

**SUPPORTING STATEMENT: PART A**

**August 18, 2022**

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

OMB# 0920-1128

Point of Contact:  
Nicole Davis

Centers for Disease Control and Prevention  
National Center for Injury Prevention and Control  
4770 Buford Highway NE MS F-62  
Atlanta, GA 30341-3724  
phone: 770-488-6385  
email: [dwg4@cdc.gov](mailto:dwg4@cdc.gov)

## CONTENTS

<u>Section</u>	<u>Page</u>
SUMMARY TABLE.....	3
A. JUSTIFICATION.....	3
A.1. Circumstances Making the Collection of Information Necessary	4
A.2. Purpose and Use of Information Collection.....	6
A.3. Use of Improved Information Technology and Burden Reduction	8
A.4. Efforts to Identify Duplication and Use of Similar Information	8
A.5. Impact on Small Businesses or Other Small Entities.....	14
A.6. Consequences of Collecting the Information Less Frequently...	14
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5(d)2.....	14
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	15
A.9. Explanation of Any Payment or Gift to Respondents.....	16
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	16
A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	17
A.12. Estimates of Annualized Burden Hours and Costs.....	17
A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	19
A.14. Annualized Cost to the Government.....	19
A.15. Explanation for Program Changes or Adjustments.....	20
A.16. Plans for Tabulation and Publication and Project Time Schedule	23
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate....	24
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	24

### Attachments

A	Authorizing Legislation: Public Health Service Act
B	Published 60-Day Federal Register Notice
B1	Public Comment
C	Research/Non-research Determination
D	SUDORS Data Elements
E	Retrieving and refiling records
F	SUDORS Cross Table Changes
F1	SUDORS Screen Shots Changes
G	Privacy Impact Assessment (PIA)
H	SUDORS reports to OMB
I	Summary NCIPC / DOP and NCHS Collaboration

## Summary Table

- A.
- **Goal of the study** – Continue collecting data for State Unintentional Drug Overdose Reporting System (SUDORS) - Detects state and local community changes in unintentional and undetermined intent drug-related overdose mortality and provides in-depth state and local (e.g., county) information on risk factors for fatal drug overdose deaths that can inform the selection and targeting of interventions in all 50 states, and the District of Columbia. CDC requests OMB approval for this revision to make the following changes: 1) remove data collection activities in Puerto Rico, and 2) update the burden estimate to reflect the increase in drug overdose deaths.
  - **Intended use of the resulting data** – Improve identification and response to changes in fatal unintentional and undetermined intent drug-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 (ME/C) reports as well as death certificates on unintentional and undetermined intent drug-related overdose deaths in their state into a CDC web-based platform.
  - **The subpopulation to be studied** – Individuals who died of an unintentional or undetermined intent drug overdose.
  - **How data will be analyzed** – Descriptive analyses such as frequencies and rates.

## Justification

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

This is a revision request for 3 years for the currently approved “State Unintentional Drug Overdose Reporting System (SUDORS) - OMB# 0920-1128,” expiration date 1/31/2023. SUDORS assists with ongoing surveillance of fatal unintentional and undetermined intent drug-related overdoses to support prevention and response efforts. Specifically, participating health departments must abstract medical examiner and/or coroner (ME/C) data and death certificate (DC) data on CDC required data elements into SUDORS (Attachment D, E) including modifications to some data elements (Attachments F, F1).

In 2020, 91,799 drug overdose deaths occurred in the United States; the age-adjusted rate in 2020 was 31% higher than the rate in 2019<sup>1</sup> and provisional data indicate an estimated 105,752 drug overdose deaths occurred between November 2020 and October 2021.<sup>2</sup> . Approximately 75% of drug overdose deaths in 2020 involved an opioid,<sup>3</sup> and opioid overdose deaths are 8.5 times the number they were in 1999.<sup>4</sup> While the opioid overdose epidemic worsens in scope and magnitude, it is also becoming more complex.

## Background

In response to the growing severity of the opioid overdose epidemic, the US government declared the opioid overdose epidemic a public health emergency on October 26, 2017,<sup>5</sup> joining

at least eight states that have declared the opioid epidemic a statewide emergency.<sup>6</sup> The opioid overdose epidemic is one of the U.S. Department of Health and Human Services (HHS) top priorities. In 2017, HHS launched a 5-point Opioid Strategy: 1) Access: Better Prevention, Treatment, and Recovery Services, 2) Data: Better Data on the Epidemic, 3) Pain: Better Pain Management, 4) Overdoses: Better Targeting of Overdose-Reversing Drugs, and 5) Research: Better Research on Pain and Addiction.<sup>7</sup> SUDORS is a critical element of HHS's second goal to support timelier and more specific data through accelerating CDC's reporting timelines of drug overdose data.

