

***SUPPORTING STATEMENT: PART A***

**October 4, 2017**

**State Unintentional Drug Overdose Reporting System (SUDORS)**

OMB# 0920-1128

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- B1 Public comment
- C Institutional Review Board (IRB) documentation
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## Summary Table

- **Goal of the study** – Detect state and local community changes in opioid-related mortality faster and provide in-depth state and local (e.g., county) information on risk factors for fatal overdose that can inform the selection and targeting of interventions in states with high rates of opioid-related overdose deaths. CDC requests OMB approval for 3 years for this revision to include all 50 states, increasing the burden from the 16 states currently approved. The new states will be funded in August/September 2017 and will need to begin surveillance work and reporting by October 2017 to be in compliance with the deliverable dates in the FOA. In addition, there have been updates to the web-based system to improve performance, functionality, and accessibility, and additional fields have been added to the opioid overdose module to allow for capturing of more detailed information.
- **Intended use of the resulting data**- Improve identification and response to changes in fatal unintentional opioid-related overdose trends at the local, state, and national level.
- **Methods to be used to collect** – State public health departments will be funded to abstract standardized data elements from Medical Examiner/Coroner reports (ME/C) as well as death certificates on unintentional opioid-related overdose deaths in their state into a CDC web-based platform.
- **The subpopulation to be studied** – Individuals who died of an unintentional opioid-related drug overdose
- **How data will be analyzed** - Descriptive analyses such as frequencies and rates.

### A.

#### Justification

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

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) seeks OMB approval for the revision of the currently approved State Unintentional Drug Overdose Reporting System (SUDORS) - OMB# 0920-1128, expiration date 08/31/2018. SUDORS assists with ongoing surveillance of fatal unintentional and undetermined opioid-related drug overdoses to support prevention and response efforts in states with a high burden of opioid-related overdose morbidity and mortality. The purpose of the revision is twofold: 1) increase burden hours associated with increasing the number of states using the SUDORS OMB package from the 16 approved to all 50 states; and 2) implement updates to the web-based system to improve performance, functionality, and accessibility as well as minimal revisions to the SUDORS collection instrument. The capacity of SUDORS to collect information

about the circumstances of fatal drug overdose that is not available from death certificates provides crucial data to inform more systematic approaches to combat the overdose epidemic. These data will also be key to determine the effectiveness of overdose prevention and treatment strategies. Specifically, this data collection revision seeks to expand SUDORS approval to all 50 states. As the Department of Health and Human Services and the White House pursue national solutions to the opioid crisis, it is vital to have detailed data that reflect the full scope of the opioid crisis across all states to best target and assess policy interventions.

## Background

In 2015, there were over 52,000 drug overdose deaths, including over 44,000 unintentional drug overdose deaths, in the United States. From 2000 to 2014 nearly half a million persons in the United States have died from drug overdoses<sup>i</sup>. In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes<sup>ii</sup>. In 2014, opioids were involved in 61% of fatal drug overdoses<sup>iii</sup> and this is a substantial underestimate because the specific drug causing an overdose is not listed on death certificates for 1 in 5 drug overdose deaths<sup>iv,v</sup>. America's opioid overdose epidemic involves two distinct but interrelated trends: a fifteen-year increase in overdose deaths involving prescription opioid pain relievers (OPR), and a recent surge in illicit opioid-related overdose deaths driven largely by heroin. Overdose deaths involving opioids, both OPR and heroin, in the US have quadrupled since 1999, with 28,647 reported fatalities in 2014. Overdose deaths involving opioids increased by 14 percent from 2013 to 2014<sup>vi</sup>.

A surge in OPR-related overdoses deaths has been paralleled and driven by increases in OPR prescribing rates which have also quadrupled since 1999<sup>vii</sup>. Deaths related to natural and semisynthetic opioids, which include the most commonly prescribed OPR, oxycodone and hydrocodone, increased by 9 percent from 2013 to 2014<sup>viii</sup>.

From 2013 to 2014, heroin-related overdose death rates increased by 26 percent and have more than tripled since 2010. The recent surge in deaths involving heroin is linked to the misuse of OPR. Past misuse of OPR is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or misuse<sup>ix</sup>. In addition, the increased availability of heroin, combined with its relatively low price (compared with diverted OPRs) and high purity appear to be major drivers of the upward trend in heroin use and overdose<sup>x</sup>. Also, a sharp increase in deaths involving synthetic opioids, excluding methadone, of 80 percent from 2013 to 2014 coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid that is often mixed with or sold as heroin. Therefore, increases in illicit fentanyl-associated deaths may represent an emerging and troubling feature of the rise in illicit opioid overdoses<sup>xi,xii</sup>

In an effort to address this problem, multiple national and state initiatives have been launched. The U.S. Department of Health and Human Services (HHS) has made addressing the opioid misuse problem a high priority and is focused on implementing evidence-based approaches to reduce: 1) opioid overdoses and overdose-related mortality and 2) the prevalence of opioid use disorder<sup>xiii</sup>. As part of this effort, CDC is publishing draft guidelines for prescribing opioids for

chronic pain to increase safer prescribing practices<sup>xiv</sup>. Also, in FY15 CDC funded 16 states through *Prescription Drug Overdose Prevention for States* (CDC-RFA-CE15-1501) to implement, advance and evaluate comprehensive state-level interventions for prevention prescription drug overuse, misuse, and overdose. Interventions of priority address drivers of the prescription drug overdose epidemic, particularly the misuse and inappropriate prescribing of OPR. Finally, states are also responding to the problem as evidenced by the National Governor's Association convening the *Prescription Drug Misuse Reduction Policy Academy*<sup>xv</sup>, a state declaring opioid misuse a public health emergency<sup>xvi</sup>, a governor dedicated his entire state of union to drug addiction, especially related to opiates<sup>xvii</sup>, and the President of the Association of State and Territorial Health Officials (ASTHO) challenging its members to reduce the rate of nonmedical use and the number of unintentional overdose deaths involving controlled prescription drugs by 15 percent by 2015<sup>xviii</sup>.

