SUPPORTING STATEMENT: PART A

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Drug Overdose Surveillance and Epidemiology (DOSE)

OMB #0920-1268

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SUMMARY TABLE

- **Goal of the study** This serves as a revision request for the currently approved ICR. Revisions are requested to revise the number of eligible states, change the data collection template, and revise burden.
- **Intended use of the resulting data** Improve local, state, and regional situational awareness of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdose trends and response to acute local and multi-state drug outbreaks.
- **Methods to be used to collect** The project will leverage ED syndromic data and hospital discharge data on ED visits already routinely collected by state health departments and the District of Columbia health department. No new data will be systematically collected from EDs. and health departments will be reimbursed by CDC for the burden related to sharing ED data with CDC. Fifty-one funded health departments (50 state health departments and the District of Columbia) will rapidly share existing ED data with CDC on a monthly basis using the *Rapid ED* overdose data form and standard CDC case definitions. Data may come from different local ED data systems, but is expected to cover at least 75% of ED visits in the jurisdiction (e.g., state). Specifically, some health departments conduct rapid overdose surveillance using local ED syndromic systems or hospital discharge data, while others conduct surveillance using CDC's National Syndromic Surveillance Program (NSSP), which receives near real-time ED data from health departments or their partners on approximately 71% of ED visits in the United States. Regardless of the data source, CDC will require all participating health departments to provide counts of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepines, and other emerging drug overdoses by county, age group, sex, race/ethnicity, and time (i.e., month and year) in a standardized manner using the Rapid ED overdose data form, which is an Excel data template. This form also collects data quality indicators such as percent of ED visits missing data on key variables (i.e., metadata). In order to assess and improve rapid ED data sharing, all 51 participating health departments will also be asked to share counts of ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, race/ethnicity, and time (i.e., month and year) from more finalized hospital discharge files, the current surveillance standard. The data will be shared with CDC on a quarterly or yearly basis using a standardized Excel data form, the ED discharge overdose data form, and standard CDC case definitions.
- The subpopulation to be studied Individuals who visit an ED to receive treatment for a drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdose.
- How data will be analyzed Descriptive analyses such as frequencies and changes in the rate of ED visits involving drug, opioid, heroin and stimulant overdoses by region, state, and local jurisdiction. Longitudinal statistical analyses such as Joinpoint regression will be used to describe trends. Also, monthly, quarterly, and yearly changes in key indicators will be monitored to identify outbreaks. Finally, drug overdose counts from rapid ED surveillance and hospital discharge files will be compared to inform improvements.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This is a revision request for the currently approved Drug Overdose Surveillance and Epidemiology (DOSE) - OMB# 0920-1268, expiration date 08/31/2022. CDC is requesting OMB approval for an additional 3 years to continue data collection efforts. The DOSE system originally received approval to collect data from 50 states, the District of Columbia and Puerto Rico, and currently captures data from 47 states and the District of Columbia. We seek to expand to all 50 states and the District of Columbia in 2023. Puerto Rico is being removed from DOSE eligibility and will not be sharing data. DOSE captures and rapidly shares existing ED data on counts of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses using two standard data forms (i.e., the Rapid ED overdose data form and the ED discharge overdose data form) and standard CDC case definitions. Revisions noted below are for three purposes: (1) to revise the number of eligible recipients from current and future data collection efforts; (2) to change the data collection template to include race/ethnicity and the new drug types; and (3), and revise burden estimates. A future revision or change request will provide final state enrollment numbers in 2023 following the release of a new funding announcement for DOSE (pending award Fall 2023).

Several circumstances make DOSE necessary. First, there have been rapid increases in opioid overdose deaths since 2013¹ and numerous severe fentanyl and fentanyl analog outbreaks occurring across the United States²,3,4,5,6. In addition, the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017¹ highlighted the urgent need to rapidly establish and enhance timely surveillance of drug overdoses. DOSE provides data critical to inform timely local, state, and regional response, especially to acute and/or widespread multi-state outbreaks.

Second, CDC was appropriated funding in FY 2019 to expand to all 50 states and the District of Columbia drug overdose ED surveillance funded through the CDC Enhanced State Opioid Overdose Surveillance Funding Opportunity (ESOOS; CDC-RFA-CE16-1608).8 Initiated in 12 states in September 2016, ESOOS funded 32 state health departments and the District of Columbia to rapidly share ED data collected by their agency with CDC on the number of suspected drug, opioid, and heroin overdoses. Participating health departments used their own state-based case definitions of ED visits involving suspected drug, opioid, and heroin overdoses and select how they are going to share data with CDC (i.e., are not required to fill out a standardized template). This expansion that occured in FY 2019 was a component of CDC's Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904). DOSE replaced and enhanced ESOOS ED data sharing. OD2A funding expires in September 2023; however, we are requesting three additional years for DOSE data collection in anticipation of continued DOSE activities past the current OD2A funding cycle.

Over the past several years of implementing DOSE, we have learned key lessons to inform the enhanced data sharing that we hope to continue to implement:

- 1. Having standard, national case definitions for drug overdose is extremely important for dissemination efforts. With all states using the same definition, we feel more confident that states are more comparable across time.
- 2. Using a form [the "*Rapid ED overdose data form*" (Att. D)"] has improved CDC data processing time. In addition, CDC has developed SAS programs and R code for states to use to analyze the data and output results into the form, which has reduced state data processing time.
- 3. Creating and testing new case definitions is paramount to better understanding this evolving epidemic. States are now required under DOSE to share data on suspected all drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses. This responds to sharp increases in deaths involving (for example) stimulants as well as increased co-use and mixing of opioids with stimulants and benzodiazepines over the past few years. ^{9,10,11} Though this is a revision to the previously approved collection form (Att. D and Att. E), OMB approval was granted in our original request to create and collect data on new drug overdose indicators.
- 4. Some states are unable to share syndromic surveillance data, thus allowing flexibilities for sharing of hospital discharage data using the form [the "ED discharge overdose data form" (Att. E)] has been beneficial. ED syndromic systems are designed to collect rapid preliminary data on changes in illness and injuries such as drug overdose. These systems, however, often do not provide an accurate estimate of the full burden of illnesses and injuries because they are based on preliminary data. Responding to this limitation, DOSE will continue to compare counts and rates of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses from rapid ED data sharing with the same counts calculated using more finalized hospital discharge data files (the current public surveillance standard used to assess the burden of drug overdoses treated in EDs).
- 5. States have been working towards improving the data quality of new fields such as those that capture patient race and ethnicity. CDC and states have worked together to assess some of these fields and as completeness and accuracy improves, states are now able to share data on patient race and ethnicity. Thus, CDC would like to now require the sharing of patient race and ethnicity. This is a revision to the previously approved collection form (Att. D and Att. E) and will require OMB approval.

