SUPPORTING STATEMENT: PART A

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State Unintentional Drug Overdose Reporting System (SUDORS)

OMB# 0920-1128

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A.

- **Goal of the study –** Detect state and local community changes in unintentional and undetermined intent drug-related overdose mortality faster and provide 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, the District of Columbia and Puerto Rico. CDC requests OMB approval for 3 years for this 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.
- **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 the currently approved State Unintentional Drug Overdose Reporting System (SUDORS) - OMB# 0920-1128, expiration date 10/31/2020. 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. As of September 2019, SUDORS is being integrated as a component of CDC's Overdose Data to Action (OD2A) Notice of Funding Opportunity (NOFO). As part of this transition, SUDORS is being expanded and revised to better respond to the evolving opioid endemic and increasing deaths involving stimulants (e.g., methamphetamines and cocaine).

CDC requests OMB approval as soon as possible in order to facilitate on-time transition to OD2A reporting requirements. The revisions are also important to inform the ongoing response to the US opioid epidemic which is both an HHS priority[1] and a national public health emergency.[2]

The current revision has four major components:

1. **Expanding to 52 health departments:** Increased Congressional appropriation in FY19 to expand SUDORS nationwide as a component of CDC's Overdose Data to Action (OD2A) Notice of Funding Opportunity (NOFO) (CDC-RFA-CE19-1904, posted February 1, 2019) requires expanding the number of participating jurisdictions from 50 to 52.
2. **Collecting data on all drug overdose deaths, instead of just opioid overdose deaths:** Due to increases in some types of non-opioid overdose deaths (e.g., methamphetamines),[3] emerging threats posed by new drugs[4] or non-opioid synthetic drugs,[5] and sharp increases in opioid overdose deaths co-involving stimulants,[6] SUDORS is proposing expanding the scope of the data collection to capture data on all unintentional and undetermined intent drug overdose deaths instead of just unintentional and undetermined intent opioid overdose.
3. **Sharp increase in drug overdose deaths since 2015:** This revision adjusts the SUDORS burden estimate to account for the dramatic increase in all manner drug overdose deaths (i.e., unintentional, suicide, undetermined, and homicide) from 52,404 in 2015[7] to 70,237 in 2017[8] since the submission of the previous SUDORS revision.
4. **NVDRS web enhancements and improvements in SUDORS data elements:** This revision includes minimal changes to the collection instrument as well as updates to the web-based system to improve performance, functionality, and accessibility for funded states. These functionality changes will include updating the web-based interface and plans to build a toxicology import in 2020 and 2021. These revisions are based on lessons learned from the state programs submitting and using SUDORS data as part of Enhanced State Opioid Overdose Surveillance (ESOOS), or CDC-RFA-CE16-1608, during 9/2016 to 8/2019. ESOOS was merged into the OD2A program and is no longer funded as an independent program. Attachment F (the Survey Updates Documentation) and Attachment F1 (screenshots) provide a detailed crosswalk of current questions and the revisions. Also, an overview of key changes is provided in *Section 15. Explanation for Program Changes or Adjustments.*

Background

Drug overdose deaths in the United States increased by 16% per year from 2014 through 2017 and increased by 10% from 2016 to 2017 to over 70,000 deaths.[9] More than two out of three drug overdose deaths in 2017 involved an opioid,[10] and opioid overdose deaths have increased six-fold from 1999 to 2017.[11] While the opioid overdose epidemic worsens in scope and magnitude, it is also becoming more complex. The increase in opioid overdose deaths involves three distinct, but interrelated waves:

