

SUPPORTING STATEMENT: PART A

February 10, 2016

State Unintentional Drug Overdose Reporting System (SUDORS)

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Attachments

- A Authorizing Legislation: Public Health Service Act
- B Published 60-Day Federal Register Notice
- B1 Public comment
- C Institutional Review Board (IRB) documentation
- D SUDORS Data Elements
- E SUDORS Screen Shots

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.
- **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 and/or 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 State Unintentional Drug Overdose Reporting System (SUDORS) will conduct ongoing surveillance of fatal unintentional opioid-related drug to support prevention and response efforts in states with a high burden of opioid-related overdoses. CDC requests OMB approval for 3 years for this new data collection.

Background

From 2000 to 2014 nearly half a million persons in the United States have died from drug overdosesⁱ. In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashesⁱⁱ. In 2014, opioids were involved in 61% of fatal drug overdosesⁱⁱⁱ 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^{iv,v}. 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^{vi}.

A surge in OPR-related overdose deaths has been paralleled and driven by increases in OPR prescribing rates which have also quadrupled since 1999^{vii}. 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^{viii}.

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 abuse^{ix}. 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^x. 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^{xi,xii}

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 abuse 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^{xiii}. As part of this effort, CDC publishing draft guidelines for prescribing opioids for chronic pain to increase safer prescribing practices^{xiv}. Also, 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, abuse, 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 Abuse Reduction Policy Academy*^{xv}, a state declaring opioid abuse a public health emergency^{xvi}, a governor dedicated his entire state of union to drug addiction, especially related to opiates^{xvii}, 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^{xviii}.

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) will support 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 will provide detailed information on risk factors for 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 select and target interventions that address the risk factors most prevalent in their communities. Interventions that could be used by communities include distributing naloxone^{xix} to first responders and community members, enhancing access and use of evidence-based substance use treatment^{xx}, identifying and disrupting illegal distribution of OPRs through physician offices (i.e., often referred to “pill mills”)^{xxi}, 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^{xxii}.

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 fatal drug overdoses. This programs are 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).

2. Purpose and Use of Information Collection

The purpose of SUDORS is to generate public health surveillance information on unintentional opioid-related drug overdoses across multiple states, within a state, and within local communities to support states and local communities 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 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^{xxiii}.
 - A powerful opioid, fentanyl, is produced by pharmacies and also illicitly manufactured. Toxicology tests conducted by ME/Cs cannot determine the source^{xxiv}, but scene evidence and full toxicology findings (e.g., mixed with heroin most often occurs with illicitly manufactured heroin) can help distinguish whether the fentanyl was manufactured illicitly or by pharmaceuticals.
 - ME/C reports will be reviewed to determine whether the overdose was related to substance abuse, 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 opioid or heroin).
 - The death certificate does not report the specific drug causing an overdose for about 20 percent of drug overdoses^{xxv}. A portion of this results from the use of

general terms such as “narcotic” on the death certificate^{xxvi}. 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-related overdoses. Expanded naloxone distribution is a major component of the HHS Secretary’s initiative to combat opioid abuse^{xxvii}.
 - Assist states and local communities 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 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 abuse 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 abuse^{xxviii},
 - 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^{xxix},
 - Track the percent of decedents who were recently released from residential treatment, a risk factor for overdose^{xxx}
- Inform state and local health departments about shifts in the adulteration of the heroin supply or polysubstance abuse patterns. Understanding this issue could inform emergency medical response. For instance, recent adulteration of heroin with fentanyl, a power opioid analgesic, may increase the chance of an opioid overdose, the need for multiple naloxone administrations, and the number of fatal opioid overdoses^{lxxxii}.
- 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 16 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 a 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). States will be selected through a competitive cooperative funding opportunity, Enhanced State Surveillance of Illicit Opioid-related Morbidity and Mortality (CDC-RFA-CE16-1608). The states will be finalized by mid-August. The method for selecting the 16 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 abuse, mental health status, toxicology findings, recent release from an institution, and contact with criminal justice. Additional drug overdose specific questions will also be added to capture risk factor information specific to drug overdoses such as if and when naloxone was administered, the number of bystanders presents 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/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 abuse 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).