The need for improved surveillance of heroin-related overdoses was also recognized in the Consolidate Appropriations Act, 2016, H.R. 2029 which provided CDC funding to enhance surveillance of heroin. In order to address the need for surveillance information on opioid-related risk factors, especially heroin, the State Unintentional Drug Overdose Reporting System (SUDORS) supports the collection of data on all opioid-related unintentional fatal drug overdoses including county and zip code of residency and where the overdose occurred with an 8-month time lag (e.g., complete data collection on opioid-related drug overdose deaths occurring from January to June 2017 by February 28, 2018).

The SUDORS system provides detailed information on risk factors for unintentional and undetermined opioid-related overdose deaths (e.g., recent discharge for residential treatment or prison, recent arrest, recent relapse using opioid-related drugs, no bystanders were present when the overdose occurred, mental health conditions, a surge in adulterated heroin that is especially potent, or new patterns in polysubstance drug use) at the local level (e.g., county and zip code). Having local level data is critical to assist communities to select and target interventions that address the risk factors most prevalent in their communities. Interventions that could be used by communities include distributing naloxone<sup>xix</sup> to first responders and community members, enhancing access and use of evidence-based substance use treatment<sup>xx</sup>, identifying and disrupting illegal distribution of OPRs through physician offices (i.e., often referred to "pill mills")<sup>xxi</sup>, or implementing comprehensive efforts including prescribing guidelines and intensive education of clinicians and community members to promote safer prescribing of opioid pain relievers for chronic non-cancer pain<sup>xxii</sup>.

In FY16, CDC was appropriated funds to work with state health departments to improve the timeliness of fatal opioid overdose surveillance by developing the Enhanced State Opioid Overdose Surveillance program (ESOOS; FOA #CE16-1608), with 16 states originally approved in this OMB application and 12 states funded. The FOA provides states a delivery schedule for reporting fatal opioid overdoses to CDC using SUDORS. The next data delivery will occur in October 2017. In FY17, ESOOS received a significant increase in funding through congressional appropriation to expand the number of states using the SUDORS OMB package for mortality data collection. There is an increased likelihood of obtaining additional appropriated funds in FY18. As a result, CDC requests OMB approval for 3 years for this revision to include all 50 states, increasing the burden from the 16 states currently approved. The new states will be

funded in August/September 2017 and will need to begin surveillance work and reporting by October 2017 in order to be in compliance with the deliverable dates in the FOA. Burden is calculated only for the public agencies (vital statistics and medical examiners/coroners) to retrieve and then refile records. The data requested from vital statistics or ME/C (i.e., the two parties who incur burden as a result of the data collection) does not change.

There are minimal changes to the collection instrument in this revision; however, there have been updates to the web-based system to improve performance, functionality, and accessibility for funded states. Minimal changes to the SUDORS module include revisions to question wording and response choices, as well as additional categories available to capture information that previously could only be captured in a narrative field, to better capture contextual information such as day/time a decedent was last seen alive, whether a decedent had a recent opioid use relapse, evidence of prescription drug use, and evidence of rapid overdose. These revisions are based on lessons learned from the state programs using SUDORS for data collection (Enhanced State Opioid Overdose Surveillance; currently funded ESOOS awardees, from two Epi-Aids in Massachusetts and Ohio, and from consultations with experts on illicit drug use). Attachment F (the Survey Updates Documentation) and Attachment F1 (screenshots) provide a detailed crosswalk of current questions and the revisions. These changes would not affect burden hours per response. Updates to burden estimates include projected hours for all 50 states.

SUDORS will leverage the existing web-based data collection platform, the National Violent Death Reporting System (NVDRS) OMB# 0920-0607, to collect medical examiner and coroner (ME/C) information, including toxicology, and death certificate information on unintentional and undetermined fatal drug overdoses. This program is authorized under section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act and section 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act (See Attachment A).

OMB's terms of clearance for the currently approved package were: "Approval for 2 year OMB clearance is granted with the understanding that CDC will provide updates to OMB (via phone teleconference) every 6 months on their progress toward achieving more streamlined and collaborative data collection efforts in coordination with NCHS." CDC understands that OMB's interest is in maximizing the long-term investment in working with State health departments and medical examiners/coroners to improve the timeliness of fatal opioid overdose surveillance. As such, DUIP/NCIPC will continue to devote resources to continuing to collaborate with NCHS to improve the quality and comprehensiveness of opioid death reporting on State death certificates. CDC has uploaded a supplemental document entitled "CDC Response to SUDORS OMB Request" that explains progress to date.