- The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing from 3,442 in 1999 to 17,029 in 2017.[12,13]
- The second wave began in 2010, with rapid increases in overdose deaths involving heroin from 3,036 in 2010 to nearly 15,500 deaths in 2017.[14]
- The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids excluding methadone from 3,105 in 2013 to almost 28,500 deaths in 2017[15]. This increase is driven by overdoses involving fentanyl, particularly those involving illicitly-manufactured fentanyl (IMF). Fentanyl is a synthetic and short-acting opioid analgesic that is 50-100 times more potent than morphine and approved for managing acute or chronic pain associated with advanced cancer. Although pharmaceutical fentanyl can be diverted for misuse, most cases of fentanyl-related morbidity and mortality have been linked to illicitly manufactured fentanyl and fentanyl analogs, referred to as IMF. IMF is sold via illicit drug markets for its heroin-like effects and often mixed with heroin as a combination product—with or without the user's knowledge—to increase its euphoric effects.[16,17] Additionally, IMF has been increasingly distributed as counterfeit prescription pills or mixed or used with cocaine or other stimulants.[18,19] Finally, an array of potent fentanyl analogs (i.e., compounds that are chemically related to fentanyl) are now being distributed in the United States and increasingly contributing to drug overdose deaths.[20] Some of these fentanyl analogs such as carfentanil are much more potent than fentanyl and pose acute public health threats.[21]

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,[22] joining at least eight states that have declared the opioid epidemic a statewide emergency.[23] 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.[24] 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 will provide 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 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. 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,[25] 2) the proliferation of illicitly-manufactured fentanyl analogs and their involvement in outbreaks,[26,27,28,29,30] 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.[31] As the factors driving increased drug overdose deaths have become more complex, expanding SUDORS to capture all drug overdose deaths is required to inform interviews. Explanation of this change is described in *Section 15. Explanation for Program Changes or Adjustments.*

Interventions that could be used by communities to address the risk factors tracked by SUDORS include distributing naloxone[32] to first responders and community members, enhancing access and use of evidence-based substance use treatment[33], identifying and disrupting illegal distribution of OPRs through physician offices (i.e., often referred to "pill mills")[34], 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[35].

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 SUDORS is 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 are 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. Specifically, 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. Similarly, whether a fentanyl positive test in a drug overdose death suggests illicitly-manufactured fentanyl or prescription fentanyl requires reviewing ME/C reports, including scene evidence (e.g., injection suggesting illicit drugs) and full toxicology findings (e.g., fentanyl mixed with heroin most often occurs with illicitly manufactured fentanyl).
    - In 2018, CDC used SUDORS data to report the percent of opioid overdose deaths involving only illicit opioids, only prescription opioids and both illicit and prescription opioids for 11 of the 12 states originally funded to implement SUDORS. This is a critical step forward in surveillance because the involvement of illicit and prescription drugs in opioid overdose deaths substantially varied by state and state interventions need to be customized to the types of opioid overdose deaths occurring in their state.

- 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[36].
    - 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. Analysis of SUDORS data across 11 states found that a bystander was present in over 40% of opioid-related overdose deaths, but naloxone was administered by the bystander in fewer than 5% of deaths.[37]
- 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.
    - In January 2019, Rhode Island presented SUDORS circumstance data related to mental health and substance use disorders of opioid overdose decedents to the Governor's Task Force meeting. The presentation has led to follow-up conversations with the Office of the Attorney General about more in-depth analyses of these circumstances.
    - In 2018, CDC published, **Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017**, which used SUDORS data to examine how key risk factors for opioid overdose death (e.g., percent of decedents released from an institution the month before the fatal overdose) varied depending on whether illicit, prescription, or both illicit and prescription opioids were involved in the overdoses.[38]
- 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.[39]
    - In 2017 and 2018, SUDORS data provided critical insight into the rapidly growing number of overdose deaths related to fentanyl and fentanyl analogs,[40] increases in overdose deaths involving carfentanil (an extremely potent fentanyl analog),[41] and increasing deaths co-involving both fentanyl and heroin.[42] CDC updated its public health advisory related to fentanyl and fentanyl analogs in 2018 based on some of this data.[43]
- 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.[44]

Because the data collection relies on ME/C investigations of fatal drug overdoses which are not standardized across the Unites 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.

3. Use of Improved Information Technology and Burden Reduction

Data entry is accomplished by the 52 participating health department 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 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 timely.