DOSE background

In 2020, a total of 91,799 drug overdose deaths occurred, corresponding to an age-adjusted rate of 28.3 per 100,000 population and a 31% increase from the 2019 rate (21.6). From 2013 to 2019, the synthetic opioid-involved death rate increased 1,040%, from 1.0 to 11.4 per 100,000 age-adjusted (3,105 to 36,359). The psychostimulant-involved death rate increased 317%, from 1.2 (3,627) in 2013 to 5.0 (16,167) in 2019. Non-fatal overdoses are on the rise as well; ED data from DOSE indicates increases from 2018 to present. 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. The opioid overdose epidemic is one of the U.S. Department of Health and Human Services (HHS) top priorities. In 2021, HHS expanded their Overdose Prevention Strategy to focus on four strategic priorities: primary prevention, harm reduction, evidence-based treatment, and recovery support.

DOSE is a critical element of HHS's first goal under primary prevention to support research and surveillance to collect timelier and more specific data through accelerating the speed at which CDC's reports drug overdose data. DOSE data collection integrates, expands, and enhances previous data sharing efforts with public health departments initiated under ESOOS. The goal of DOSE is to conduct surveillance of approximately 75% of all ED visits for drug overdoses through the end of the Overdose Data to Action (OD2A) cooperative agreement in 2023. In 2019, OD2A provided funding for 66 jurisdictions; 47 states and the District of Columbia share data with DOSE. Though we had hoped to capture data from all 50 states and the District of Columbia, only 47 states and the District of Columbia applied for this funding announcement. We describe our progress to date in more detail in Section 2.

DOSE is made possible because the vast majority of the participating health departments are already rapidly collecting extensive data on ED visits in their jurisdiction and using these data for the identification of public health concerns including flu, heat-related illness, and hurricane-related health issues. Prior to the implementation of ESOOS, most states, however, were not routinely using these data to identify ED visits related to suspected drug overdoses, nor were they analyzing this data in a timely manner, or sharing these data with CDC. DOSE ensures participating jurisdictions use their data to track suspected overdoses by providing participating jurisdictions standardized definitions of ED visits involving drug, opioid, heroin and stimulant overdoses. This facilitates rapid identification and tracking of ED data on drug overdose.

Also, no single ED surveillance system has national coverage, but almost all of participating health departments use one of three systems - the NSSP BioSense System, local ED syndromic surveillance, or hospital discharge files. DOSE integrates data across these three types of ED surveillance to quickly build a national surveillance system while leveraging existing ED data collection efforts. DOSE can use data across the three types of ED surveillance systems because the key data requirement is the ability to detect change over time (e.g., data consistently collected within the jurisdiction overtime) and not comparability across participating health departments (e.g., same data collection methods deployed across state health departments overtime).

A brief background of the three ED data systems integrated into DOSE is provided below:

- 1. *CDC National ED Syndromic Surveillance*: The Division of Health Informatics and Surveillance (DHIS) in the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) in CDC operates the National Syndromic Surveillance Program (NSSP) BioSense Platform (OMB #0920-0824) through which state and local health departments share preliminary data such as the chief complaint of the patient seeking care at the ED (e.g., "heroin overdose") and/or diagnosis codes, primarily International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)¹⁸ diagnosis codes, assigned the ED visit on approximately 71% of ED facilities in the US. Chief complaint data are often received by the NSSP BioSense Platform within 48 hours of date of the ED visit and updated to include ICD-10-CM diagnosis codes within a few weeks, if available. CDC is prioritizing the sharing of data through the NSSP BioSense platform due to the speed at which it currently collects ED data, its high rate of ED participation (>6,000 EDs participating), and its ability to leverage existing CDC efforts (See *Efforts to Identify Duplication and Use of Similar Information* section).
- 2. *State or Territorial ED Syndromic Surveillance:* Participating health departments may operate their own local ED syndromic system that is not associated with NSSP BioSense.

These local ED syndromic systems often collect data very similar to NSSP BioSense such as patient chief complaint and ICD-10-CM diagnostic codes.

3. Hospital ED Discharge Data: Some health departments have no or limited syndromic surveillance of ED visits. These health departments, however, may be able to leverage hospital discharge data on ED visits that is routinely collected by most states. Hospital discharge data are collected for billing purposes, uses standardized ICD-10-CM coding, and most states use Uniform Billing Version 04 (UB-04) administrative claims data to collect ICD-10-CM diagnosis and procedure codes. Although these data have a two year time lag nationally, CDC has found that some states have access to preliminary hospital discharge data that meet the requirements of DOSE.

Key advantages to DOSE compared to initiating a new ED data collection are:

- 1. DOSE can be rapidly implemented and scaled to all 50 states and the District of Columbia with minimum burden on state health departments because it relies on sharing and improving ED data already being collected by state and local health departments.
- 2. DOSE ensures local health departments ED syndromic efforts are integrated into national surveillance instead of duplicated.
- 3. DOSE leverages instead of duplicating existing CDC work through CDC NSSP and ESOOS to rapidly share state and local health departments ED data with CDC.
- 4. DOSE ensures that local health departments are involved in the collection, ownership and use of the ED data collected. This is critical because state and local health departments are primarily responsible for responding to local drug overdose outbreaks and changes in the opioid overdose epidemic, have extensive local knowledge of their local ED data that fosters identification of data quality problems including identifying false positives, and are critical partners in developing tools to monitor illnesses and injury.^{19, 20}

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 (Att. A1). Also, Subtitle Q in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) specifically grants authority to CDC for overdose data and collection activities including, "Improving the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances," "Enhancing the comprehensiveness of controlled substance overdose data by collecting information on such overdoses from appropriate sources such as...emergency departments," and "Working to enable and encourage the access, exchange, and use of information regarding controlled substance overdoses among data sources and entities" (Att. A2).

2. Purpose and Use of Information Collection

All data sharing between CDC and health departments in DOSE is driven by two standardized data forms, the *Rapid ED overdose data form* and the *ED discharge overdose data form*, and CDC cases definitions of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses. The justification of the two forms and the key variables they collects is described in detail below.

Form 1: Rapid ED overdose data forms (Att D)

Health departments able to share syndromic surveillance data with CDC will be required to complete the *Rapid ED overdose data form* (Att. D) on a monthly basis using data from existing local ED data collection efforts, described above.

- 1. **Frequency that this data form is reported to CDC.** The goal of the program is to have health departments submit monthly reports to CDC in order to detect and respond to drug overdose outbreaks or shifts in trends in a timely manner.
- 2. **Key variables shared with CDC**. Key variables why they are collected is described in Table below.