The SUDORS system provides specific information on drugs contributing to an overdose as well as detailed information on risk factors for unintentional and undetermined intent (e.g., evidence equally supported or could not distinguish between two possible intents such as unintentional or suicide) drug overdose (UUDO) deaths. Risk factors include recent discharge from residential treatment or prison, recent arrest, recent return to 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. These risk factors can be tracked at the regional, state, or local level (e.g., county and zip code). The following characteristics of the opioid overdose epidemic make it critical to track the specific drug(s) contributing to drug overdose deaths: 1) fentanyl now is the leading drug contributing to drug overdose deaths,<sup>8</sup> 2) the proliferation of illicitly-manufactured fentanyl analogs and their involvement in outbreaks,<sup>9,10,11,12,13</sup> and 3) increasing co-occurrence of opioids with stimulants (e.g., cocaine and methamphetamines), and co-occurrence of benzodiazepines and gabapentin in the post-mortem toxicology findings of overdose decedents.<sup>14</sup>

Interventions that could be used by communities to address the risk factors tracked by SUDORS include distributing naloxone<sup>15</sup> to first responders and community members, enhancing access and use of evidence-based substance use treatment, identifying and disrupting illegal distribution of OPRs through physician offices (i.e., often referred to "pill mills")<sup>16</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>17</sup>.

SUDORS leverages 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 intent 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).

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

The purpose of this revision request is to continue collecting data for SUDORS to generate public health surveillance information on unintentional and undetermined intent drug overdose deaths across multiple states, within a state, and within local communities. These data support states and local communities to better select and target intervention strategies that address the risk factors driving fatal drug-related overdoses in their community. Key usage of SUDORS data

is provided below:

- Assist state and local communities to better understand the extent to which drug-related overdose deaths are related to the misuse of prescription drugs versus use of illicitly produced drugs such as heroin or illicitly manufactured fentanyl. For example, toxicology and scene evidence (e.g., drug paraphernalia) only available on ME/C reports are often needed to determine if drug overdoses testing positive for morphine on toxicology are related to the use of prescription morphine or heroin. 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 misuse<sup>18</sup>.
- 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 including: 1) percent of decedents who were receiving OPRs when the opioid-related overdose occurred, 2) percent of decedents who were receiving substance use treatment, and 3) the percent of decedents who were released from incarceration within the last month, a risk factor for overdose.
- Inform state and local health departments about shifts in the adulteration of the heroin supply or polysubstance use patterns emerging in overdose deaths. Understanding this issue could inform public health and emergency medical response.<sup>19</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.<sup>20</sup>

CDC obtained OMB approval in 2020 for the current revision to make the following changes: 1) expand data collection from the 50 jurisdictions currently approved to include 52 jurisdictions (i.e., all 50 states, Puerto Rico and the District of Columbia), 2) expand data collection from its current focus on opioid overdose deaths to a broader focus on drug overdose deaths, 3) account for increasing data collection burden related to large increases in drug overdose deaths, and 4) update the web-based system to improve performance, functionality, and accessibility as well as add data elements to the State Unintentional Drug Overdose Reporting System (SUDORS) module to capture more detailed information.

The data obtained during the 2020 approved changes was used for six publications and multiple presentations. The information was useful for highlighting the following, which is information not available through other CDC data systems:

- During 2019–2020, illicitly manufactured fentanyls (IMF) involved overdose deaths increased sharply in midwestern, southern, and western jurisdictions. During 2020, approximately 40% of IMF-involved deaths also involved stimulants, and 56% of decedents had no pulse when first responders arrived. Injection drug use was reported in 25% of deaths, and noninjecting routes of drug use in 27% of deaths. Adapting overdose prevention and response efforts to address risk factors associated with IMFs and using innovative approaches to address the endemic nature of IMFs, various routes of IMF use, and frequent polysubstance use could slow increase in IMF-involved deaths.<sup>21</sup>

- Xylazine contributed to death in approximately one half of deaths in which it was detected and was primarily co-involved with fentanyl. The detection of xylazine and its involvement in overdose deaths in multiple jurisdictions is concerning and warrants continued surveillance to inform overdose response and prevention efforts.<sup>22</sup>
- From April–June 2019 to April–June 2020, prescription and illicit benzodiazepine-involved overdose deaths increased 21.8% and 519.6%, respectively. During January–June 2020, 92.7% of benzodiazepine-involved deaths also involved opioids, and 66.7% involved illicitly manufactured fentanyls. Improving naloxone availability and enhancing treatment access for persons using benzodiazepines and opioids and calling emergency services for overdoses involving benzodiazepines and opioids, coupled with primary prevention of drug use and misuse, could reduce morbidity and mortality.<sup>23</sup>
- Showed that integrating DC data with medical examiner/coroner reports, including postmortem toxicology and death investigation findings, can improve identification of (1) heroin and pharmaceutical morphine involvement in overdose deaths and (2) fentanyl source (illicitly manufactured versus pharmaceutical).<sup>24</sup>
- Illicitly manufactured fentanyls (IMFs), heroin, cocaine, or methamphetamine (alone or in combination) were involved in 83.8% of overdose deaths during January–June 2019; at least one potential opportunity for intervention was identified in 62.7% of overdose deaths. Targeting crucial opportunities for intervention with evidence-based overdose prevention programs can help reverse increases in drug overdose deaths. Interventions to reduce overdose deaths involving illicit opioids and stimulants, particularly IMFs, are needed and should be complemented by efforts to prevent initiation of prescription drug misuse and illicit drug use.<sup>25</sup>
- The declines in overdose deaths with the fentanyl analogs carfentanil, furanylfentanyl, acrylfentanyl, and cyclopropylfentanyl detected contributed to previously reported declines in opioid-involved overdose deaths during 2018 among 25 states, even as deaths with fentanyl detected increased over time (4). This suggests a shift away from illicit fentanyl analog distribution to distribution of illicitly manufactured fentanyl. Timely toxicologic surveillance is critical to accurately detect opioid-involved overdose deaths and, in turn, to inform interventions that could mitigate health consequences of rapid illicit drug market changes.<sup>26</sup>