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 (see OMB No. 0920-0607, exp. 11/30/2020) 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 consider 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 overtime 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 trained 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 Unintentional Injury Prevention (DUIP), 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 CIO's in CDC to ensure coordination and integration of opioid surveillance activities across CDC.

In accordance to OMB's terms of clearance, CDC-NCIPC has provided OMB two reports on the progress of collaborations with NCHS in August 2018 and March 2019 (Attachment H). The current collaborations between DUIP and NCHS are summarized in the table below.

Description of Current DUIP and NCHS Collaboration	OMB NOA Terms of Clearance Addressed
New ME/C guidance on certifying drug toxicity deaths completed: DUIP funded and NCHS convened a working group of epidemiologists, medical examiners and coroners (ME/C), vital records agency personnel, and representatives of CDC to identify methods for improving the reporting of drug overdose deaths on the death certificate. • **Deliverable:** As a result of the workgroup, NCHS drafted guidance for ME/Cs in "*A Reference Guide for Certification of Drug Toxicity Deaths*" that was released in May 2019.[45]	Addresses OMB term of clearance to improve the standardization of data collected from ME/Cs.
Complete effort to pilot an interoperable interface with popular ME/C electronic case management system: NCHS completed a DUIP-funded effort to pilot-test the feasibility, utility and scalability of creating interoperable interfaces with popular ME/C electronic case management systems (i.e., MDILog or VertiQ). The project funded the Occupational Research and Assessment (ORA) which collaborated with the National Association of Medical Examiners and the International Association of Coroners & Medical Examiners. • **Lesson learned:** While the pilot confirmed the utility of creating an electronic database of toxicology findings, the pilot also identified substantial barriers to establishing interoperable toxicology data and other data elements not required on the death certificate. Examples of barriers include the lack of standard data collection elements and processes across ME/C systems and the fact that vendors may be driven to develop technology to generate a profit.	Addresses OMB term of clearance to support development of ME/C standards and improving electronic interoperability of ME/C case management systems that incorporate toxicology information and findings from death scene investigations into vital statistics systems.
Ten state interoperability project: The main collaborative activity between NCHS and NCIPC is being funded through CDC's Opioid Response Coordinating Unit (ORCU). This 16-month initiative began in fall 2018 and received $5.9 million in funding. The initiative consists of	This initiative addresses two OMB terms of clearance: 1) broad development of ME/C

Description of Current DUIP and NCHS Collaboration	OMB NOA Terms of Clearance Addressed
three separate components: 1) improve investigation of drug overdose deaths by updating the National Association of Medical Examiners (NAME) position paper on death investigation best practices and developing training materials to implement recommendations, 2) enhance the capacity of vital registration jurisdictions to collect quality drug information on death certificates, and 3) improve the timeliness and quality of death certificate data as well as access to other medical examiner and/or coroner (ME/C) data by improving the information flow among ME/C agencies, state vital records offices, NCHS and state surveillance systems such as SUDORS or the National Violent Death Reporting System. In order to accomplish the second and third goal, 10 state vital registration jurisdictions (IA, IN, KS, LA, MD, MS, NV, NM, UT and DC) have joined an existing NCHS project to enhance interoperability between ME/C case management systems and state vital records office electronic death registration systems. Recipients are working to improve the timeliness and quality of mortality records transmitted to NCHS, especially for the reporting of drug-involved deaths. Specifically, states are expected to work towards transmitting at least 90% of their drug-involved deaths to NCHS within 90 days. Also, these 10 states must work towards electronically transmitting relevant mortality records to a state public health surveillance program within 2 days of receiving the cause of death codes from NCHS. • **Project update:** All 10 funded states have created and submitted project plans to NCHS with details of current barriers to timely collection and transmission of drug mortality records. Also, states have proposed specific strategies to overcome identified barriers. It is too early in the implementation of these projects to report on lessons learned. Staff from NCHS, DUIP, and DVP had a call with colleagues in the District of Columbia to discuss their project plan on 8/27/2019 and explore enhancements to the death certificate import into NVDRS and SUDORS that would incorporate FHIR standards. • **Other notes:** Instead of funding NCHS and DUIP collaborative activities through the current *Overdose Data to Action Notice of Funding Announcement (CDC-RFA-CE19-1904)* mentioned in the previous August 2018 update, ORCU allocated funding to this project because the project and mechanism were more appropriate.	standards and improving electronic interoperability of ME/C case management systems that incorporate toxicology information and findings from death scene investigations into vital statistics systems and 2) piloting interoperability efforts across multiple states.
Improve automatic coding of drug overdose deaths by NCHS: CDC's Opioid Response Coordinating Unit (ORCU) is providing NCHS $1.9 million of funding to modernize the cause of death coding system to auto code more deaths with ICD-10-CM codes and provide more detail on substances contributing to drug overdose deaths. Specifically, the three key components of this NCHS 16-month project are: 1) accelerating efforts to modernize the NCHS cause of death coding system to increase the percentage of records automatically coded from 80% to over 90%, 2) accelerating the development of detailed coding for drug-involved deaths to better capture all the specific drugs involved and 3) providing short-term funding to minimize delays in manual coding of deaths by hiring additional contract staff to manually code deaths not automatically coded. • **Project update:** It is too early in the implementation of these projects	This project will increase both NCHS and state electronic access and sharing of data on the specific drugs contributing to overdose deaths. Consequently, it addresses the OMB term of clearance to broadly implement electronic death reporting.