Variable	Justification for collecting
Count of ED	Detect emerging drug overdose problems that would not be detected by variables
visits suspected	tracking specific drug classes such as opioids. For instance, overdose outbreaks
to involve drug	involving fentanyl analogs ^{21,22} or synthetic cannabinoids ²³ may not be identified in
overdoses	the ED and be classified as drug overdoses involving unknown drugs.
	Some local ED electronic data systems use drop down selections for entering
	patient's chief complaint. This results in many ED visits involving overdoses being
	generically classified as "drug overdoses".
Count of ED	More than 2 out of 3 drug overdose deaths involves an opioid and recent severe
visits suspected	drug overdose outbreaks involve opioids.
to involve	Collection of ED data on opioid overdoses was found to be feasible and useful in
opioid	pilot studies, response to outbreaks, ²⁴ and work in ESOOS. ^{25,26}
overdoses	The general category of "opioids" will be tracked instead of specific types of
	opioids (e.g., oxycodone or fentanyl) because EDs may not test for specific types
	of opioids, ED chief complaint text often only list "opioid overdose", and patient's
	may not know the specific opioid that they took due to purchasing counterfeit
	prescription drugs or using adulterated illicit drug products. ^{27, 28}
Count of ED	• The sharp increases in heroin overdoses since 2010 coupled with the adulteration
visits suspected	of heroin with fentanyl highlight the need to track heroin overdoses. ^{29,30}
to involve	While other types of opioids proved difficult to track using ED data, work in
heroin	ESOOS consistently found it was feasible to track heroin overdoses. Heroin
	overdoses can be identified due to physicians or first responders ability to detect
	evidence of injection drug use (e.g., new track marks or drug paraphernalia found
	by EMS responders) and/or witness accounts provided to EMS responders.
Count of ED	• Recent increases in stimulant overdoses such as cocaine and methamphetamine
visits suspected	and co-use with opioids ^{31,32} have highlighted the need to implement surveillance of
to involve	stimulant overdoses.
stimulants	ESOOS has shown the feasibility of tracking stimulant overdoses and a CDC Continue to a society of the continue to t
Count of ED	definition is currently available in NSSP BioSense for health departments to use.
Count of ED	Due to the rapidly evolving nature of the opioid overdose epidemic and supposition as yearly CDC anticipates the proof to greate at least three party eventors.
visits suspected to involve other	surveillance work, CDC anticipates the need to create at least three new overdose
new and	indicators that capture overdoses that involve specific drugs not currently tracked
emerging drugs	(e.g., benzodiazepines) or only tracked by drug class (e.g., cocaine is part of the stimulant indicators). The current list includes: fentanyl, cocaine,
emerging drugs	methamphetamine, and benzodiazepines.
Sex, age group,	Aggregating data on drug, opioid, heroin, and stimulant overdose by sex, age group,
race/ethnicity,	race/ethnicity, and county is critical to assist CDC as well as state and local health
and county	departments target interventions on demographic groups and geographic areas

Variable	Justification for collecting
level data by	impacted by drug overdoses outbreaks or large changes.
drug overdose	
indicators	
Percent of ED	ED visits involving drug overdose are primarily identified by analyzing patient's chief
visits with	complaint and diagnosis codes fields, primarily ICD-10-CM diagnosis codes. Thus,
chief complaint	important data quality indicators are the percent of ED visits with chief complaint data
text and	and the percent of ED visits with diagnosis codes.
diagnosis codes Median word	The median word length of the chief complaint is tracked because the ability to
length of the	identify suspected drug overdoses is impacted by the length and quality of text data
chief complaint	entered into the chief complaint text field. Based on previous experience working with
ciner complaine	health departments, chief complaints with fewer words are less likely to contain
	information on the a) the type of drug involved (e.g., opioids) and b) overdose
	symptoms (e.g., trouble breathing).
Mean and	The mean and maximum of diagnosis codes, primarily ICD-10-CM diagnosis codes,
maximum	collected by jurisdiction s varies (e.g., one jurisdiction may allow hospitals to enter 10
number of	codes while another allows 16 codes). Since CDC drug overdose case definitions
diagnosis codes	search all diagnosis codes, tracking the number of submitted diagnosis codes is
	important because they may result in slight differences between jurisdiction ability to
	identify suspected drug overdose cases (e.g., jurisdictions collected more ICD-10-CM codes might be slightly more likely to identify an ED visit as involving a drug
	overdose).
Metadata on	Local ED data systems may experience major changes that impact data quality (e.g.,
local	ED data sharing delayed due to the implementation of a new EHR system). In order to
surveillance	effectively identify and address these types of changes, DOSE will ask all participating
systems	health departments to report major changes in ED participation or data quality each
	month.

3. **Use of the data form by CDC**. CDC will use this data form to detect outbreaks and rapid changes in drug, opioid, heroin, and stimulant outbreaks to inform response.

Form 2: ED discharge overdose data form (Att E)

Health departments able to share discharge data with CDC will be required to complete the *ED* discharge overdose data form (Att. E) on a quarterly or yearly basis. The *ED* discharge overdose data form is similar to the *Rapid ED* overdose data form and thus the description in this section focuses on its unique characteristics.

1. **Frequency that this data form is reported to CDC.** The goal of the program is to have health departments submit quarterly reports to CDC because this will allow a timely analysis of the burden of drug overdoses in the jurisdiction as well as timely analysis of the quality and accuracy of the rapid ED data collection in the jurisdiction. Through previous CDC collaborative work with state health departments, CDC found that a substantial percent of health departments are not involved in the collection of their local hospital discharge data and thus receive the data with large time lags of a year or more. Consequently, about half or 23 participating health departments are expected to only submit hospital discharge data yearly.

- 2. **Key variables shared with CDC**. The variables included in the *ED discharge overdose data form* are almost identical to the variables included in the *Rapid ED overdose data form*, discussed above. The few differences are:
 - a. Not systematically tracking major changes in hospital participation. Because the hospital discharge data collection is well established in many states and reported quarterly or yearly to CDC instead of monthly, major reporting disruptions are not expected to occur frequently. Thus, metadata about major changes in the hospital discharge data is not collected to reduce burden on participating health departments. The number of submitting hospitals, however, is still collected each quarter in order to detect possible changes requiring follow-up from CDC staff.
 - b. Distinguishing ED visits involving unintentional and undetermined-intent drug overdoses from ED visits involving drug overdoses related to intentional self-harm. The ICD-10-CM diagnosis coding system tracks the medically documented intent of the person treated for a drug overdose in the ED (e.g., overdosed as part of a suicide attempt or accidentally overdosed while taking a drug for the euphoric feeling it produces). Since interventions to reduce intentional overdoses related to self-harm may differ from those related to substance abuse, the participating health departments will be asked to aggregate their data by intent (i.e., unintentional versus self-harm).
- 3. **CDC use of the data form.** This form will be used in two ways:
 - a. Hospital discharge data is the current standard for tracking drug overdose burden associated with ED visits and hospitalizations. Consequently, comparing trends in ED visits involving suspected drug, opioid, heroin, and stimulant overdoses calculated using hospital discharge data with trends calculated using rapid preliminary ED data will help identify strengths and weaknesses in the rapid preliminary ED data sharing effort. This in turn will inform system improvements. Even if the hospital discharge data has a time lag of a year or more instead of quarterly, these comparisons will still be useful in accessing and improving the general quality of the rapid preliminary ED data reported to CDC.
 - b. Current delays in reporting ED data and hospitalization data on drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses from hospital discharge files is approximately two years. This inhibits response and assessment of the overall burden of drug overdose. The current data sharing effort is a now a four-year pilot, with this extension request, to access whether the analysis and dissemination of ED and hospitalization burden data on drug overdoses can be accelerated through targeted data sharing.

