

***SUPPORTING STATEMENT: PART B***

**May 25, 2017**

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

OMB# 0920-1128

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## **B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

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### **Attachments**

- A Authorizing Legislation: Public Health Service Act
- B Published 60-Day Federal Register Notice
- B1 Public comment
- C Institutional Review Board (IRB) documentation
- D SUDORS Data Elements
- E Retrieving and refiling records
- F SUDORS Updates Documentation
- F1 SUDORS Updated Screen Shots
- G Privacy Impact Assessment (PIA)

## **B. Collection of Information Employing Statistical Methods**

### **1. Respondent Universe and Sampling Methods**

A complete census of opioid-related fatal unintentional drug overdoses (UDO) within each given state is sought, so no sampling methods will be employed. The 50 states will be selected through a competitive process. States with high drug overdose death rates in 2014 will receive preference as described in the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality FOA (CDC-RFA-CE16-1608). State drug overdose death rates are used as a proxy for opioid-related overdose deaths because the specific drug(s) contributing to a drug overdose are not listed for approximately 1 in 5 drug overdoses and this varies substantially across states<sup>i,ii</sup>. Thus, only drug overdose death rates can be compared across states and not drug-specific rates such as opioid-related overdose deaths.

Because this data collection effort is a census and no sampling is employed, the data system will provide a full characterization of UDO deaths in participating states. This information, however, will not be generalizable to the United States or other states.

### **2. Procedures for the Collection of Information**

The system will be 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 agents. To fully characterize each unintentional and undetermined opioid-related drug overdose death, states collect information about each incident from death certificates and coroner/medical examiner records (ME/C). Most states find it easiest to begin data collection (i.e., identify a death as an unintentional drug overdose) with death certificates because the state health department itself collects death certificates. States with centralized medical examiner offices (i.e., only a single office serving the whole state), however, may be able to identify opioid-related drug overdose deaths more rapidly than the death certificate. Approximately 240 data elements can be collected on each drug overdose death from these principal sources. Not all elements are required, and not all elements will be used for each death; use depends on information and evidence specific to each death record (i.e., built in skip-patterns). See attached list of data elements (Attachment D).

Data collection can be done either by manual abstraction from the primary data sources or by electronic transfer or importation, whichever proves faster. Data collection is staged so that basic counts of fatal unintentional/undetermined drug overdoses, preliminary toxicology, and demographic information can be provided to CDC within 6 months of the date of death and more detailed information about potential causal factors can be provided within 8 months.

Only de-identified information is entered into the web-based data collection tool and states are responsible for linking ME/C and death certificate information at the local level.

### **Estimation Procedures**

No estimation procedures will be employed.

## **Degree of Accuracy**

The following procedures will be used to check accuracy:

- 1) Numbers of unintentional and undetermined opioid-related drug overdose deaths will be compared against counts published by the National Center of Health Statistics on CDC Wonder (See <http://wonder.cdc.gov/mcd-icd10.html>)
- 2) The web-based platform contains numerous built-in validity checks that prevent abstractors from entering invalid data or conflicting data (e.g., the date of death is earlier than the date of injury or male is pregnant).
- 3) By the end of year 1, additional validity check programs will be designed to look for specific issues with opioid-related drug overdose deaths (e.g., flagging heroin-related deaths that list the route of ingestion as the route of admission). These reports will be circulated to states at least twice a year.
- 4) In order to ensure CDC coding guidelines are being used, a randomly selected sample of a least 75 cases per state will be reviewed on a yearly basis. Feedback will be provided to the state.
- 5) CDC will work with states to develop standard protocols for analyzing complex variables such as toxicology results.

## **Unusual Problems**

There are more legal issues associated with unintentional and undetermined drug overdoses, especially if there is any suspicion of a suicide or homicide, than with deaths from natural causes. Medical examiner and coroners may be reluctant to release files for abstraction while a death investigation is in process. This may cause delays in receiving and entering data. The program can address and minimize this issue by building strong relationships between public health departments and ME/C offices.

An additional barrier is that many states have decentralized ME/C systems (e.g., a separate coroner and/or medical examiner office for each county) and consequently records on unintentional and undetermined drug overdose deaths are non-centralized and not recorded in a standard manner. Only 15 states and the District of Columbia have statewide medical examiner systems with centralized records; the remainder have county medical examiners and/or coroners<sup>iii</sup>. Collecting data in states with large numbers of ME/C offices can be challenging as state health departments must build individual relationships with each office to share data. Working with state or regional associations of ME/C is one approach that will be encouraged to minimize this problem.

Moreover, ME/C information is not standardized and may not be computerized. Time consuming abstraction from primary sources by trained abstractors will be required. Eventually efforts to develop an electronic death certificate and ME/C's greater use of electronic data collection may dramatically reduce the need for data abstraction.

### **3. Methods to Maximize Response Rates and Deal with Non-response**

This issue is not relevant with this methodology.

### **4. Tests of Procedures or Methods to be Undertaken**

SUDORS is leveraging the data collection platform and lessons learned from the National Violent Death Reporting System (NVDRS). States began collecting data for NVDRS in 2003. NVDRS uses a web-based data entry platform with streamlined coding system to facilitate data abstraction efficiency (see Attachment E for screenshots of variables to be collected by SUDORS). By leveraging the data collection system and approach of NVDRS, SUDORS is implementing a feasible and tested system.

**5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

There are no statistical aspects related to this surveillance system.

The data will be collected by state health department staff. Data will be transmitted via the web to CDC-based server.

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

<sup>ii</sup> Warner, M., et al. (2013). "State variation in certifying manner of death and drugs involved in drug intoxication deaths." Academic Forensic Pathology 3(2): 231-237.

<sup>iii</sup> Frontline (2011). "Map Death in America." Retrieved February 5, 2016, from <http://www.pbs.org/wgbh/pages/frontline/post-mortem/map-death-in-america/>.