Description of Current DUIP and NCHS Collaboration	OMB NOA Terms of Clearance Addressed
to report on lessons learned.	

Future collaborative priorities for NCHS and DUIP will be driven by lessons learned from the 10 state interoperability project.

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 at this time 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.[46] 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 a large number of 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, DUIP 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. A number of current DUIP 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.[47] 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 2020 and 2021, SUDORS will 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) DUIP 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, DUIP is building relationships with the Society for Forensic Toxicologists. These relationships will help DUIP 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 DUIP 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 funded in 47 states, Puerto Rico, 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 (see OMB No. 0920-1268, exp. 8/31/2022). 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[48] and the possibilities of the fatal overdoses

occurring before medical treatment is possible due to no one witnessing the overdose[49] or the rapid progression of overdoses involving fentanyl and fentanyl analogs.[50]

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. 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 drug overdose on a yearly basis such as the 26% increase in heroin-related overdose deaths from 2013 to 2014[51] or the 16% per year increase in drug overdose deaths from 2014 through 2017[52] 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 2017 by December, 2018).

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 May 30, 2019, Volume 84, Number 104, pages 25055-25056 (**Attachment B**). No public comments were received.

B. Efforts to Consult Outside the Agency
NCIPC currently collaborates with 32 states and District of Columbia on the SUDORS data collection though the ESOOS collaborative agreement. As part of ESOOS, a SUDORS workgroup, which comprises data abstractors and epidemiologists from the 33

health departments participating in ESOOS as well as CDC staff, has met at least quarterly 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 this revision have been informed or initiated in response to feedback from health departments participating in the SUDORS workgroup.

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[53].

