. Estimates of Annualized Burden Hours and Costs

The estimated annualized burden hours to complete this information collection are shown in Table 1 and the estimated annualized interviewee costs for participating in this information collection are shown in Table 2. Interviewee costs are given in terms of their time only. The estimated burden hours and cost for the recruiters to identify potential clinical end users and to collect their contact information is also included in these tables.

Key Project Staff/Stakeholder Interviews: Annually, it will take 40 hours of interviewee time to complete all of the planned interviews with key project staff and stakeholders necessary for the planned evaluation of the PEHRIIE program. The annual estimated total cost to interviewees for these interviews will be $1822.80.

- Based on pilot-interviews with three interviewees, each key project staff/stakeholder interview will take approximately 45 minutes to complete. Each interviewee will be interviewed once.
- Based on discussions with the primary project coordinators in each of the nine states participating in the PEHRIIE program, interviews will be conducted with an average of 10 key project staff members/stakeholders in each state (for a total of 91 interviews) as well as 14 key project staff members/stakeholders representing five companies working with multiple states involved in the PEHRIIE program, for a total of 105 key project staff/stakeholder interviews. Because interviewees have been identified based on their roles within each of the PEHRIIE projects, near universal participation is expected for in-person interviews or over the phone if an in person interview cannot be arranged for logistical reasons.
- It will take 79 hours to complete all key project staff/stakeholder interviews.
- According to the Bureau of Labor Statistics data for the lowest and highest earners in this respondent category, the average hourly wage for the individuals to be interviewed using the Key Project Staff/Stakeholder interview guide is $45.57. Therefore, the estimated cost to interviewees is $3600.03 to complete these interviews.

Clinical End User Interviews: Annually, it will take 59 hours of interviewee time to complete all of the clinical end user interviews necessary for the planned evaluation of the PEHRIIE program. The annual estimated total cost to interviewees for these interviews will be $4326.47.

- Based on pilot-interviews with three interviewees, each clinical end user interview will take approximately one hour to complete. Each interviewee will be interviewed once.
- Based on discussions with the primary project coordinators in each of the nine states participating in the PEHRIIE program, end user interviews will be conducted at an average of four implementation sites in each of the nine states, for a total of 39 implementation sites. Interviews will be conducted with three clinical end users per implementation site for a total of 117 clinical end user interviews. Because of the large pool of potential interviewees at each end user site and a general expressed desire for improvements to state PDMPs similar to those planned under the PEHRIIE program by the provider community, no difficulty is anticipated in meeting the target of three clinical end users per site.
- It will take 117 hours of interviewee time to complete all end user interviews.
- According to the Bureau of Labor Statistics, the average hourly wage for the medical providers who comprise this respondent category is $73.33. Therefore, the estimated cost to interviewees is $8579.61 to participate in these interviews.

Clinical End User Recruiters: Annually, it will take 20 hours of recruiter time to identify potential clinical end user interviewees, to collect the contact information for these clinical end users, and to disseminate this collected information to the CDC evaluation team. The annual estimated total cost to recruiters for this work will be $946.80.

- Based on the time required for individuals serving in a similar recruiting role to identify potential clinical end users for the pilot-interviews, collect their contact information, and disseminate that information to the CDC evaluation team, each recruiter will spend approximately one hour to

complete. Thirty-nine recruiters will be completing this work for a total of 39 hours of recruiter time spent on this information collection.

- According to the Bureau of Labor Statistics, the average hourly wage for medical and health services managers who are likely to be acting as recruiters for this information collection is $47.34. Therefore, the estimated cost to recruiters is $1846.26 to participate in this information collection.

The total annual estimated burden hours for this information collection are 119 hours and the estimated annual cost to interviewees will be $7096.07.

Table 1. Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Key Project Staff and Stakeholders	Interview Guide for Key Project Staff and Stakeholders (Attachment 3)	53	1	45/60	40
Clinical End Users	Interview Guide for End Users (Attachment 4)	59	1	1	59
Clinical End User Recruiters	N/A	20	1	1	20
				Total:	**119**

Table 2. Estimated Annualized Burden Costs

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Key Project Staff and Stakeholders	Interview Guide for Key Project Staff and Stakeholders	53	1	45/60	40	$45.57	$1822.80

Clinical End Users	Interview Guide for End Users	59	1	1	59	$73.33	$4326.47
Clinical End User Recruiters	N/A	20	1	1	20	$47.34	$946.80
						Total:	**$7096.07**

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

This information collection activity does not include any other annual cost burden to interviewees. No capital or startup costs will be incurred.

A.14. Annualized Cost to the Government

The primary costs to the government resulting from this information collection are associated with labor costs for personnel and travel costs to conduct the planned interviews.

The team conducting this interview is composed of two subject matter experts at Brandeis University who are working under Intergovernmental Personnel Act (IPA) agreements, two ORISE Fellows working full time on this evaluation, one Evaluation Fellow working part time on this evaluation, and a Commissioned Corps Officer (O-4) overseeing the work. Tasks associated with this information collection include developing the evaluation plan and information collection instruments, applying for IRB determination, scheduling and conducting interviews, preparing post-interview summary statements and obtaining accuracy approval when necessary, data analysis and interpretation, and writing both state-specific and overall final evaluation reports. The breakdown of tasks and estimated efforts associated with this information collection are shown in Table 3. The estimated total government labor costs will be $227,889 and the annualized cost will be $113,945.