## **2. Purpose and Use of Information Collection**

The purpose of SUDORS is to generate public health surveillance information on unintentional and undetermined opioid-related drug overdoses across multiple states, within a state, and within local communities to support states and local communities to select and target intervention strategies that address the risk factors driving fatal opioid-related overdoses in their community. A few examples of how data collected as part of SUDORS could support prevention and



response to opioid-related overdoses are provided below. SUDORS data could:

- Assist state and local communities to better understand the extent to which opioid-related overdose deaths are related to the misuse of prescription drugs versus use of illicitly produced opioids such as heroin. This will help better track the burden in trends in opioid-related drug overdoses.
  - Toxicology and scene evidence (e.g., drug paraphernalia) are often needed to determine if drug overdoses testing positive for morphine on toxicology are related to the use of prescription morphine or heroin<sup>xxiii</sup>.
  - A powerful opioid, fentanyl, is produced by pharmacies and also illicitly manufactured. Toxicology tests conducted by ME/Cs cannot determine the source<sup>xxiv</sup>, but scene evidence and full toxicology findings (e.g., when mixed with heroin most often occurs with illicitly manufactured heroin) can help distinguish whether the fentanyl was manufactured illicitly or by pharmaceutical companies.
  - ME/C reports will be reviewed to determine whether the overdose was related to substance misuse, taking prescribed OPR in a manner not prescribed (e.g., taking extra dosages because decedent was feeling pain), or accidental ingestion (e.g., a very young child ingests a prescribed opioid or heroin).
  - The death certificate does not report the specific drug causing an overdose for about 20 percent of drug overdoses<sup>xxv</sup>. A portion of this results from the use of general terms such as “narcotic” on the death certificate<sup>xxvi</sup>. Consequently, reviewing the ME/C report, including toxicology, should improve the classification and thus tracking of opioid-related drug overdose deaths.
- Help states target counties and zip codes experiencing increasing opioid-related deaths for the distribution of naloxone, an antidote to opioid overdoses. Expanded naloxone distribution is a major component of the HHS Secretary’s initiative to combat opioid misuse<sup>xxvii</sup>.
  - Assist states and local communities to better implement naloxone distribution programs by tracking challenges to the use of naloxone. For instance, in order for naloxone programs to be effective, bystanders need to recognize the signs of an opioid-overdose, administer naloxone, and/or call 9-1-1 for assistance. SUDORS will track the percent of opioid-related deaths where a bystander was present and when and who administered naloxone.
- Support state and local communities to identify opportunities to intervene before a fatal overdose occurs by examining the decedents’ contacts with key institutions within a month of the overdose:
  - Track the percent of decedents who were receiving OPRs when the opioid-related overdose occurred,
  - Track the percent of decedents who were receiving substance misuse treatment to determine the extent to which access to treatment or access to effective evidence-based treatment are issues. Expansion of Medication-assisted Treatment (MAT) to reduce opioid use disorders and overdose is a major component of the HHS Secretary’s initiative to combat opioid misuse<sup>xxviii</sup>,
  - Track the percent of decedents receiving mental health treatment to determine the extent to which people with mental health conditions should be targeted for interventions,

- Track the percent of decedents who were released from incarceration within the last month, a risk factor for overdose<sup>xxix</sup>,
- Track the percent of decedents who were recently released from residential treatment, a risk factor for overdose<sup>xxx</sup>
- Inform state and local health departments about shifts in the adulteration of the heroin supply or polysubstance misuse patterns. Understanding this issue could inform emergency medical response. For instance, recent adulteration of heroin with fentanyl, a powerful opioid analgesic, may increase the chance of an opioid overdose, the need for multiple naloxone administrations, and the number of fatal opioid overdoses<sup>lxxxix</sup>.
- Determine whether fatal overdoses are related to how the drug was taken (e.g., injected, swallowed, sniffed, smoked, etc.) so interventions can target groups most at risk of a fatal overdose.
- Inform national policy by providing in-depth risk factor information, described above, on a subset of states with high rates of drug overdose deaths and better understand variations across high burden states.

Up to 50 state health departments will be asked to collect standardized variables from death certificate (DC) and medical examiner and coroner (ME/C) reports on all unintentional drug overdoses in their jurisdiction with an 8-month time lag (e.g., complete data collection on opioid-related drug overdose deaths occurring from January to June 2017 by February 28, 2018). The method for selecting the states is described in detail in Supporting Statement B.

SUDORS will leverage the NVDRS web-based platform to collect data on DC and ME/C reports. The web-platform allows importing of DC data and has established protocols for abstracting information on a number of important risk factors for fatal drug overdoses only available in the ME/C report: history of substance misuse, mental health status, toxicology findings, recent release from an institution, and contact with criminal justice. Additional drug overdose specific questions are added to capture risk factor information specific to drug overdoses such as if and when naloxone was administered, the number of bystanders present when the decedent overdosed, evidence from the scene (e.g., drug paraphernalia), and information on recent opioid prescriptions.

The data collection has at least two limitations. Because the data collection relies on ME/C investigations of fatal drug overdoses which are not standardized across the United States, differences may exist in the extent to which different jurisdictions collect information on key circumstances or contributing factors related to an overdose such as decedent's history of substance use/treatment or controlled substances prescribed to the decedent at time of death. For instance, ME/C in some states have complete access to the controlled substance prescription history of decedents while in other states this information is restricted or not easily accessed. Second, data is abstracted from information collected during a field investigation of the death and not a systematic data collection such as a survey.