On February 27th and February 28th, 2019, the National Center for Injury Prevention and Control (NCIPC) at CDC, in collaboration with the Association of State and Territorial Health Officials (ASTHO) convened a meeting of organizations working with opioid morbidity (e.g. ED syndromic and hospital billing data) and mortality surveillance data (e.g., ME/C agencies that provide data to SUDORS) with the goal of sustaining existing partnerships, building new partnerships, and planning strategically for future surveillance efforts. Specific meeting objectives included: 1) brief participants on the fundamentals of the ESOOS program including SUDORS – what it is, how we got here, and where we are heading with regards to the need for data to action activities; 2) understand current opioid overdose data activities of partners (if applicable); 3) identify needs of partners; 4) discuss how CDC can support partners and vice versa; and 5) determine next steps and action Steps (e.g. Letters of Support, further identification of additional partners and points of contact to serve as SME advisors and technical reviewers). The following key SUDORS partners attended the meeting: 1) National Association of Medical Examiners (NAME); 2) International Association of Coroners and Medical Examiners (IAC&ME); 3) Society for Forensic Toxicologists (SOFT); 4) National Association of Public Health Statistics and Information Systems (NAPHSIS); 5) Center for Forensic Research and Education, 6) Association of Public Health Laboratories (APHL) and 7) American Society of Crime Laboratory Directors (ASCLAD). As part of this meeting, CDC discussed with NAME enhancements that can be made into NAME's updated guidance on investigating drug overdose deaths, including possible guidance on toxicology testing. The goal is to hold a similar partner meeting on an annual basis to collect ongoing feedback on SUDORS and other DUIP surveillance activities from key partners.

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 52 participating health departments (i.e., all 50 states, Puerto Rico, 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 52 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, a number of 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) to prevent the inadvertent identification of an individual through the combination of various demographic

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 32 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:
- The previous burden estimates were based on opioid-related overdose deaths that occurred among all 50 states in 2015, or 33,091. The revision will use the total number of unintentional or undetermined intent drug overdose deaths in the US in 2017, or 64,998, and add 667, an estimate of the number unintentional and undetermined intent drug overdose deaths in Puerto Rico[54], for a total of 65,665 deaths. The total number of unintentional or undetermined intent drug overdose deaths per jurisdiction was estimated by dividing the total number of drug overdose deaths, 65,665, by the number of participating health departments, 52, or approximately 1,263 deaths per participating health department.
- 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 refiling records (Att. E)	52	1,263	30/60	32,838
Total					32,838

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 ($27.34) as estimated by the Bureau of Labor Statistics (https://www.bls.gov/oes/current/999001.htm#00-0000, accessed on September 10, 2018) was used to estimate burden costs. Public Agencies who retrieve and refile records estimate costs at [32,838 burden hours x $27.34/hour] = $897,791. 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	52	1,263	30/60	32,838	$27.34	$897,791
Total						$897,791

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
MISO contract for improvements of the data collection software	$150,000
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 guidance, and providing technical assistance to CDC as well as state and local health departments (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
Contract to fund 3 data managers (100%)	$262,500
Other Direct Costs	
Subcontractors	$0
Travel and subsistence	$0
Total Estimated Contract Costs	**$1,012,500**

*The exact cost may change as the exact funding amount is still being determined.

Government costs

Personnel	Tasks	Avg. cost/yr
2 Senior scientists (75%)	Program oversight and strategic direction	$245,436
5 Epidemiologists (75%)	• Direct technical assistance to 52 health departments participating in SUDORS. • Responsible for data quality checking in approximately 10 jurisdictions • Work to enhance SUDORS data quality and guidance. • Conduct surveillance using SUDORS data • Disseminate SUDORS data	$390,000
14 Public health advisors (5%)	Programmatic, budgetary, administrative management and oversight of SUDORS as part of OD2A NOFO	$61,250
1 Data manager (100%)	• Manage and improve the receipt, cleaning, validation and standardized analysis of SUDORS data. • Maintain documentation about data management and standards.	$104,000
Indirect staff costs		$200,172
Sub-total		**$1,000,858**
Contract Costs		$1,012,500
Total		**$2,013,358**

Total annual contractual and government staff costs are approximately $2 million per year. 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

Each of the four major revisions to SUDORS submitted as part of this package are described below:

1. **Expanding to 52 health departments:** Congressional appropriations and SUDORS clearance estimates have increased three times since the inception of SUDORS in FY16.