The current revision has the following changes:

- Data collection will no longer take place in Puerto Rico because past performance indicated that capacity and infrastructure were not sufficient for the recipient to successfully collect data in accordance with funding requirements.
- The burden estimate has been updated to reflect the increase in drug overdose deaths. Therefore, the burden estimate in this revision is higher than the previously approved burden of 32,838 because the previous burden estimates were based on the number of unintentional and undetermined intent drug overdose deaths that occurred among all 50 states in 2017, or 64,998 deaths. The revision will use the total number of unintentional or undetermined intent drug overdose deaths in the US in 2020, or 87,302. The total number of unintentional or undetermined intent drug overdose deaths per jurisdiction was estimated by dividing the total number of drug overdose

deaths, 87,302 by the number of participating health departments, 51, or approximately 1,711 deaths per participating health department. This created an increase from the previously approved burden of 32,838.

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

Data entry is accomplished by the 51 participating health department offices via the secure NVDRS/SUDORS 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 participating health departments will use the same web-platform to enter information on violent deaths through NVDRS, participating health departments can increase efficiency and decrease burden by designing similar data collection and data abstraction processes across violent and drug overdose deaths.
3. Training of new data abstractors is simplified for NVDRS-funded jurisdictions because they can build on the historical experience of using the NVDRS web platform.
4. Participating health departments with access to electronic data can reduce data entry burden by using electronic import options for death certificate and ME/C data. CDC is working to further reduce burden by expanding current electronic import functionality to also accept post-mortem toxicology testing data.

The web-based data collection platform also improves data quality by including 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 timelier.

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

There is no similar ongoing surveillance system to SUDORS in existence. SUDORS, however, enhances its data collection by leveraging the web-based data collection system used by the National Violent Death Reporting System (NVDRS) and collaborating with the National Center for Health Statistics (NCHS) to improve the timeliness of death certificate data on drug overdose deaths. Both collaborative efforts are described below, including how SUDORS is distinct from NVDRS and death certificate data collected by NCHS.

#### **SUDORS coordination with the National Violent Death Reporting System (NVDRS)**

The purpose of NVDRS is to collect data on violent deaths (i.e., homicides and suicides) and circumstances associated with violent deaths (e.g., arguments, financial distress, or intimate partner problems). Drug overdose deaths are considered unintentional and thus outside the scope of NVDRS. Thus, SUDORS is not duplicative of NVDRS. Also, SUDORS will collect unique information on drug overdose deaths such as the route of administration of the drug(s) contributing to the fatal overdose (e.g., injection), the presence of bystanders at the overdose

scene, scene evidence of illicit or prescription drug use, and the administration of naloxone by first responders that is not collected on violent deaths by NVDRS.

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. With the specific drugs involved in drug overdose deaths shifting quickly (e.g., fentanyl and fentanyl analogs), SUDORS needs to collect data with a six-month time lag to be effective. This is substantially faster than current NVDRS timelines. To achieve more rapid reporting, 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. Although SUDORS currently collects many of the same variables as NVDRS, the information that SUDORS collects is expected to change over time based on feedback from recipients and key stakeholders. This will result in SUDORS including additional variables and dropping other variables (i.e., grayed or blanked out in the data entry system). In fact, this SUDORS revision and the previous revision of SUDORS have demonstrated a rapid expansion and enhancement of information collected on drug overdose deaths. These changes increasingly make the data collected by SUDORS and NVDRS 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.

SUDORS is using the NVDRS web-based platform instead of creating a new data collection system to both reduce burden on respondents and maximize federal government resources. Specifically, two advantages of using the NVDRS web-based platform instead of creating a new data collection system are the following:

- 1) Staff at many local public health departments have already received training in accessing and using the NVDRS web-based system. These staff also receive trainings on new NVDRS web functionality. By leveraging NVDRS historical and ongoing training, SUDORS reduces the training burden on staff in many health departments participating in SUDORS,
- 2) The use of the NVDRS web-based platform also substantially reduces CDC development and maintenance costs such as being compliant with ongoing security and privacy standards compared to developing a new system. NVDRS 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, and location of death) and can be expanded to accommodate the unique needs of the SUDORS data collection.