### **3. Use of Improved Information Technology and Burden Reduction**

Data entry is accomplished in state health department offices or medical examiner or coroner

(ME/C) offices via the secure NVDRS web-based platform. Data are continuously transmitted via the web to a secure CDC-based server. This has four advantages:

1. The web-based platform enhances the ability of authorized users to securely enter the data from multiple sites or directly from coroner or medical examiner offices.
2. Because states will use the same web-platform to enter information on violent deaths through NVDRS and unintentional overdose deaths through SUDORS, state health departments can increase efficiency and decrease burden by designing similar data collection and data abstraction processes across violent and unintentional drug overdose deaths.
3. Training of new data abstractors is simplified for NVDRS-funded states because they can build on the historical experience of using the NVDRS web platform.
4. States with access to electronic data can reduce data entry burden by using electronic import options for death certificate and ME/C data.

The web-based data collection platform also improves data quality by providing abstractors easy access to help functions and coding manuals. Also, the interface includes internal validation checks and other quality control measures that capture data entry errors as they occur. This reduces the burden because identifying and fixing errors after data entry is complete is more difficult and timely.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

There is no similar ongoing surveillance system in existence. Currently, NVDRS does not collect information on unintentional drug overdoses. Even though vital statistics (i.e., death certificates) collects information on drug overdose deaths, this information focuses on when and why deaths occurred, but does not provide information on risk factors for the overdose such as recent release from an institution or mental health history. SUDORS will be able to abstract more comprehensive drug misuse histories of decedents and circumstances around their deaths from ME/C reports. Additionally, deaths will be directly linked to available toxicology reports that will provide the most complete view of drugs contributing to an overdose including how the drug was taken (e.g., injection versus smoking).

SUDORS is using the NVDRS web-based platform because:

- 1) Using an existing web-based data collection platform instead of creating a new platform substantially reduces development costs, training costs, and burden on states collecting SUDORS data by allowing abstractors to use the same data system to enter both violent deaths and unintentional overdose deaths.
- 2) The web-based platform has been designed to support abstraction of standardized data elements from death certificates and ME/C reports that SUDORS will collect (e.g., demographic description of decedents, toxicology reports, location of death).
- 3) Additional questions targeting drug overdose specific risk factors have been developed and rapidly made available to states.

SUDORS is a new data collection instead of an amendment to NVDRS because the purpose of SUDORS is different from NVDRS. This results in the programs having different requirements, imposing different burdens on the public, and becoming more distinct overtime. In order to be

effective, SUDORS needs to collect data with an eight month time lag which is substantially faster than current NVDRS. Thus, SUDORS is not collecting law enforcement information which has a long time lag even though NVDRS does collect this information. This means the burden estimates for the two systems will be different. Also, SUDORS can rapidly begin data collection by leveraging the NVDRS system and collecting information on many of the same variables. The information that SUDORS collects is expected to change overtime based on feedback from awardees and key stakeholders. This will result in new versions that include additional variables being added and other variables being dropped (i.e., grayed or blanked out in the data entry system). These changes are expected to increasingly make SUDORS and NVDRS variables different. Also, SUDORS may explore additional linkages with data sources such as state prescription drug monitoring programs (i.e., state programs that track all controlled substance prescriptions) that are very relevant to drug overdose, but not as useful to NVDRS. This again would contribute to significant differences in scope and burden estimates of the two systems.

Currently, in efforts to comply with OMB requirements, DUIP has convened several calls with NCHS to identify opportunities to enhance collaboration and coordination in collecting ME/C data. Both NCHS and DUIP collect information from ME/C. As a result of discussions, two action items described below were identified and begun.

- 1) DUIP and NCHS are exploring collaborations between the grantees of the ESOOS program and grantees of the NCHS Vital Statistics program aimed at improving the quality of data on cause of death on death certificates. Specifically, we are working to identify 1 or 2 states that are funded by both NCHS and DUIP to explore what data are collected, prioritize which data could be shared across systems, and identify better ways to share/link data and make systems interoperable.
  - a. DUIP has shared with NCHS the list of funded states under the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality Program, to identify states that are funded by both NCHS and DUIP programs that could collaborate on discussions to identify data that are critical for meeting joint goals and explore methods for enhancing quality, speed or reporting, and interoperability. As part of this process, DUIP and NCHS are identifying and supporting state interest in collaboration.-
  - b. DUIP will continue to have regular meetings with NCHS to discuss lessons learned from their respective meetings with awardees and opportunities for coordination.
- 2) DUIP and NCHS are funding a project involving Occupational Research and Assessment (ORA) in association with both the National Association of Medical Examiners and the International Association of Coroners & Medical Examiners that was looking to create, implement and conduct a proof-of-concept project directed toward helping address accurate real-time data reporting of drug mortality data. This project would utilize a pilot-test of ME/C data interfaces for 5 medical examiner offices that use MDILog or VertiQ electronic case management system, and would help set specifications (e.g., export schema for toxicology data) for ME/C software interfaces going forward to ensure that ME/C data are made available in a consistent, scalable, and secure manner. We are

expecting a second detailed proposal soon. This is a superior approach than a state collaboration because it leverages a large existing electronic case management system and this pilot project has the potential to be scaled up.