Each of the three expansions are described and explained below. This revision requests that the SUDORS clearance estimates be increased from 50 to 52 participating health departments due to recent increases in congressional funding in FY19.

a. In FY16 due to a rapid increases in opioid overdose deaths starting in 2014,[55,56] CDC proposed to launch a pilot involving up to 16 states to collect enhanced data on opioid overdose deaths. States with the largest fatal opioid overdose burden or sharply increasing fatal opioid overdose burden during 2013-2014 were prioritized. In FY16, Congress appropriated funds to work with state health departments to improve the timeliness and quality of nonfatal and fatal opioid overdose surveillance by developing the Enhanced State Opioid Overdose Surveillance program (ESOOS), or CDC FOA #CE16-1608. SUDORS was a component of ESOOS and 12 states were funded to implement SUDORS in FY16.[57]
b. In FY17 in response to continued increases in opioid overdose deaths primarily driven by overdose deaths involving illicitly-manufactured fentanyl,[58,59] ESOOS received a substantial increase in congressional appropriations that enabled ESOOS to expand funding from 16 states to 32 states and the District of Columbia. Also, the goal of SUDORS became to fund all 50 state health departments instead of just high burden states because all states were vulnerable to rapid increases in opioid overdose deaths and the types of opioid overdose deaths varied substantially across state.[60] CDC revised the SUDORS clearance to incorporate up to 50 potential awardees, in the event of a further increase in the appropriation and to align with SUDORS goal of national coverage.
c. The US government declared the opioid overdose epidemic a national public health emergency on October 26, 2017. In FY 2019, CDC received expanded appropriations and implemented Overdose Data to Action (OD2A) Notice of Funding Opportunity (NOFO), or CDC-RFA-CE19-1904, posted February 1, 2019.[61] ESOOS (including SUDORS) is a component of OD2A and is no longer funded independently. OD2A began funding SUDORS in 47 states, the District of Columbia and Puerto Rico in September 2019. SUDORS was expanded to include Puerto Rico because eligibility for the OD2A NOFO for the first time included US territories and media reports suggest an increasing and serious problem with drug overdose deaths in Puerto Rico.[62] Only three states (i.e., North Dakota, Texas, and Wyoming) did not choose to apply to OD2A and are not funded to collect SUDORS data. CDC will make efforts to include these states in the future. In order to accommodate the growth of the program, CDC proposes to increase SUDORS clearance from 50 to 52 potential awardees (all 50 state health departments, Puerto Rico, and District of Columbia) in the event of a further increase in the appropriation.

2. **Collecting data on all drug overdose deaths, instead of just opioid overdose deaths:** SUDORS is proposing expanding the scope of the data collection to capture data on all unintentional and undetermined intent drug overdose deaths instead of just unintentional and undetermined intent opioid overdose deaths for three reasons.
    a. Drug overdose deaths involving cocaine and methamphetamine have begun to increase and it is critical to determine the extent to which increases are driven by

co-occurrence with opioids versus other factors.[63] More generally, most drug overdose deaths including opioid overdose deaths involve multiple drugs.[64,65]

b. Second, new non-opioid drugs pose overdose risk that requires broad drug overdose surveillance. For instance, synthetic cannabinoids have been associated with more drug overdose deaths[66] and kratom, a plant native to Southeast Asia that can produce stimulant effects in low doses and some opioid-like effects at higher doses, has been found to contribute to drug overdose deaths.[67]
c. Third, the collection of data on all drug overdoses will support enhanced situational awareness of the extent to which non-opioid prescription drugs are involved in overdoses. This in turn may foster more rapid recognition and response to emerging safety issues with prescription drugs.