### **SUDORS coordination with vital statistics**

Even though the National Vital Statistics System (NVSS) collects information on drug overdose deaths via death certificates, this information differs from SUDORS. Death certificate data 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 or on all the

specific drugs detected in the decedent which can inform targeting of interventions. In contrast, by reviewing the full ME/C report, SUDORS provides more comprehensive drug use histories of decedents and tracks the immediate circumstances around the drug overdose death such as whether a bystander was present or whether the decedent was recently released from an institution. Additionally, SUDORS abstracts data from toxicology reports that provide the most complete view of drugs contributing to the overdose death as well as other drugs present. This can help identify both drugs contributing to overdoses as well as drug use patterns potentially associated with a high number of overdose deaths (i.e., what drugs are people experiencing a fatal overdose using and can this drug use pattern be targeted for intervention).

The Division of Overdose Prevention (DOP), CDC is collaborating with the National Center for Health Statistics (NCHS), CDC to streamline and improve the quality and timeliness of drug overdose data collected on the death certificate as outlined in the previous NOA terms of clearance for SUDORS. These improvements may indirectly improve SUDORS, which contains information abstracted from the death certificate. Also, one of the collaborations supporting interoperability among ME/C case management systems, state vital statistics, and state surveillance systems may directly enhance SUDORS reporting in some states. Finally, CDC operates the Opioid Response Coordinating Unit (ORCU) that brings together all centers in CDC to ensure coordination and integration of opioid surveillance activities across CDC.

In accordance with OMB's terms of clearance, CDC-NCIPC has provided OMB seven reports on the progress of collaborations with NCHS. These were provided in August 2018, March 2019, January 2020, August 2020, February 2021, August 2021, and March 2022(Attachment H). Previous reviews from OMB requested collaborations between NCIPC / POD and NCHS, the status of current collaborations is summarized in the provided attachment (See Attachment I).

Future collaborative priorities for NCHS and NCIPC/DOP will be driven by lessons learned from the above activities.

Previous and ongoing work on interoperability has found that scaling up an interoperable exchange of medical examiner and coroner (ME/C) case management with vital statistics and state surveillance programs such as SUDORS on variables not collected on the deaths certificate will be incremental and require customized efforts across states. Consequently, broad implementation is likely to require more than five years. Key challenges supporting this assessment are:

- 1) Currently, there are no national standards for ME/C data collection beyond the death certificate. NCHS has ongoing work to create standards for the data elements on the death certificate and the next step is to develop standards for toxicology data.
  - a. Traditional data standards are inappropriate for SUDORS variables currently because the completion of these variables requires review of multiple free text fields and pdfs that vary across ME/C systems.
- 2) Even if standards were created, substantial outreach and support would be needed to foster implementation of the standards by ME/C agencies because ME/C systems are

governed at the state and/or local level. Lessons learned from fostering electronic health record use among health care providers can be leveraged to inform this process.

- 3) According to a survey of 898 of 2,128 eligible ME/C agencies, only 32% reported having a computerized information management system, with another 30% having record-keeping systems that used both manual hardcopies and computerized systems. Finally, 31% of ME/C agencies reported only having a manual record-keeping system.<sup>27</sup> The large percent of ME/C offices without electronic case management systems highlights the need to build this infrastructure as a prerequisite to expanding interoperability with ME/C data.
- 4) The electronic information management systems used by ME/C agencies varied substantially with in-house systems being the most common, especially among ME/C offices investigating large number of deaths. This suggests the need to build and maintain interoperable interfaces among many systems, including a substantial number of custom systems.
- 5) Pilot work coupled with work with states indicates that electronic records often include PDFs (e.g., a PDF of toxicology results) which are more difficult to analyze and diverse data elements that make analyses across different systems challenging.

In response to this context, DOP has targeted working on creating interoperable toxicology data because of its critical public health importance and the feasibility of fostering electronic data exchange of ME/C information management systems with toxicology labs and state surveillance systems such as SUDORS and NVDRS. Several current DOP projects are working to build a foundation for interoperable toxicology data.

- 1) Significant differences exist among the toxicology testing protocols ME/C agencies use to investigate suspected drug overdose deaths.<sup>28</sup> As part of the OD2A NOFO, described earlier, CDC will require state health departments, Puerto Rico, and the District of Columbia to provide funding to foster comprehensive toxicology testing of drug overdose deaths for opioids. CDC will be providing applicants guidance on what constitutes comprehensive toxicology testing when funding of OD2A begins in September 2019. This effort will help move ME/C agencies towards more common toxicology testing standards.
- 2) In 2022 and 2023, SUDORS will continue to explore the feasibility and utility of developing a function for the NVDRS web-based system to automatically import toxicology test results. This envisioned import would enable the automatic (i.e., import a text file with the data for multiple deaths directly into the program) instead of manual entry of data on the substances tested for and detected in drug overdose deaths. This will minimize the time it takes for abstractors to enter the data into the system. Examining the feasibility and utility of a toxicology import function will assist efforts to identify core toxicology variables.
- 3) DOP is building relationships with and providing funding to key national ME/C and toxicology stakeholders such as the National Association of Medical Examiners (NAME) and the International Association of Coroners and Medical Examiners (IAC&ME). Also, DOP is building relationships with the Society for Forensic Toxicologists. These relationships will help DOP identify better ways to distribute funding to support more comprehensive testing of drug overdose deaths and support implementation of toxicology testing and data standards.