To date, the DOSE system has been extremely successful at meetings its stated objectives. Currently, DOSE operates in the 47 states and the District of Columbia currently funded by OD2A (three states did not request CDC funding in the current cycle but may for the next funding cycle in 2023). Of these 48 health departments, 43 share syndromic data with CDC monthly and 26 share at least quarterly discharge data. A total of 33 health departments provide CDC access to their syndromic surveillance data from emergency departments in CDC's NSSP system. Please see **Figure 1** below for a graphic depiction of current state data sharing. **Figure 2** depicts the requested state data sharing for DOSE going forward, which includes 50 states and the District of Columbia with 45 health departments sharing syndromic (35 sharing in NSSP) and

28 sharing discharge. Access to this timely data has allowed us to improve situational awareness of federal, state, and local health departments of emerging drug overdose outbreaks and the progression of the opioid overdose epidemic. Health departments have used this data to populate state data dashboards and develop alerts for local communities. In addition, health departments have used this data in concert with public safety partners to gain a better overall picture of outbreaks in their communities.

Figure 1: Current state data sharing for DOSE

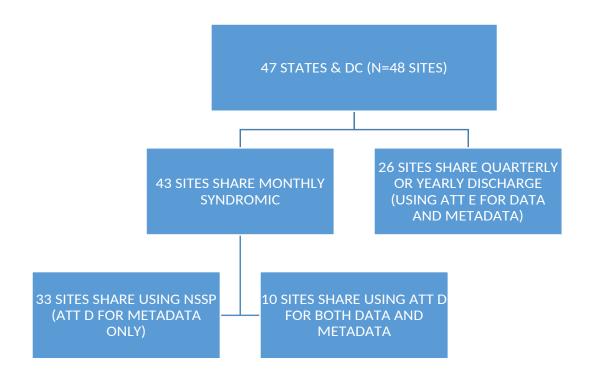
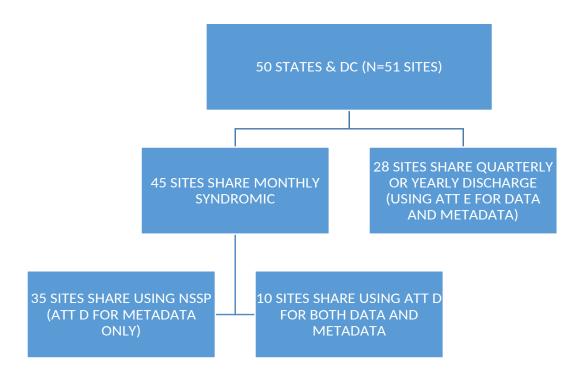


Figure 2: Requested and expected state data sharing for DOSE in 2023



Data from the DOSE system has also raised public awareness of the progression of the opioid overdose epidemic and other emerging drug overdose threats in their area. As recently as February 2021, we have updated two areas of CDC's website using data from DOSE (https://www.cdc.gov/drugoverdose/data/nonfatal/drugs-overall.html; https://www.cdc.gov/drugoverdose/data/nonfatal/states/covid-19.html). Notabily, following the onset of the COVID-19 pandemic, state and local health department reliance on timely syndromic surveillance data to detect trends in all types of injuries and diseases has increased. To provide the public information on drug overdoses treated in emergency departments during the onset of the pandemic, CDC quickly developed a new website showcasing the DOSE data (https://www.cdc.gov/drugoverdose/data/nonfatal/states/covid-19.html). This has allowed states to see the changes in drug overdoses from 2019 through September 2021. In addition, CDC staff have used DOSE data to report on drug overdoses involving more than one substance (https://www.cdc.gov/mmwr/volumes/69/wr/mm6934a1.htm) and overdoses involving benzodiazepines (https://www.cdc.gov/mmwr/volumes/70/wr/mm7034a2.htm).

DOSE data has also been used in in 10 peer-reviewed and MMWR publications (see below a list) and was featured in a special supplement in *Public Health Reports* (https://journals.sagepub.com/toc/phr/136/1_suppl).

- 1. Pickens, C. M., Scholl, L., Liu, S., Smith, H., & Snodgrass, S. (2021). Development and Validation of a Syndrome Definition for Suspected Nonfatal Unintentional/Undetermined Intent Stimulant-Involved Overdoses. *Public Health Reports*, 00333549211054489.
- 2. Liu S, O'Donnell J, Gladden RM, McGlone L, Chowdhury F. Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines 38 States and the District of Columbia,

- 2019–2020. MMWR Morb Mortal Wkly Rep 2021;70:1136–1141. DOI: http://dx.doi.org/10.15585/mmwr.mm7034a2
- 3. Vivolo-Kantor, A. M., Smith IV, H., & Scholl, L. (2021). Differences and similarities between emergency department syndromic surveillance and hospital discharge data for nonfatal drug overdose. Annals of Epidemiology. doi: 10.1016/j.annepidem.2021.05.008
- 4. Vivolo-Kantor, A., Pasalic, E., Liu, S., Martinez, P. D., & Gladden, R. M. (2021). Defining indicators for drug overdose emergency department visits and hospitalisations in ICD-10-CM coded discharge data. Injury prevention, 27(Suppl 1), i56-i61. doi: 10.1136/injuryprev-2019-043521
- 5. Scholl, L., Liu, S., Vivolo-Kantor, A., Board, A., Stein, Z., Roehler, D. R., ... & Smith, H. (2021). Development and Validation of a Syndrome Definition to Identify Suspected Nonfatal Heroin-Involved Overdoses Treated in Emergency Departments. Journal of Public Health Management and Practice, 27(4), 369-378. doi: 10.1097/PHH.00000000000001271
- 6. Liu, S., & Vivolo-Kantor, A. (2020). A latent class analysis of drug and substance use patterns among patients treated in emergency departments for suspected drug overdose. Addictive behaviors, 101, 106142. doi: 10.1016/j.addbeh.2019.106142
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In addition to reporting out on drug overdoses, CDC DOSE staff have provided extensive technical assistance to health departments participating in DOSE. Our goal was to build a system that captured at least 75% of all non-federal ED visits. At present (January 2022), the DOSE system captures, on average, 85% of ED visits in 47 states and the District of Columbia. We will continue to build state and local health department capacity to both increase and maintain high facility coverage to better track drug overdose trends and outbreaks in their community.