DUIP also strongly encourages states funded through ESOOS to provide resources to their state vital statistics program to support improvements in the collections of death certificate and ME/C data in their state. DUIP will also review state approaches to collecting death certificate and ME/C data to identify possible new strategies for enhancing coordination of DUIP and NCHS's efforts.

In addition to extensive consultation, including in-person meetings and phone calls, with the Division of Violence Prevention at CDC about integrating SUDORS into NVDRS, we also consulted with SAMHSA by phone about their previous data collection through the Drug Misuse Warning Network Medical Examiner/Coroner (ME/C).

## **5. Impact on Small Businesses or Other Small Entities**

This study does not impact small businesses or other small entities. It impacts public agencies such as health departments, and medical examiner/coroner offices, whose records are accessed in the course of data collection.

## **6. Consequences of Collecting the Information Less Frequently**

The rapid changes in opioid-related drug overdose on a yearly basis such as the 26% increase in heroin-related overdose deaths from 2013 to 2014<sup>xxxii</sup>, highlight the need for timely data collection to support ongoing national, state, and local efforts to reduce opioid-related morbidity and mortality. The current system is striving to collect data with an 8-month time lag (e.g., complete data collection on opioid-related drug overdose deaths occurring from January to June 2017 by February 28, 2018).

If SUDORS information is not collected, consistent in-depth information on the circumstances related to unintentional drug overdose deaths will not be available and this will inhibit targeting of prevention efforts. Additionally, SUDORS will work to provide preliminary drug overdose death counts within 8 months (e.g., complete data collection on opioid-related drug overdose deaths occurring from January to June 2017 by February 28, 2018) which is faster than current estimates from vital statistics which has a time lag of a year or more. This will allow better tracking of the impact of current prevention initiatives. Delays in data collection would impede the ability of the ESOOS program to obtain more rapid mortality data that can inform deployment of prevention and intervention strategies to address the ongoing opioid epidemic and be responsive to the congressional intent of the program funding.

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

This data collection complies fully with the guidelines in 5CFR 1320.5.

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

### **A. Federal Register Notice**

A 60-day Federal Register Notice was published in the Federal Register on August, 14, 2015, vol. 80, No. 157, pp. 48861-48862 (Attachment B). CDC received one non-substantive comment (Attachment B1) and replied with a standard CDC response. OMB waived the requirement for a 60-day Federal Register Notice for this revision request because the scope of the data collection remains the same, and other than the burden estimate, the original 60-day FRN generally still holds for this updated data collection; the primary change is that there is an increase from 12 states to 50 states participating in the data collection.

### **B. Efforts to Consult Outside the Agency**

NCIPC consulted with the currently funded NVDRS states to learn and build upon the extensive work already performed to establish NVDRS. Multiple phone calls were conducted with two NVDRS states that had collected ME/C data on unintentional drug overdoses or were planning to in the near future. In addition, feedback on new risk factors to include in the data collection were solicited from all NVDRS states. Finally, intensive consultation with states during Epi-Aid responses to drug overdose outbreaks highlighted important questions and strengths and limitations of data sources<sup>xxxiii,xxxiv</sup>.

The drug overdose questions related to use of prescription opioids are informed by two consultations. First, CDC engaged in intensive consultation with experts and the public as part of an effort to write guidelines for prescribing opioids for chronic pain. An in-depth description of the process and draft guidelines are available at:

<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. Second, CDC has consulted extensively with the Brandeis Center for Excellence, a leader in analyzing prescription data, on appropriate metrics to detect inappropriate or higher risk opioid prescribing practices<sup>xxxv</sup>.

The current project also builds on the work performed and external consultation performed by NVDRS when the NVDRS web-system was designed.

## **9. Explanation of Any Payment or Gift to Respondents**

No incentives, payments or gifts will be provided to survey participants

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

This submission has been reviewed by the NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply for SUDORS. SUDORS is housed within the NVDRS web-based system. The NVDRS system has a current Authorization to Operate. The Privacy Impact Assessment (PIA) is attached (Attachment G).

Although sensitive information will be collected by state health departments (the respondents), all personally identifying information is stripped from the files before the case-level data is sent

to CDC. Only selected staff working in the state SUDORS program will have access to state information. States will treat their data in a secure manner and protect it with all applicable state laws for the protection of public health surveillance information.

This surveillance system is coordinated and funded at the federal level, but is dependent on separate data collection efforts in each state managed by the state health departments or their bona fide agent. Data from the participating 50 states will be entered in the NVDRS web-based platform maintained by CDC. Data will be continuously transmitted via the web to a secure CDC-based server. The data collection will integrate the same validation and security measures implemented by NVDRS. Also, CDC will provide state project personnel coding training to help increase data quality.

CDC and state health departments will conduct analyses of the data and share aggregate results with the public through a public use data set. States will only enter de-identified information into the CDC run web-based platform. Thus, the proposed data collection will have little or no effect on the respondent's privacy. Data from all states will be entered in the NVDRS web-based platform maintained by CDC. This is secondary data and is dependent on separate data collection efforts in each state managed by the state health departments or their bona fide agent.