- 4) NCHS and DOP have discussed the need to collaborate on creating and maintaining a national drug list. This list would be critical to analyze and group drugs identified in toxicology reports by drug class.

Together these four efforts build a stronger foundation from which to collaborate with NCHS on building interoperable toxicology data in the future.

### **Coordination between Drug Overdose Surveillance Epidemiology (DOSE) and SUDORS**

Also founded in 47 states and the District of Columbia by the Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904) notice of funding opportunity (NOFO), the Drug Overdose Surveillance and Epidemiology (DOSE) system is designed to provide situational awareness of changes in nonfatal drug overdoses, including identifying drug overdose outbreaks, by conducting monthly surveillance of emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level. SUDORS and DOSE complement each other. Specifically, SUDORS collects the following unique information not captured by DOSE:

- 1) SUDORS collects data on fatal drug overdoses while DOSE collects information on nonfatal overdoses treated in E.Ds. While often similar, trends in nonfatal overdoses may differ from fatal overdoses for reasons including the expanded distribution of naloxone (an antidote to opioid overdose) to both first responders and lay people that may decrease the percent of opioid overdoses that are fatal<sup>29</sup> and the possibilities of the fatal overdoses occurring before medical treatment is possible due to no one witnessing the overdose<sup>30</sup> or the rapid progression of overdoses involving fentanyl and fentanyl analogs.<sup>31</sup>
- 2) SUDORS collects in-depth information on drug overdose deaths including forensic toxicology findings and circumstances of overdose, while DOSE focuses on tracking changes in the incident of drug overdoses. Thus, SUDORS provides in-depth information on drugs contributing or present in drug overdoses as well as circumstances of overdoses (e.g., recent relapse or recent release from prison) not available in DOSE.

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

This study does not impact small businesses or other small entities

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

The continued increases in drug overdose deaths, coupled with the rapidly evolving drug supply, highlight the need for timely data collection to support ongoing national, state, and local efforts to reduce drug-related morbidity and mortality. The current system is striving to collect data with a 6-month time lag (e.g., complete data collection on drug overdose deaths occurring from January to June 2023 by December 2023).

If SUDORS information is not collected, consistent in-depth information on the circumstances related to unintentional and undetermined intent drug overdose deaths will not be available and this will inhibit targeting of prevention efforts. Delays in data collection would impede the ability of the SUDORS program to obtain more rapid mortality data that can inform deployment of prevention and intervention strategies to address the ongoing opioid overdose 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 April 18, 2022. Volume 87, Number 74, pp 22890 (Attachment B). CDC received one anonymous non-substantive comment (Attachment B1).

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

NCIPC currently collaborates with 47 states and District of Columbia on the SUDORS data collection through the Overdose Data to Action collaborative agreement. As part of OD2A, a SUDORS workgroup, which comprises data abstractors and epidemiologists from the 48 health departments participating in SUDORS as well as CDC staff, has met monthly to discuss ways of improving the quality of data and identifying new data elements to include in SUDORS that can enhance the public health impact of SUDORS. Many of the changes to the NVDRS web system submitted as part of the previous OMB revision were informed or initiated in response to feedback from health departments participating in the SUDORS workgroup. In addition, NCIPC collaborates with the National Association of Medical Examiners and Coroners and the International Association of Coroners and Medical Examiners through IPAs and cooperative agreements with the Association of State and Territorial Health Officials and the National Network of Public Health Institutes to provide feedback on SUDORS data elements and data interpretation. 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**

The CDC Office of the Chief Information Officer has determined that the Privacy Act does not apply to this information collection request. 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 51 participating health departments (i.e., all 50 states, and the District of Columbia) 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 the 51 participating health departments will conduct analyses of the data. 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. Data from all states will be entered in the NVDRS web-based platform maintained by CDC. Participating health departments will only enter de-identified information. Thus, the proposed data collection will have little or no effect on the respondent's privacy.

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

- Data are maintained securely throughout the data collection and data processing phases.
- Data are stored on a secure CDC-based server accessed via a secure web platform. Authorized public health users only will be able to download de-identified datasets from their jurisdiction (e.g., Washington state SUDORS staff can only access data on deaths in Washington).
- Supplemental data (i.e., any information not included in the web-based system) collected by participating health departments such as paper abstraction worksheets or additional information collected on drug overdose deaths will be stored at the state, district or territorial level in secured computers that reside within the local health department's firewalls. Such information will never be sent from the local health department 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 cells that include 9 or fewer people when various combinations of demographic or drug overdose characteristic information are presented) to prevent the inadvertent identification of an individual through the combination of various demographic and/or drug overdose characteristics.
- Only authorized CDC staff working on the SUDORS team have access to the de-identified web-based data.

## **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 or undetermined intent drug overdose or their next of kin. Information on sensitive issues, e.g., mental illness and

substance misuse or substance use disorder, has already been collected by state and local ME/C agencies through the death scene investigation process. SUDORS is funding states to abstract and record this information (i.e., conduct an analysis of secondary data) 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 local health departments because they will be abstracting information from electronic or paper vital statistics or ME/C records into the CDC web-based data system. Burden was estimated through SUDORS experience working with 47 health departments and the District of Columbia as well as NVDRS burden estimates. NVDRS has approximately 15 years of experience working with health departments to collect similar data on violent deaths to inform its estimates of annualized burden hours and costs.