3. Use of Improved Information Technology and Burden Reduction

DOSE is leveraging improved information technology to reduce burden on participating health departments in the following ways:

1. Data from over 6,000 hospitals and around 71% of ED visits in the US is currently shared with CDC through the NSSP BioSense platform. Just two years ago NSSP included a little over 4,000 hospitals with around 60% coverage. DOSE efforts have significantly

helped health departments onboard facilities to increase coverage. Since 2016, the primary computer program used to process and analyze this data is the Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE). DOSE expects that 35 health departments (33 state health departments and District of Columbia) will provide CDC access to their ED data within the NSSP BioSense platform using ESSENCE. At present, as of January 2022, 33 health departments (32 state health departments and the District of Columbia) provide CDC access to their data in NSSP and will continue to do so. On at least a monthly basis, CDC DOSE staff will use its access to complete the *Rapid ED overdose data form*. Participating health departments will only be asked to verify the accuracy of the CDC generated reports and support CDC complete the *Rapid ED overdose data form* metadata. CDC production of the reports greatly reduces burden on participating health departments. Two other advantages of sharing case-level ED data through this platform are:

- a. NSSP BioSense is constantly improving their data sharing platform and analysis tools such as ESSENCE. This data collection effort will continue to leverage these improvements as they are implemented by CDC.
- b. CDC DOSE staff are closely collaborating with the CDC NSSP BioSense team to better automate analysis of suspected drug, opioid, heroin and stimulant overdoses. This includes creating tools to help CDC as well as state and local health departments identify and respond to data quality issues. Additionally, local and state health departments will be able to apply the standardized DOSE definitions of suspected drug, opioid, heroin and stimulant overdoses to identify trends in their local ED data in near-real time.
- 2. For the health departments able to share syndromic data (N=43), 10 are not expected to share case-level ED data with CDC through NSSP BioSense. To assist these states:
 - a. DOSE has developed SAS, R, and ESSENCE programming code (Note: some health departments use a local version of ESSENCE that is not part of CDC NSSP) that automatically identifies ED visits involving drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses and formats the data in a manner consistent with the *Rapid ED overdose data form*. This will substantially reduce the burden on participating health departments of completing the *Rapid ED overdose data form*.
 - b. DOSE will require that the health departments share ED data using the *Rapid ED* overdose data form and standard CDC case definitions. The *Rapid ED* overdose data form is an Excel template, which reduces burden on participating health departments in the following ways:
 - Enables health departments to create computer programs and standard operating procedures for sharing the data with CDC using CDC's standard format. State health departments have requested CDC design and adhere to standard data sharing protocols.
 - ii. Excel is widely used and most likely will not require staff from participating health departments to acquire new training,
 - iii. Many statistical programs can export data into Excel,
 - iv. Manual data entry is user friendly, and

- v. CDC staff can build multiple automated data quality checks into the Excel data sheet that capture data errors early and prevent the need and burden on participating health departments of submitting revised reports to CDC.
- 3. All funded state health departments will be asked to share hospital discharge data with CDC quarterly (N=28 expected) or yearly (N=23 expected) using the *ED discharge overdose data form* and standard CDC case definitions. Similar to the Rapid ED overdose data form, the ED discharge overdose data form is an Excel template, which reduces burden on participating health departments in multiple ways discussed above.
- 4. Participating health departments will share the *Rapid ED overdose data form* and *ED discharge overdose data form* with CDC using a National Center for Injury Prevention and Control (NCIPC) interface hosted on the CDC Secure Access Management Service (SAMS) Partner's Portal, referred to as the NCIPC Partner's Portal. Two advantages of the NCIPC Partner's Portal are:
 - a. The NCIPC Partner's Portal will improve data quality and reduce burden on participating health departments by automatically identifying data submission errors by participating health departments. Real-time identification of data submission errors enables rapid fixes and reduces the chance participating health departments will need to make multiple data submissions to CDC.
 - b. The NCIPC Partner's Portal is a website designed to provide centralized access to external users (e.g., state and local health departments) to data and computer applications operated by CDC.³⁴ The NCIPC Partner's Portal leverages the CDC SAMS Partner's Portal because CDC SAMS is an established secure method for sharing data that is widely used by state and local health departments. Thus, the time required to gain access to and use of the portal will be minimal.

4. Efforts to Identify Duplication and Use of Similar Information

DOSE maximizes the use of federal government data by leveraging ED data already collected by the NSSP BioSense platform (mentioned previously on *A1. Circumstances Making the Collection of Information Necessary*) and communicating on an ongoing basis with other federal collections of ED data. CDC's Division of Overdose Prevention (DOP) is engaged in an intensive collaboration with the Division of Health Informatics (DHIS), the CDC division that operates NSSP BioSense. The collaboration enhances rapid surveillance of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses by leveraging the approximately 71% of ED facilities in the US that are shared by local health departments or their partners with CDC through the NSSP BioSense Platform.

CDC prefers that participating health departments share ED data with CDC through the NSSP BioSense platform. The NSSP BioSense platform is the preferred mechanism because it minimizes burden on participating health departments by allowing CDC to complete the *Rapid ED overdose data form* while maximizing data quality by enabling collaborative analyses between CDC and health departments. In CDC's Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904), DOP strongly encouraged all eligible health departments to share ED data with CDC through NSSP BioSense and funded those who agree at higher levels than health departments sharing ED data from other sources (e.g., local ED

syndromic systems or hospital discharge).

DOP took a number of actions to identify and contact other federal programs collecting ED data to ensure coordination and avoid duplication. Through previous conversations with OMB, NCHS, SAMHSA, and CDC's Opioid Response Coordinating Unit (ORCU), five federal government data systems in addition to NSSP BioSense were identified as potentially overlapping with the current data collection. Below, a brief description of each data system is provided as well as why DOSE is not duplicative with the data collection.

ED data	Description	Time lag	Purpose of ED	A	dditional Value		Recent
system	•	J	system		of DOSE		contact
Health Care Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS) ³⁵ administered by the Agency of Healthcare Research and Quality (AHRQ) OMB #: 0935- 0206	37 states contribute data to NEDS. In 2016, the database contains a sample of around 33 million ED visits that can be used to make national estimates of ED visits involving specific illnesses and injury. Key data include ICD-10-CM diagnosis and procedure codes as well as medical charge and patient demographics.	~ 2 years	NEDS data are used to estimate the national burden of ED visits related to drug overdoses.	•	DOSE includes state-level and county-level data that can be used to identify local outbreaks and provide local communities situational awareness of the progress of the epidemic in their communities. DOSE data will be rapidly available (within one month of ED visit) and thus can inform more rapid response to changes in local and regional drug overdose patterns.	•	DOP regularly analyzes HCUP data through the CDC data hub ³⁶ as part of our efforts to understand the opioid overdose epidemic Review of HCUP materials
Health Care Utilization Project (HCUP) State Emergency Department Databases (SEDD) ³⁷ administered by the Agency of Healthcare Research and Quality (AHRQ) OMB #: 0935- 0206	SEDD includes all ED visits that did not result in a hospitalization from about 37 states. Data and access conditions vary across state. As of May 1, 2019, 22 states provided access to 2016 data and 11 states provided access to 2017 data.	~ 2-3 years	SEDD data are used to estimate the burden of ED visits related to drug overdoses by state. Only a subset of states provide public access to their data.	•	DOSE data will be rapidly available (within one month of ED visit) and thus can inform more rapid response to changes in local and regional drug overdose patterns. DOSE will provide more timely and comprehensive regional and national situational awareness of drug overdose trends as more states will publicly report drug overdose trends.	•	DOP regularly analyzes HCUP data through the CDC data hub ³⁸ as part of our efforts to understand the opioid overdose epidemic Review of HCUP materials
The Drug Abuse Warning Network (DAWN) operated by SAMHSA ³⁹	In fall 2018, SAMHSA restarted the DAWN surveillance system after a 7 year period of inactivity. Trained abstractors employed by the	Reporting frequency is still be determined, but likely will be monthly to quarterly.	The new DAWN is bringing in hospitals in three categories: 1) hospitals purposively selected from areas with high drug overdose burden; 2) hospitals	•	DOSE will provide timely local and regional situational awareness because it will monitor at least 75% of ED visits across all 50 states and the	•	Multiple phone conversations were held between summer 2018 and winter 2019 with original