Interviews will be conducted over the course of four-day in-state visits to each of the nine states. An extra 1.5 days were included in the cost estimates to account for travel time to and from each state for a total of 49.5 travel days required to complete these interviews. Three additional one day trips will be required to conduct interviews with out of state vendors that are working with multiple states involved in the PEHRIIE program. An extra 1.5 days were included in the cost estimates to account for travel time for a total of 7.5 additional days required for these interviews. Two additional vendors working with multiple states are located within PEHRIIE-funded states, making separate travel to those sites not necessary. Altogether, this information collection will require 12 out of state trips and 57 total travel days. One Fellow and one subject matter expert will travel for each trip. Total travel costs were therefore estimated to be $30,582, based on the following costs:

- Based on the average GSA CityPairs rates from either Atlanta or Boston to the primary city of interviews for each trip, the total airfare costs for 24 round trip tickets (12 trips x 2 people) is $13,728.
- Based on the average GSA CONUS hotel rate of $77 per day, the estimated total hotel costs for 96 nights of hotel stays (12 trips x 4 nights x 2 people) is $7392.
- Based on the average GSA CONUS M&IE per diem rate of $46 per day, the estimated total per diem costs for 114 days of travel is $5244.
- Based on the average US Government Car Rental Program ceiling rate for a midsize car, the estimated total rental car costs for 60 days (12 trips x 5 days) is $4218.

As shown in Table 4, the only other anticipated costs to the government are for supplies ($300). Therefore, the total estimated cost to the government for this information collection is $258,771 and the annualized cost is $129,386.

Table 3. Estimated Annualized Government Labor Costs

Personnel Category	Tasks	Level of Effort	Estimated Cost per Individual	Number of Individuals	Cost
IPAs	Develop Evaluation Plan and Information Collection Instruments; IRB Determination; Information Collection; Data analysis; Data interpretation and report writing	53%	$31,005	2	$62,010
ORISE Fellows	Develop Evaluation Plan and Information Collection Instruments; IRB determination; Interview scheduling; Information collection; Interview transcriptions, development of notes summaries, accuracy approval; data analysis; data interpretation and report writing	52%	$21,580	2	$43,160
Evaluation Fellow	Develop Evaluation Plan and Information Collection Instruments; IRB determination; data analysis; data interpretation and report writing	20%	$6,990	1	$6,990
CDC Commissioned Corps FTE	Oversee development of the Evaluation Plan and Information Collection Instruments, IRB Determination, Information Collection, Data analysis, Data interpretation, and report writing	3%	$1,785	1	$1,785
Total:					$113,945

Table 4. Estimated Annualized Cost to the Government for Information Collection

Cost Source	Total Cost
Government Labor	$113,945
Other Direct Costs:	
Travel	$15,291
Field Expenses	$0
Computing	$0
Copying	$0
Telephone	$0
Supplies	$150
Postage	$0
Total Estimated Annualized Costs	$129,386

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Project Time Schedule

Following the completion of each set of interviews, the interviewers will compare and compile notes for each interview. Where interviewees gave permission for audiotaping of the interviews, the recordings will be used to clarify any points unclear or in question from interviewer notes, and the interviewers will create a finalized interview summary.

Following the completion of the interview collection, two analysts will collaboratively create a coding schema that will be used by each analyst independently to code each final interview notes summary. Coding schema will be applied as consistently as practicable across states while still allowing for important individual state findings to emerge. They will then conduct a thematic analysis of the collected qualitative data as well as across and within case analyses in order to address the following evaluation questions:

Process Questions

1. To what extent did grantees implement activities as planned?
2. To what extent did grantees improve the quality of their PDMP data?
3. To what extent did grantees improve PDMP access and usability?
4. To what extent did grantees establish or improve interoperability with other PDMPs?
5. To what extent did grantees establish or improve integration with HIT systems?
6. What were the costs and resources needed to implement and sustain PDMP interoperability and integration with other systems?

Outcome Questions

1. To what extent did the grant increase use of PDMP data?
2. What impact did the PEHRIIE project have on providers' prescribing or dispensing behaviors?

Final results will be compiled into state-specific summary reports and a final comprehensive report that will be distributed to the primary stakeholders in the SAMHSA PEHRIIE program, including agency officials at SAMHSA and the CDC, state PDMP administrators and health technology experts, colleagues at the PDMP Center of Excellence at Brandeis University, and other interested parties. Additional dissemination may include publication in peer-reviewed journal articles and presentations at conferences or meetings.

Table 5: Data Collection Timetable

TASK	End Date
Develop Evaluation Plan and Information Collection Instruments	6 months prior to OMB approval
IRB determination	4 months prior to OMB approval
Interview Scheduling	6 months after OMB approval
Information Collection	24 months after OMB approval
Development of thematic summaries of interview notes	24 months after OMB approval
Data analysis	24 months after OMB approval
Data interpretation and report writing	26 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.

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