The burden was estimated as follows:

1. The previous burden estimates were based drug overdose deaths that occurred among all 50 states in 2017, or 64,998. The revision will use the total number of unintentional or undetermined intent drug overdose deaths in the US in 2020, or 87,302. The total number of unintentional or undetermined intent drug overdose deaths per jurisdiction was estimated by dividing the total number of drug overdose deaths, 87,302 by the number of participating health departments, 51, or approximately 1,711 deaths per participating health department. This created an increase from the previously approved burden of 32,838.
2. To develop the burden estimates per participating health department, we estimated that for each death vital statistics would require about 0.25 hours to retrieve, refile, and provide death certificate data to SUDORS. Similarly, ME/C agencies would require 0.25 hours per death to retrieve, refile, and provide ME/C reports to SUDORS. Summing the burden across vital statistics and ME/C agencies results in a burden of about 0.5 hours, or 30 minutes per death. Expanded use of electronic vital statistics and ME/C systems should reduce this burden over time.
  - a. The ME/C and vital statistics burden excludes abstracting data elements from the retrieved files because abstraction is completed by the local public health department staff or contractors who are funded by CDC to complete this task.
  - b. SUDORS’ burden estimates exclude state, district or territorial staff time spent abstracting data because these abstractors are funded by CDC to do this work.

### 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 refileing records	51	1,711	30/60	43,631

	(Att. E)				
Total					43,631

**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. Because staff retrieving and sharing specified data with CDC will vary substantially across organizations, the mean hourly wage of federal, state, and local government employees (\$29.87) as estimated by the Bureau of Labor Statistics (<https://www.bls.gov/oes/current/999001.htm#00-0000>, accessed on March 21, 2022) was used to estimate burden costs.

**Estimated Annualized Respondent Burden 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	51	1,711	30/60	43,631	\$29.87	\$1,303,258
Total						\$1,303,258

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

There is no record keeping 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>
Contract for maintenance and improvements of the data collection software	\$500,000
Contracts and cooperative agreements with national data partners to assist SUDORS in collecting data from ME/C agencies, creating SUDORS data collection standards and creating data collection guidance, and providing technical assistance to CDC as well as state and local health departments on data collection (e.g., National Association of Medical Examiners (NAME), International Association of Coroners and Medical Examiners (IAC&ME), Council of State and Territorial Epidemiologist (CSTE) and Association of State and Territorial Health Officials (ASTHO))*	\$500,000

<b>Total Estimated Contract Costs</b>	<b>\$1,000,000</b>
---------------------------------------	--------------------

Government costs

<b>Personnel</b>	<b>Tasks</b>	<b>Avg. cost/yr.</b>
2 Senior scientists (75%)	Program oversight and strategic direction	\$255,000
6 Epidemiologists (75%)	<ul style="list-style-type: none"> <li>• Direct technical assistance to 52 health departments participating in SUDORS.</li> <li>• Responsible for data quality checking in approximately 10 jurisdictions</li> <li>• Work to enhance SUDORS data quality and guidance.</li> <li>• Conduct surveillance using SUDORS data</li> <li>• Disseminate SUDORS data</li> <li>• Manage and improve the receipt, cleaning, validation, and standardized analysis of SUDORS data.</li> </ul>	\$490,000
15 Public health advisors (5%)	Programmatic, budgetary, administrative management and oversight of SUDORS as part of OD2A NOFO	\$78,000
Indirect staff costs		\$246,900
<b>Total</b>		<b>\$1,069,900</b>

Total government cost is \$2,069,900.

### 15. Explanation for Program Changes or Adjustments

The major revision to SUDORS submitted as part of this ICR are described below:

Data collection will no longer take place in Puerto Rico because past performance indicated that capacity and infrastructure were not sufficient for the recipient to successfully collect data in accordance with funding requirements.

The burden estimate has been changed to reflect the increase in drug overdose deaths. The previous burden estimates were based drug overdose deaths that occurred among all 50 states in 2017, or 64,998. The revision will use the total number of unintentional or undetermined intent drug overdose deaths in the US in 2020, or 87,302. The total number of unintentional or undetermined intent drug overdose deaths per jurisdiction was estimated by dividing the total number of drug overdose deaths, 87,302 by the number of

participating health departments, 51, or approximately 1,711 deaths per participating health department. This created an increase from the previously approved burden of 32,838.