ED data	Description	Time lag	Purpose of ED	Additional Value	Recent
system			system	of DOSE	contact
OMB # 0930- 0078	DAWN data contractor will mine existing hospital electronic health record (EHR) systems. DAWN began data abstraction in mid-2019 with a 25 hospitals, and grew to a total of 49 hospitals at the end of 2020. The new DAWN will be an early warning system that detects increases in drugrelated ED visits, or outbreaks, and characterizes the outbreak using unique information such as specific drug or drug brand, manually abstracted from direct chart review. DAWN will also detect the emergence of new psychoactive substances and identify all ED visits that are related to drugs such as adverse events or injuries caused by drug use as well as drug overdoses.		sampled from suburban and rural areas with high levels of fatal drug overdoses; and 3) hospitals sampled from areas stratified by region, fatal drug overdose rates and counts. This design provides a framework suitable for sentinel surveillance and for national estimation, should the system expand.	District of Columbia, or over 6,000 hospitals. DOSE will include data from all communities, regardless of overdose burden.	DAWN program staff. Frequent email conversation continued through 2020 with key SAMSHA, DAWN staff. Current staff transitions and COVID-19 have decreased the amount of contact between CDC staff and DAWN staff. Next meeting is scheduled in 2022. Key contact person: Sean Lynch, Division of Surveillance and Data Collection, CBHSQ, SAMHSA.
National Electronic Injury Surveillance System Cooperative Adverse Drug Event Surveillance (NEISS- CADES) project conducted by CDC in collaboration with FDA and Consumer Product Safety Commission. 40 OMB #: 3041-	NEISS-CADES collects nationally representative data from a sample of under 100 hospitals and uses data abstractors to collect in-depth information on ED visits on adverse events related to prescription drug use including overdose. In 2017, NEISS-CADES began collecting ED visits involving prescription opioid overdoses as well as ED visits involving adverse events. NEISS-CADES has	~1 to 2 years	NEISS-CADES data are used to estimate the national burden of ED visits related to drug overdoses and adverse events. The system cannot make regional or state estimates and does not collect information on opioid overdoses related to illicit opioids such as heroin or illicitly- made fentanyl or allow for state estimates.	DOSE works to provide timely local and regional situational awareness of the epidemic, especially outbreaks, in a timely manner. DOSE will capture information on opioid overdoses related to illicit opioids such as heroin or illicitlymade fentanyl	Ongoing discussions because DUIP contributes and collaborates on the data collection. Key Contact Person: Dan Budnitz, Division of Healthcare Quality Promotion, NCEZID, CDC

ED data pescription system abstractors manually review targeted ED visits Time lag Purpose of ED system of DC	OSE contact
abstractors manually review targeted ED visits	0000000
Emergency Department Survey (SEDS) acute care hospitals. leverages data from the Helth Statistics representative, National National Hospital Care Survey (NHCS). 41 Continues to become National hospitals' receives data from the National Main acute and procedural codes from the UB-04 administrative claims data to identify and describe drug-	situational ss because onitor at % of ED ross all 50 dd the of ia, or over ospitals. ata will be available one month isit) and inform oid response ges in drug e patterns. athers data ance systems g local epartments C are using e data to otbreaks and Chis is a element of nic in the summer and fall of 2018. • Discussion of standard case definition development in the winter of 2019. • Consistent email discussions between CDC staff and NCHS staff including Amy Brown. • Key Contact Person: Carol DeFrancis, Ambulatory and Hospital Care Statistics Branch, NCHS

As DOSE is implemented, DOP will continue to communicate with other federal ED data collections to avoid duplication and identify opportunities for collaboration. Possible opportunities for collaboration include:

- Comparisons of DOSE findings with SEDSS, HCUP or DAWN findings in similar geographic areas or hospitals could help inform revisions and improvements in DOSE's syndromic definitions of ED visits involving drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses.
- If a DAWN hospital reports an outbreak or is located in an area identified by DOSE as experiencing a drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug outbreaks, DAWN data could provide critical in-depth information on specific drugs involved and clinical symptoms of a drug overdose to inform the response. This in-depth data is a unique strength of the DAWN system.

5. Impact on Small Businesses or Other Small Entities

This study does not impact small businesses or other small entities. It impacts state health departments and the District of Columbia whose ED records will be shared with CDC.

6. Consequences of Collecting the Information Less Frequently

If DOSE collects data less frequently, the following adverse consequences will occur:

- Federal and state governmental situational awareness of emerging drug overdose outbreaks and the progression of the opioid overdose epidemic, currently a national public health emergency, will be substantially slowed. This will erode the ability of federal and state health departments to rapidly respond to drug overdose outbreaks. Rapid situational awareness is especially critical now as overdoses related to fentanyl and heroin have sharply increased and been accompanied by multiple local and state reports of severe and often widespread opioid overdose outbreaks since 2013. 44,45,46,47,48 Also, the nature and complexity of drug overdoses continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl, cocaine products laced with fentanyl, increasing overdoses involving synthetic cannabinoids and large increases in overdose deaths involving methamphetamines and cocaine. Without monthly national data sharing between participating health departments and CDC through DOSE, intervention efforts will continue to fall far behind changes in the drug market and usage patterns driving drug overdoses.
- Public situational awareness of emerging drug overdose outbreaks and the progression of the opioid overdose epidemic will be substantially slowed. This may slow intervention efforts by non-governmental organizations and citizens. Currently, limited timely local and state data are available on nonfatal and fatal drug overdoses. The National Center of Health Statistics publishes preliminary drug overdose death data from death certificates with a 7-month delay.⁵³ These data, however, are only available at the state level, reports a 12-month rolling average which will be slow to detect change, and does not provide any information by demographic groups. National and state hospital discharge data on drug overdose ED visits is available from the Health Care Utilization Project with a two to three year delay and not available for all states.⁵⁴
- Local health department surveillance and response to suspected, drug, opioid, heroin and stimulant overdoses would be diminished. First, there would be a longer time lag in local health departments learning about large multi-state outbreaks that threaten to affect their jurisdiction. Second, DOSE reporting is accompanied by data quality efforts. Reducing the frequency of these data quality efforts would likely lead to less timely and effective identification of data quality problems that could diminish the ability of a local health department to accurately detect overdose outbreaks.