3. **Sharp increase in drug overdose deaths since 2015:** This revision adjusts the SUDORS burden estimate to account for the dramatic increase in all manner drug overdose deaths (i.e., unintentional, suicide, undetermined, and homicide) from 52,404 in 2015[68] to 70,237 in 2017[69] since the submission of the previous SUDORS revision. Primarily driven by increases in unintentional drug overdose deaths, this increase in drug overdose deaths substantially impacts SUDORS burden estimates. SUDORS burden is associated with the time it takes ME/C agencies and vital statistics agencies to retrieve and refile records on each unintentional and undetermined intent drug overdose death. Consequently, as the numbers of drug overdose deaths increase, the burden will also increase. This is especially true for the significant number of ME/C agencies that share paper or a combination of electronic and paper files with participating health departments.[70]
4. **NVDRS web enhancements and improvements in SUDORS data elements:** This revision includes minimal changes to the collection instrument as well as updates to the web-based system to improve performance, functionality, and accessibility for funded states. These revisions are based on lessons learned from the state programs submitting and using SUDORS data as part of ESOOS. Attachment F (the Survey Updates Documentation) and Attachment F1 (screenshots) provide a detailed crosswalk of current questions and the revisions. These changes would not affect burden hours for response because there is no burden for abstraction of data elements for SUDORS, since the respondents are medical examiner and coroners as well as state vital statistics. Changes include:
    a. Capturing information on whether the decedent had recently visited an emergency department (i.e., an opportunity for intervention).
    b. Tracking the type of substance use treatment the decedent was receiving.
    c. Improving classification of fentanyl-involved overdose deaths as related to illicitly-manufactured fentanyl or prescribed fentanyl by collecting more data on whether the decedent was prescribed fentanyl or used diverted prescription fentanyl.
    d. Adding a SUDORS checkbox to rapidly identify SUDORS cases irrespective of data entered (e.g., a data entry error could currently exclude some cases and this variable provides an important double-check).
    e. Collecting enhanced data on the identity of bystander(s) present at an overdose (e.g., family member or another person using drugs) and the bystander's response to the overdose including reasons they did not respond (i.e., did not recognize the

symptoms of overdose). Information can inform training programs for laypeople who are at high risk of witnessing an overdose.

f. Abstracting key parts of the decedent's medical history that may have contributed to overdose risk (e.g., sleep apnea, asthma or chronic obstructive pulmonary disease) or provide insight into their opioid use (e.g., history of back pain or chronic pain).
g. Collected more detailed information first responders' treatment of the decedent (e.g., use of CPR or oxygen) as well as the condition of the decedent on arrival (e.g., no pulse).
h. Designing and implementing a toxicology import in 2020 and 2021. Currently, state abstractors manually enter toxicology findings.

CDC requests OMB approval as soon as possible in order to facilitate on-time transition to OD2A reporting requirements. The revisions are also important to inform the ongoing response to the US opioid epidemic which is both an HHS priority[71] and a national public health emergency.[72]

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**).**[73] 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 2020 by December, 2020) instead of the current 8-month time lag (e.g., complete data collection on drug overdose deaths occurring from January to June 2020 by February 2020). 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) coupled with the fact that 16 jurisdictions are expected to receive SUDORS funding for the first time in September 2019 will result in a substantial number of participating health departments reporting data to CDC with an 8-month lag. Over time, CDC will 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
Preliminary analysis files, including counts of unintentional drug overdose based on vital statistics and ME/C reports	6 months
Final analysis files prepared	12 months
Public release through web-based interface or surveillance report	18 months

Publications such as MMWR	At least two articles per year

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, district, or territory. 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, [74, 75,76] and drugs commonly mixed or co-used with opioid such as benzodiazepines[77]. 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). [78] 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 or Puerto Rico may choose to start 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 work with these states over time 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.

[1] Additional information on the 5-point HHS strategy is available at: https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.

[2] Additional information on President Trump's Initiative to Stop Opioid Abuse, https://www.whitehouse.gov/opioids/.

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[6] Seth, P., et al. (2018). "Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015–2016". Morbidity and Mortality Weekly Report 67(12):349–358.

[7] Rudd, R.A., et al. (2016). "Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015". Morbidity and Mortality Weekly Report 65(50-51):1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1.

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[11] Additional information on the opioid epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html.

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[15] Ibid.

[16] 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.

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[21] Ibid.

[22] Additional information on President Trump's Initiative to Stop Opioid Abuse, https://www.whitehouse.gov/opioids/.

[23] 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/.

[24] Additional information on the 5-point HHS strategy is available at: https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.

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[32] 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

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