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

Data aggregated across states will be presented in tabulations of outcomes such as overdose deaths involving illicit versus prescription drugs and identification of opportunities for the prevention drug overdose deaths (See **Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017** for an example).<sup>32</sup> These will be released in CDC publications such as *MMWR* or in other peer-reviewed publications. Although health departments participating in SUDORS will still report data to CDC twice a year, a key goal is to reduce the reporting time-lag to a 6-month time lag (e.g., complete data collection on drug overdose deaths occurring from January to June 2023 by December 2023) instead of the current 8-month time lag (e.g., complete data collection on drug overdose deaths occurring from January to June 2023 by February 2024). This aligns with an HHS prioritized goal of accelerating CDC’s reporting of drug overdose data. Differences in ME/C agencies across the US (e.g., decentralized at the county level versus state) have resulted in a substantial number of participating health departments reporting data to CDC with an 8-month lag. CDC will continue to work with these health departments to reduce the time lag to 6-months and secure the participation of the 3 state health departments that do not participate in SUDORS.

Time Schedule

Task	Time Period
Collection and Preliminary analysis files, including counts of unintentional drug overdose based on vital statistics and ME/C reports	6 - 36 months
Final analysis files prepared	12 months
Public release through web-based interface or surveillance report/data brief/publication	18 months

Initial reports will include crude rates for unintentional and undetermined intent drug overdose deaths, overdose deaths related to opioid pain relievers (OPR), and overdose deaths related to illicit drugs (e.g., heroin and illicitly manufactured fentanyl) by state or district. Sex, race, and age-specific rates will be presented as well as preliminary toxicology findings. Toxicology analyses will focus on specific drugs commonly contributing to drug overdose deaths, emerging threats such as fentanyl and fentanyl analogs,<sup>33, 34,35</sup> and drugs commonly mixed or co-used with opioid such as benzodiazepines<sup>36</sup>. 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 these surveillance data because all unintentional and undetermined intent drug overdose deaths in

a jurisdiction are collected (i.e., this is a census of unintentional and undetermined intent drug overdose deaths). A few states have chosen to implement SUDORS by collecting all drug overdose deaths occurring in a subset of their counties that account for greater than 75% of unintentional or undetermined drug overdose deaths occurring in their state or over 1,500 unintentional or undetermined drug overdose deaths. CDC will continue to work with these states to collect all drug overdose deaths occurring in their state. This subset option was created based on feedback from large states such as California that argued multiple years were needed to establish SUDORS in large states with high numbers of UUDO deaths.

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

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>1</sup> Hedegaard H, Miniño AM, Spencer MR, Warner M. Drug overdose deaths in the United States, 1999–2020. NCHS Data Brief, no 428. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: <https://dx.doi.org/10.15620/cdc:112340>.
- <sup>2</sup> Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021.
- <sup>3</sup> Ahmad FB, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019. Retrieved October 10, 2018 from <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.
- <sup>4</sup> Additional information on drug overdose deaths estimates, <https://wonder.cdc.gov/>
- <sup>5</sup> Additional information on President Trump’s Initiative to Stop Opioid Abuse, <https://www.whitehouse.gov/opioids/>.
- <sup>6</sup> Additional information on the 8 states that have declared the opioid epidemic a statewide emergency, <http://www.astho.org/StatePublicHealth/Emergency-Declarations-in-Eight-States-to-Address-the-Opioid-Epidemic/01-11-18/>.
- <sup>7</sup> Additional information on the 5-point HHS strategy is available at: <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html>.
- <sup>8</sup> Hedegaard H, Bastian BA, Trinidad JP, Spencer M, Warner M. Drugs most frequently involved in drug overdose deaths: United States, 2011–2016. National Vital Statistics Reports; vol 67 no 9. Hyattsville, MD: National Center for Health Statistics. 2018.
- <sup>9</sup> O’Donnell JK, et al. (2017). “Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016”. *Morbidity and Mortality Weekly Report* 66(43):1197–1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>.
- <sup>10</sup> Gladden, R.M., Martinez, P., and Seth, P. (2016). “Fentanyl Law Enforcement Submissions and Increases in Synthetic Opioid–Involved Overdose Deaths — 27 States, 2013–2014”. *Morbidity and Mortality Weekly Report* 65(33):837–843. DOI: <http://dx.doi.org/10.15585/mmwr.mm6533a2>.
- <sup>11</sup> O’Donnell, J, et al. (2018). “Notes from the Field: Overdose Deaths with Carfentanil and Other Fentanyl Analogs Detected — 10 States, July 2016–June 2017”. *Morbidity and Mortality Weekly Report* 67(27):767–768. DOI: <http://dx.doi.org/10.15585/mmwr.mm6727a4>.
- <sup>12</sup> CDC. Rising numbers of deaths involving fentanyl and fentanyl analogs deaths, including carfentanil, and increased usage and mixing with non-opioids. HAN no. 413. Atlanta, GA: US Department of Health and Human Services, CDC; 2018. <https://emergency.cdc.gov/han/han00413.asp>
- <sup>13</sup> Somerville, N.J., et al. (2017). “Characteristics of Fentanyl Overdose — Massachusetts, 2014–2016.” *Morbidity and Mortality Weekly Report* 66(14):382–386. DOI: <http://dx.doi.org/10.15585/mmwr.mm6614a2>.
- <sup>14</sup> Mattson, C.L., et al. (2018). “Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017”. *Morbidity and Mortality Weekly Report* 67(34):945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>.
- <sup>15</sup> Additional information on HHS Secretary’s initiative to reduce opioid-related overdoses and opioid use disorder, [http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm)
- <sup>16</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>17</sup> Paone, D., et al. (2015). "Decrease in rate of opioid analgesic overdose deaths." *Ibid.* 64(18): 491-494.
- <sup>18</sup> Additional information on HHS Secretary’s initiative to reduce opioid-related overdoses and opioid use disorder, [http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib\\_OpioidInitiative.cfm](http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.cfm).
- <sup>19</sup> CDC. Increases in Fentanyl Drug Confiscations and Fentanyl-related Overdose Fatalities. HAN no. 384. Atlanta, GA: US Department of Health and Human Services, CDC; 2015. <https://emergency.cdc.gov/han/han00384.asp>.
- <sup>20</sup> Mattson, C.L., et al. (2018). “Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11