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

This data collection will require monthly reporting of aggregate ED data on suspected drug,

opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses using the *Rapid ED overdose data form*. This is more rapid than quarterly data sharing recommended by OMB. Monthly sharing of ED data is critical to fulfill the mission of DOSE, which is timely response to drug overdose outbreaks and emerging changes in drug overdoses. Data collected less frequently will slow response and consequently may increase harm caused by drug overdose outbreaks.

Rapid situational awareness is especially critical now as overdoses related to fentanyl and heroin have sharply increased and been accompanied by multiple local and state reports of severe and often widespread opioid overdose outbreaks since 2013. 55,56,57,58,59 Also, the nature and complexity of the drug overdoses continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl, 60 cocaine products laced with fentanyl, 61 increasing overdoses involving synthetic cannabinoids 62 and large increases in overdose deaths involving methamphetamines and cocaine. 63 Without monthly national data sharing between participating health departments and CDC through DOSE, intervention efforts will continue to fall far behind changes in the drug market driving drug overdoses.

DOSE works to mitigate the burden of monthly reporting on participating health departments by:

- 1. Providing funding to participating health departments to offset burden related to completing required data sharing forms, the *Rapid ED overdose data form* and *ED discharge overdose data form*, on a monthly basis and quarterly basis, respectively,
- 2. Providing substantial technical assistance to participating health departments in completing reports. This includes:
 - a. CDC staff completing the *Rapid ED overdose data form* each month for the estimated 35 health departments sharing case-level ED with CDC through NSSP BioSense.
 - b. For participating health departments not sharing through NSSP BioSense, CDC is developing SAS, R and ESSENCE programming code (Note: some health departments use a local version of ESSENCE that is not part of CDC NSSP) that will allow the participating health department to identify suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses in their ED data and aggregate the data in a format consistent with the *Rapid ED overdose data form*. This will substantially reduce the burden of completing the form.

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 26, 2021, vol. 86, No. 78, pp. 22052-3 (Att. B). For this notice CDC received and responded to four comments. All comments supported the collection, some proposed to include a mental health component to the collection and others proposed ways to mitigate unreported cases in rural areas. This proposed collection is one aspect of a larger investment made by HHS and CDC called Overdose Data to Action (OD2A). OD2A focuses on understanding and tracking the complex and changing nature of the drug

overdose epidemic and highlights the need for seamless integration of data into prevention strategies, therefore no changes were made to the data collection instruments based on these comments (Att. B1).

B. Efforts to Consult Outside the Agency

DOP, NCIPC is currently receiving feedback from state public health departments and the District of Columbia on improving rapid ED surveillance of suspected drug overdoses who are participating in DOSE. Secondly, intensive consultation with Ohio, ⁶⁴ Massachusetts, and Rhode Island ⁶⁵ during three Epi-Aid responses to drug overdoses outbreaks coupled with technical assistance to other states responding to increases in drug overdoses highlight key opportunities and challenges of using ED data for rapid surveillance of overdoses.

DOP, NCIPC also consulted with NCHS, CDC; SAMHSA; NCEZID, CDC; and ORCU, CDC to learn from and avoid duplication with other federal government efforts to collect data on ED visits involving drugs (mentioned previously on *A4.Efforts to Identify Duplication and Use of Similar Information*)

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. (Att. F).

Four main strategies will be implemented to maintain the confidentiality of the data.

- 1. State health departments and the District of Columbia (the respondents), will only share with CDC aggregate data collected on two standardized forms: the *Rapid ED overdose data form* and the *ED discharge overdose data form*. Although CDC will have access to case-level ED data through NSSP BioSense for 35 health departments in order to automate completion of the *Rapid ED overdose data form*, CDC will only report on aggregate ED data entered into the *Rapid ED overdose data form*. Case-level ED data will only be used by CDC to assist public health departments complete the *Rapid ED overdose data form* on a monthly basis and assist health departments and CDC improve data quality and overdose identification.
- 2. Participating health departments will submit the *Rapid ED overdose data form* and the *ED discharge overdose data form* to CDC using the NCIPC Partner's Portal hosted on the CDC Secure Access Management Service (SAMS) site. The CDC SAMS Partner's Portal is a web site designed to provide secure centralized access to external users such as public health departments to data and computer applications operated by CDC. It can also be used to securely exchange data between CDC and participating health departments.⁶⁶
- 3. Only selected staff working in the DOSE program will have access to aggregate data entered into the *Rapid ED overdose data form* and the *ED discharge overdose data form*

- by participating health departments. Also, Excel files as well as analytical statistical files will be stored and managed on secure CDC servers.
- 4. DOSE will follow NCHS guidelines on suppression of small sample sizes in data tabulations (e.g., not report any information that involves between 1 and 9 people) to prevent the inadvertent identification of an individual through the combination of various demographic characteristics.

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

The CDC National Center for Injury Prevention and Control's OMB and human subject's liaison has determined that the activity is not research and IRB approval is not needed. This data collection is a surveillance effort and human subjects will not be involved (Att. C).

12. A. Estimates of Annualized Burden Hours and Costs

This data collection includes two data forms:

- Rapid ED overdose data form (Att D) supports rapid monthly ED surveillance of suspected drug, opioid, heroin and stimulant overdoses to detect outbreaks and provide situational awareness (Att. D). The Rapid ED overdose data form asks jurisdictions to use existing local ED data to calculate the total number of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdose that occurred each month by county and by age, sex, and race/ethnicity. Also, jurisdictions will be asked to provide metadata including coverage of the local ED surveillance system (i.e., percentage of all ED visits captured by the jurisdiction's ED surveillance) and recent major changes in the local ED data collection efforts (e.g., large number of hospitals begin or terminate participation). The burden of completing the Rapid ED overdose data form will vary across two groups: 1) health departments sharing case-level ED data with CDC through the NSSP BioSense Platform (OMB #0920-0824) and thus completing the Rapid ED overdose data form with substantial CDC assistance and 2) health departments not sharing data through NSSP BioSense Platform and completing the Rapid ED overdose data form with minimal CDC assistance. The burden for these two groups is described below.
 - O *Health departments sharing data with CDC through NSSP BioSense:* CDC expects at least 35 of the funded health departments to provide CDC access to case-level ED data through the NSSP BioSense Platform (OMB #0920-0824). Using the case-level data, CDC will complete the vast majority of the *Rapid ED overdose data form* including calculating the total number of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses that occurred each month by county and by age, sex, and race/ethnicity. CDC, however, will consult with the jurisdiction when completing metadata and this will result in a small burden. Based on CDC collaborative work with health departments using the NSSP BioSense Platform, the burden will be .5 hours per monthly report per jurisdiction. Thus, the annual burden per health department will be 6 hours (.5 hours x 12 months) or a total of 210 burden hours across the 35 responding health departments.