To ensure security of the data, a number of procedures will be implemented:

- Data is maintained securely throughout the data collection and data processing phases.
- Data is stored on a secure CDC-based server accessed via a secure web platform. Authorized state users will be able to download de-identified datasets.
- Supplemental data (i.e., any information not included in the web-based system) by state health departments such as paper abstraction worksheets or additional information collected on drug overdose deaths will be stored at the state level in secured computers that reside within state health department firewalls. Such information will never be sent from the state to the CDC or to a CDC contractor.
- The CDC web system does not store personal identifying information such as names, address, SSN, or date of birth.
- SUDORS follows NCHS guidelines on suppression of small sample sizes in data tabulations (e.g., not report any information that involves 10 or fewer people) to prevent the inadvertent identification of an individual through the combination of various demographic characteristics.

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

The CDC National Center for Injury Prevention and Control's OMB and human subject's liaison has determined that the activity is not research and IRB approval is not needed. Human participants will not be used (Attachment C)

No sensitive questions are asked directly to witnesses of fatal unintentional drug overdose or their next of kin. Information on sensitive issues, e.g., mental illness and substance misuse, has already been collected by state and local governments by ME/C through the death scene investigation process. SUDORS is funding states to abstract and record this information in a standardized format to enhance comparability and facilitate analysis.

## 12. A. Estimates of Annualized Burden Hours and Costs

There are no standard paper data collection forms to be used by states because states will be abstracting information from electronic or paper vital statistics or ME/C records into the CDC web-based data system. Although no data system currently collects the proposed information on unintentional drug overdoses, similar data collection efforts on violent deaths conducted by NVDRS were used to estimate burden. NVDRS has approximately 10 years of experience working with 18 funded states to inform its estimates of annualized burden hours and costs.

The burden was estimated as follows:

- The burden was originally calculated for 16 states with the highest drug overdose death rates in 2014. These 16 states (West Virginia, New Mexico, New Hampshire, Kentucky, Ohio, Rhode Island, Utah, Pennsylvania, Delaware, Oklahoma, Tennessee, Wyoming, Massachusetts, Nevada, Missouri, and Indiana) reported 14,013 unintentional drug overdose deaths in 2014, or an average of 875.8 deaths per state. Updates to our burden estimates include projected hours for all 50 states. In 2015, across all 50 states, 33,091 drug overdose deaths involved an opioid.
- To develop the burden estimates for all 50 states we estimated the number of hours per reported unintentional opioid-involved overdose death in the 50 targeted states (i.e., 33,091 in 2015) required for the public agencies (vital statistics and ME/C) to retrieve and then refile their records to be about 0.5 hours (0.25 hours per death for vital statistics and 0.25 hours for ME/C reports). Expanded use of electronic vital statistics and ME/C systems should reduce this burden over time.

The estimated annual burden hours request for this approval are 16,550, with an increase from the previously 7,008 burden hours approved.

### Estimated Annualized Respondent Burden Hours

Type of Respondent	Form Name	No. of Respondents	Total No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours (in hours)
Public Agencies	Retrieving and refiling records (Att. E)	50	662	30/60	16,550
Total					16,550

## 12. B. Estimated Annualized Respondent Burden Costs:

The staff who are retrieving records will vary substantially across organizations because administrative staff may pull records in large ME/C or vital statistics offices while in some smaller counties elected coroners may pull records. Thus, the average of hourly salary of federal, state, and local government employees was used or \$25.56<sup>xxxvi</sup>. Public Agencies who retrieve and



refile records estimate costs at [16,550 burden hours x \$25.56/hour] = \$423,018. In some cases, state health departments may subcontract with the public agencies or otherwise find a way to defray these costs.

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 Cost
Public Agencies	50	662	30/60	16,550	\$25.56	\$423,018
<b>Total</b>						<b>\$423,018</b>

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

Respondents will incur no capital or maintenance costs.

### 14. Annualized Cost to the Government

These costs fall into several categories, listed below:

#### Contractor phases, tasks, and estimated costs

<b>LABOR</b>	<b>COST</b>
MISO contract for maintenance of the data collection software	\$100,000
Contracts and cooperative agreements with national data partners	\$50,000
<b>Other Direct Costs</b>	
Subcontractors	\$0
Travel and subsistence	\$0
<b>Total Estimated Contract Costs</b>	<b>\$150,000</b>

#### Government costs

<b>Personnel</b>	<b>Tasks</b>	<b>Avg. cost/yr</b>
Senior Scientist (50% time)	Program oversight	\$52,500

2 Epidemiologist	Technical assistance and data usage	\$182,400
3 Public Health Advisors	Programmatic, budgetary, administrative management & oversight	\$282,225
Public Health Analyst	Data quality assurance	\$80,000
3% cost of living adjustment over 3-years		\$17,914
<b>Sub-total</b>		<b>\$615,039</b>
Contract Costs		\$150,000
<b>Total</b>		<b>\$765,039</b>

Total annual contractual and government staff costs are approximately \$765,039. This is a three year project. The total cost over three years for contractual and government staff will be three times the annual budget.