States, July 2016–June 2017”. Morbidity and Mortality Weekly Report 67(34):945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>.

<sup>21</sup> O’Donnell, J., et al. (2021). “Trends in and Characteristics of Drug Overdose Deaths Involving Illicitly Manufactured Fentanlys — United States, 2019–2020”. Morbidity and Mortality Weekly Report 70:1740-1746. DOI: <http://dx.doi.org/10.15585/mmwr.mm7050e3>.

<sup>22</sup> Kariisa, M., et al (2021). “*Notes from the field*: Xylazine Detection and Involvement in Drug Overdose Deaths — United States, 2019”. Morbidity and Mortality Weekly Report 70:1300-1302. DOI: <http://dx.doi.org/10.15585/mmwr.mm7037a4>.

<sup>23</sup> Liu, S., et al (2021). “Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines — 38 States and the District of Columbia, 2019–2020”. Morbidity and Mortality Weekly Report 70:1136-1141. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034a2>.

<sup>24</sup> O’Donnell J, Gladden RM, Kariisa M, Mattson CL. Using death scene and toxicology evidence to define involvement of heroin, pharmaceutical morphine, illicitly manufactured fentanyl, and pharmaceutical fentanyl in opioid overdose deaths, 38 states and the District of Columbia, January 2018–December 2019. Addiction. doi: 10.1111/add.15768. Epub 2021 Dec 9.

<sup>25</sup> O’Donnell, J., et al. (2020). “*Vital Signs*: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants — 24 States and the District of Columbia, January-June 2019”. Morbidity and Mortality Weekly Report 69:1740-1746. DOI: <http://dx.doi.org/10.15585/mmwr.mm7050e3>.

<sup>26</sup> O’Donnell, J., et al. (2020). “*Notes from the Field*: Opioid-Involved Overdose Deaths with Fentanyl or Fentanyl Analogs Detected — 28 States and the District of Columbia, July 2016-December 2018”. Morbidity and Mortality Weekly Report 69:271-273. DOI: <http://dx.doi.org/10.15585/mmwr.mm6910a4>.

<sup>27</sup> U.S. Drug Enforcement Administration, Diversion Control Division. (2018). *2017 Medical Examiner/Coroner Office Survey Report*. Springfield, VA: U.S. Drug Enforcement Administration.

<sup>28</sup> U.S. Drug Enforcement Administration, Diversion Control Division. (2018). *2017 Medical Examiner/Coroner Office Survey Report*. Springfield, VA: U.S. Drug Enforcement Administration.

<sup>29</sup> Guy GP Jr., Haegerich TM, Evans ME, Losby JL, Young R, Jones CM. Vital Signs: Pharmacy-Based Naloxone Dispensing — United States, 2012–2018. MMWR Morb Mortal Wkly Rep 2019;68:679–686. DOI: <http://dx.doi.org/10.15585/mmwr.mm6831e1>.

<sup>30</sup> Mattson, C.L., et al. (2018). “Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017”. Morbidity and Mortality Weekly Report 67(34):945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>.

<sup>31</sup> O’Donnell JK, et al. (2017). “Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016”. Morbidity and Mortality Weekly Report 66(43):1197–1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>.

<sup>32</sup> Mattson, C.L., et al. (2018). “Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017”. Morbidity and Mortality Weekly Report 67(34):945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>.

<sup>33</sup> O’Donnell JK, et al. (2017). “Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 — 10 States, July–December 2016”. Morbidity and Mortality Weekly Report 66(43):1197–1202. DOI: <http://dx.doi.org/10.15585/mmwr.mm6643e1>.

<sup>34</sup> CDC. Rising numbers of deaths involving fentanyl and fentanyl analogs deaths, including carfentanyl, and increased usage and mixing with non-opioids. HAN no. 413. Atlanta, GA: US Department of Health and Human Services, CDC; 2018. <https://emergency.cdc.gov/han/han00413.asp>

<sup>35</sup> O’Donnell, J, et al. (2018). “Notes from the Field: Overdose Deaths with Carfentanyl and Other Fentanyl Analogs Detected — 10 States, July 2016–June 2017”. Morbidity and Mortality Weekly Report 67(27):767–768. DOI: <http://dx.doi.org/10.15585/mmwr.mm6727a4>.

<sup>36</sup> Mattson, C.L., et al. (2018). “Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017”. Morbidity and Mortality Weekly Report 67(34):945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>.