Currently, in efforts to comply with OMB requirements, DUIP convened a call with NCHS on 7/20/2016 to identify opportunities to enhance collaboration and coordination in collecting ME/C data. Both NCHS and DUIP collect information from ME/C. From the first meeting, two action items described below were identified from the first meeting and discussion will continue.

- 1) DUIP and NCHS will explore collaborations between the grantees of the DUIP Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program and grantees of the NCHS Vital Statistics program aimed at improving the quality of data on cause of death on death certificates. 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. In late August, DUIP will share with NCHS the list of funded states under the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality Program. At that time, DUIP and NCHS will 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 will identify and support state interest in collaboration.-
 - b. DUIP will establish regular meetings with NCHS to discuss lessons learned from their respective meetings from awardees and opportunities for coordination.
- 2) As part of its FOA implementation plan, DUIP will schedule meetings with our Center informatics group to access new strategies or models for improving its collection of drug overdose death information from death certificates and medical/examiner coroner data.

DUIP also strongly encourages states funded through the Enhanced State Surveillance of Illicit Opioid-related Morbidity and Mortality (CDC-RFA-CE16-1608) to provide resources to their state vital statistics program to support improvements in the collections of deaths certificate and medical examiner/coroner 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.

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 results 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). This changes are expected to increasing 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.

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 Abuse 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 2013^{xxxii}, 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, the 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.

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.

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^{xxxiii,xxxiv}.

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^{xxxv}.

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 IRB/OMB officer, who has determined that the Privacy Act is not applicable. The current data collection activity was found not to be research on its IRB determination (See Attachment C). 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 16 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 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 abuse, 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 calculated for 16 states with the highest drug overdose death rates in 2014 because these states are being targeted by an upcoming funding announcement, Enhanced State Surveillance of Illicit Opioid-related Morbidity and Mortality (CDC-RFA-CE16-1608). 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 14,0143 unintentional drug overdose deaths in 2014, or an average of 875.8 deaths per state.
- The number of hours per reported unintentional death in the 16 targeted states (i.e., 14,0143) required for the public agencies (vital statistics and ME/C) to retrieve and then refile their records was estimated 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. SUDORS’ burden estimates do not include state staff time spent abstracting data because state abstractors will be funded by CDC to do this work.
 - a. The ME/C and vital statistics burden does not include abstracting data elements because this is completed by the state public health department staff or contractors who are funded to complete this task.

Estimated Annualized Respondent Burden Hours

Type of Respondent	Form Name	No. of Respondent	Total No. of Responses	Average Burden per	Total Burden
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		s	per Respondent	Response (in hours)	Hours (in hours)
Public Agencies	Retrieving and refiling records	16	876	30/60	7,008
Total					7,008

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^{xxxvi}. Public Agencies who retrieve and refile records estimate costs at [7,008 burden hours x \$25.56/hour] = \$179,124. 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	16	876	30/60	7,008	\$25.56	\$179,124
Total						\$179,124

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

LABOR	COST
MISO contract for maintenance of the data collection software	\$100,000
Contracts and cooperative agreements with national data partners	\$50,000
Other Direct Costs	

Subcontractors	\$0
Travel and subsistence	\$0
Total Estimated Contract Costs	\$150,000

Government costs

Personnel	Tasks	Avg. cost/yr
Senior Scientist (50% time)	Program oversight	\$52,500
1 Epidemiologist	Technical assistance and data usage	\$91,200
2 Public Health Advisors	Programmatic, budgetary, administrative management & oversight	\$188,150
Public Health Analyst	Data quality assurance	\$80,000
3% cost of living adjustment over 3-years		\$12,479
Sub-total		\$424,329
Contract Costs		\$150,000
Total		\$574,329

Total annual contractual and government staff costs are approximately \$574,329. 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

This is a new program

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
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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 MMWR	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 abuse 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 if required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

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- ^{xiii} 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
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^{xxviii} A description of the HHS Secretary's initiative to combat opioid abuse is available at:

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