## 15. Explanation for Program Changes or Adjustments

There are minimal changes to the collection instrument in this revision; however, there have been updates to the web-based system to improve performance, functionality, and accessibility for funded states. Minimal changes to the SUDORS module include revisions to question wording and response choices as well as additional items to better capture contextual information such as day/time a decedent was last seen alive, whether a decedent had a recent opioid use relapse, evidence of prescription drug use, and evidence of rapid overdose. These revisions are based on lessons learned from currently funded ESOOS awardees, from two Epi-Aids in Massachusetts and Ohio, and consultations with experts on illicit drug use. Attachment F (the Survey Updates Documentation) and Attachment F1 (screenshots) provide a detailed crosswalk of current questions and the revisions. These changes would not affect burden hours per response. Not all categories are required, and not all categories will be used for each death; use depends on information and evidence specific to each death record (i.e., built in skip-patterns). Previously, the information that will be captured by the new categories could only be captured by entering text in the narrative field. Examples of the minimal changes are below:

- 1) Due to limited funding at program start-up, a number of the items used drop down responses that only allowed abstractors to enter one response. This revision changes the structure of the items so an abstractor could select multiple responses when necessary. For example, an original item includes a drop down box for options under “Naloxone/opioid antagonist administered” where only one item can be selected and the revised item includes a check boxes for all that apply that include several responses (see “response to drug overdose” section in Attachment F1).
- 2) Review and use of the items revealed that more nuanced responses were needed for some questions. For instance, the revised screen lists all methods for using drugs (injection,

ingestion, sniffing/snorting, smoking, etc.) while the previous screen omitted some categories (see “route of drug exposure/administration” section in Attachment F1).

- 3) In order to capture information on some key variables such as presence of illicit drugs, additional items were added to help abstractors recognize death scene characteristics commonly associated with illicit drug use such as drug powders and drug paraphernalia (see “illicit or prescription drugs” section in Attachment F1).
- 4) A major finding of the Epi-Aid investigations was that new illicit drugs were causing opioid-related overdoses to progress very quickly. Consequently, items were added to capture this information (see “scene indications of drug use” section in Attachment F1).

The purpose of the SUDORS data collection and the ESOOS program is to obtain more timely mortality data than is available through vital statistics. The specific charge in FY16 and FY17 is for the ESOOS program to work with state health departments to improve the timeliness of fatal opioid overdose surveillance. Funded state health departments are required by the FOA to provide CDC via SUDORS preliminary drug overdose death counts within 8 months which is faster than current estimates from vital statistics which has a time lag of a year or more. This allows better tracking of the impact of current prevention initiatives. However, delays in data collection impede the ability of the ESOOS program to obtain more rapid mortality data that can inform deployment of prevention and intervention strategies to address the ongoing opioid epidemic and be responsive to the congressional intent of the program funding.

## 16. Plans for Tabulation and Publication and Project Time Schedule

Data aggregated across states will be presented in tabulations of outcomes such as prescription opioid and heroin overdose rates. These will be released in CDC publications such as *MMWR* or in other peer-reviewed publications.

### Time Schedule

Task	Time Period
Preliminary analysis files, including counts of unintentional drug overdose based on vital statistics and ME/C reports	8 months
Final analysis files prepared	12 months
Restricted Access Data files	18 months
Publications such as <i>MMWR</i>	At least one article per year

Initial reports will include crude and age-adjusted rates for unintentional drug overdose, overdoses related to opioid pain relievers (OPR), and overdoses related to heroin by state. Sex, race, and age-specific rates will be presented as well as preliminary toxicology findings. Final analyses will include description of drugs contributing to overdose deaths and description of key circumstances (e.g., a history of substance misuse and route of administration). In depth analyses of how risk factors vary by county and county characteristics will also be conducted. In later years, time trends will be shown.

No sophisticated statistical techniques such as statistical weighting will be required to display

this surveillance data because all unintentional drug overdose deaths in a state are collected (i.e., this is a census of unintentional drug overdose deaths).

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

There are no standard paper data collection forms to be used by states because states will be abstracting information from electronic or paper vital statistics or ME/C records into the CDC web-based data system. States may print out paper copies of the abstraction forms that they can modify. That will then be inputted into the NVDRS web-based software database. The OMB expiration date will be displayed on the opening screen of the NVDRS web-based software.

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

This collection of information involves no exception to the Certification for Paperwork Reduction Act Submissions.

- <sup>i</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.
- <sup>ii</sup> CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2015. Available at <http://wonder.cdc.gov>.
- <sup>iii</sup> CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2015. Available at <http://wonder.cdc.gov>.
- <sup>iv</sup> NCHS (2016). "Percent of drug poisoning deaths that mention the type of drug(s) involved, by State: 2013-2014." Retrieved February 4, 2016, from [http://www.cdc.gov/nchs/data/health\\_policy/unspecified\\_drugs\\_by\\_state\\_2013-2014.pdf](http://www.cdc.gov/nchs/data/health_policy/unspecified_drugs_by_state_2013-2014.pdf).
- <sup>v</sup> Warner, M., et al. (2013). "State variation in certifying manner of death and drugs involved in drug intoxication deaths." Academic Forensic Pathology **3**(2): 231-237.
- <sup>vi</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.
- <sup>vii</sup> Paulozzi, L. J., et al. (2011). "Vital Signs: Overdose of prescription opioid pain relievers - United States, 1999-2008." Morbidity and Mortality Weekly Report **60**(43): 1487-1492.
- <sup>viii</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.
- <sup>ix</sup> Jones, C. M., et al. (2015). "Vital Signs: Demographic and substance use trends among heroin users - United States, 2002-2013." Morbidity and Mortality Weekly Report **64**(26): 719-725.
- <sup>x</sup> Cicero, T., et al. (2014). "The changing face of heroin use in the United States: A retrospective analysis of the past 50 years." Journal of the American Medical Association Psychiatry **71**(7): 821-826.
- <sup>xi</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.
- <sup>xii</sup> Centers for Disease Control and Prevention (October 26, 2015). "CDC Health Advisory: Increases in fentanyl drug confiscations and fentanyl-related overdose fatalities." HAN CDCHAN-00384. Retrieved February 5, 2016, from <http://emergency.cdc.gov/han/han00384.asp>.
- <sup>xiii</sup> A description of the HHS Secretary's initiative to combat opioid abuse is available at: [http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)
- <sup>xiv</sup> Draft guidelines can be accessed at <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>.
- <sup>xv</sup> NGA (2014). "Reducing prescription drug abuse: Lessons learned from an NGA Policy Academy ". Retrieved February 5, 2016, from <http://www.nga.org/files/live/sites/NGA/files/pdf/2014/1402ReducingPrescriptionDrugAbuse-Paper.pdf>.
- <sup>xvi</sup> MacQuarrie, B. (March 27, 2014). "Governor declares an emergency on opiate abuse." Boston Globe March 27, 2014. Retrieved February 5, 2016, from <https://www.bostonglobe.com/metro/2014/03/27/with-heroin-overdoses-rise-gov-patrick-declares-public-health-emergency-mass/hOajTIJNKnSHKAnWjZ6wYL/story.html>.
- <sup>xvii</sup> Woodruff, J. (January 9, 2014). "Vermont governor confronts deadly heroin crisis as public health problem." Retrieved February 5, 2016, from [http://www.pbs.org/newshour/bb/nation-jan-june14-heroin\\_01-09/](http://www.pbs.org/newshour/bb/nation-jan-june14-heroin_01-09/).
- <sup>xviii</sup> ASTHO (2013). "ATHO President's Challenge 2014: 15 by 15: Reduce prescription drug abuse and deaths 15% by 2015." Retrieved February 5, 2016, from <http://www.astho.org/rx/2014-presidents-challenge-fact-sheet/>.
- <sup>xix</sup> A description of the HHS Secretary's initiative to combat opioid abuse is available at: [http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)

<sup>xx</sup> A description of the HHS Secretary's initiative to combat opioid abuse is available at:

[http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)

<sup>xxi</sup> Johnson, H., et al. (2014). "Decline in drug overdose deaths after state policy changes - Florida, 2010-2012." Morbidity and Mortality Weekly Report **63**(26): 569-574.

<sup>xxii</sup> Paone, D., et al. (2015). "Decrease in rate of opioid analgesic overdose deaths." *Ibid.* **64**(18): 491-494.

<sup>xxiii</sup> Harruff, R. C., et al. (2015). "Tracking the opioid drug overdose epidemic in King County, Washington using an improved methodology for certifying heroin-related deaths." Academy of Forensic Pathology **5**(3): 499-506.

<sup>xxiv</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.

<sup>xxv</sup> NCHS (2016). "Percent of drug poisoning deaths that mention the type of drug(s) involved, by State: 2013-2014." Retrieved February 4, 2016, from [http://www.cdc.gov/nchs/data/health\\_policy/unspecified\\_drugs\\_by\\_state\\_2013-2014.pdf](http://www.cdc.gov/nchs/data/health_policy/unspecified_drugs_by_state_2013-2014.pdf).

<sup>xxvi</sup> Slavova, S., et al. (2015). "Drug overdose deaths: Let's get specific." Public Health Report **130**(July-August 2015): 339-342.

<sup>xxvii</sup> A description of the HHS Secretary's initiative to combat opioid abuse is available at:

[http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)

<sup>xxviii</sup> A description of the HHS Secretary's initiative to combat opioid abuse is available at:

[http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)

<sup>xxix</sup> Binswanger, I., et al. (2015). "Clinical risk factors for death after release from prison in Washington State: A nested case control study." Addiction **October 7, 2015**.

<sup>xxx</sup> Ravndal, E. and E. Amundsen (2010). "Mortality among drug users after discharge from inpatient treatment: An 8-year prospective study." Drug and Alcohol Dependence **108**(1-2): 65-69.

<sup>xxxi</sup> Centers for Disease Control and Prevention (October 26, 2015). "CDC Health Advisory: Increases in fentanyl drug confiscations and fentanyl-related overdose fatalities." HAN CDCHAN-00384. Retrieved February 5, 2016, from <http://emergency.cdc.gov/han/han00384.asp>.

<sup>xxxii</sup> Rudd, R. A., et al. (2016). "Increase in Drug and opioid Overdose Deaths - United States, 2000-2014." Morbidity and Mortality Weekly Report **64**(50): 1378-1382.

<sup>xxxiii</sup> Paulozzi, L., et al. (2009). "A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia." Addiction **104**(9): 1541-1548.

<sup>xxxiv</sup> Mercado-Crespo, M. C., et al. (2014). "Notes from the Field: Increase in fentanyl-related overdose deaths - Rhode Island, November 2013 - March 2014." Morbidity and Mortality Weekly Report **63**(24): 531.

<sup>xxxv</sup> Information on the Brandeis Center for Excellence is available at: <http://www.pdmpexcellence.org/>

<sup>xxxvi</sup> Bureau of Labor Statistics (May 2014). "Occupational employment statistics: National industry-specific and by ownership." Retrieved February 4, 2016, from <http://www.bls.gov/oes/>.