- O Health departments sharing local syndromic ED data or hospital discharge data: CDC expects about 10 of the funded health departments (i.e., the health departments not providing CDC NSSP BioSense access) to complete the Rapid ED overdose data form using local ED syndromic or hospital discharge ED data. Based on optional CDC collaborative work with health departments on completing similar forms and the fact the health department will be completing the form instead of CDC, the burden will be 3 hours per report by a health department. Because CDC has created SAS programs that automatically identifies ED visits involving all of these drug categories we do not anticipate any burden increase when adding new drug overdose categories. The form will be completed monthly for an annual burden per health department of 36 hours (3 hours x 12 months) or a total of 360 annual burden hours across all 10 responding health departments.
- ED discharge overdose data form (Att E) supports quarterly or yearly hospital discharge surveillance of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses to evaluate rapid ED surveillance and assess drug overdose burden (Att. E). The preliminary ED data captured by the *Rapid ED* overdose data form needs to be compared and validated against hospital discharge data that uses ICD-10-CM codes, currently the standard for tracking ED visits. All participating health departments will be asked to complete the ED discharge overdose data form using ED discharge data already routinely collected in their jurisdiction. Specifically, participating health departments will calculate and report the total number of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses by county and by age, sex, and race/ethnicity and provide metadata such as coverage of the ED hospital discharge surveillance system (i.e., percentage of all ED visits captured by the jurisdiction's ED surveillance). Because CDC has created SAS programs that automatically identifies ED visits involving all of these drug categories we do not anticipate any burden increase when adding new drug overdose categories. Due to variations in the collection of local ED hospital discharge data across jurisdictions, CDC expects up to 28 health departments to submit data at least quarterly and at least 23 health departments to submit data yearly. The burden associated with each of these groups is described below.
 - O CDC estimates that up to 28 jurisdictions will submit data to CDC quarterly. Based on optional experiences of jurisdictions completing similar templates, the *ED discharge overdose data form* will take a jurisdiction 3 hours to complete and will be completed quarterly (i.e., every 3 months), for an annual burden per jurisdiction of 12 hours (3 hours x 4 submissions every year) or a total of 336 annual burden hours across 28 jurisdictions.
 - The remaining 23 jurisdictions are expected to only have the capacity to share hospital discharge data yearly. Based on optional experiences of health departments completing similar templates, the *ED discharge overdose data form* will take a jurisdiction 3 hours to complete and will be completed yearly, for an annual burden per jurisdiction of 3 hours (3 hours x 1 submissions every year) or a total of 69 annual burden hours across 23 jurisdictions.

This breakdown is also visually depicted below in **Figure 2.**

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Figure 2: Requested and expected state data sharing for DOSE in 2023

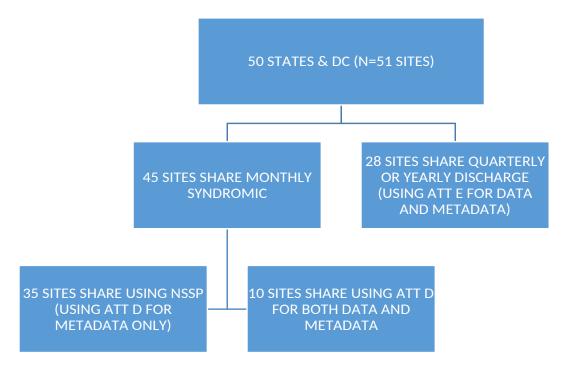


Table 1. Estimates of annualized respondent burden hours

Type of respondent	Form name	No. of respondents	Total no. of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
Participating health departments sharing aggregate data from local syndromic or hospital discharge file	Rapid ED overdose data form (Att. D)	10	12	3	360
Participating health departments sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920- 0824)*	Rapid ED overdose data form (Att. D)	35	12	30/60	210
Participating health department sharing finalized hospital discharge data on a quarterly basis	ED discharge overdose data form (Att. E)	28	4	3	336
Participating health department sharing finalized hospital discharge data on a yearly basis	ED discharge overdose data form (Att. E)	23	1	3	69
Total					975

^{*} The reporting burden for jurisdictions sharing case-level ED data with CDC is substantially lower because CDC completes most of the form for the jurisdiction and only needs to consult with the jurisdiction on completing the metadata.

Estimates of annualized respondent burden costs:

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 18Jan2022) was used to estimate burden costs.

Table 2. Estimates of annualized respondent burden costs

Type of respondent	No. of respondents	No. of responses per respondent	Total burden (hours)	Hourly wage rate	Total respondent cost
Participating health departments sharing aggregate data from local syndromic or hospital discharge file	10	12	360	\$29.87	\$10,753
Participating health departments sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920-0824)*	35	12	210	\$29.87	\$6,273
Participating health department sharing finalized hospital discharge data on a quarterly basis	28	4	336	\$29.87	\$10,036
Participating health department sharing finalized hospital discharge data on a yearly basis	23	1	69	\$29.87	\$2,061
Total					\$29,123

^{*} The reporting burden for jurisdictions sharing case-level ED data with CDC is substantially lower because CDC completes most of the form for the jurisdiction and only needs to consult with the jurisdiction on completing the metadata.

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:

A) Contractor phases, tasks, and estimated costs

Table 3. Cost to government - Contractor

LABOR	COST
Contract to fund two data managers (50%)	\$87,500
Other Direct Costs	
Subcontractors	\$0
Travel and subsistence	\$0
Total Estimated Contract Costs	\$87,500

B) Government costs

Table 4. Cost to government - Government

Personnel	Tasks	Avg. cost/yr
Senior scientist (75%)	Program oversight and strategic direction	\$ 92,039
6 Epidemiologists (75%)	 Direct technical assistance to participating health departments completing the <i>Rapid ED</i> overdose data form and the <i>ED discharge</i> overdose data form. Responsible for data quality checking in approximately 8 jurisdictions each, including addressing problems with data submitted in the <i>Rapid ED overdose data form</i> and the <i>ED discharge overdose data form</i>. Enhance national overdose definitions, data quality and data sharing protocols used in DOSE. Conduct rapid surveillance of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses in close collaboration with participating states, CDC and HHS leadership. Disseminating findings from DOSE 	\$468,000
14 Public health advisors (5%)	Programmatic, budgetary, administrative management and oversight of DOSE as part of OD2A NOFO	\$61,250

2 Data managers (100%)	 Manage and curate monthly data submitted in Rapid ED overdose data form and the ED discharge overdose data form. Implement system to rapidly and automatically identify data quality problems that need follow-up, perform preliminary analyses, and transform data for rapid posting to the public. Engage in continuous quality improvement to enhance data quality and analysis in collaboration with epidemiologist. 	\$240,000
Indirect costs for		\$861,289
staff (25%)		+
		\$215,322
Sub-total		\$1,076,611
Contract Costs		\$87,500
Total		\$1,164,111

Total annual contractual and government staff costs are approximately \$1.17 million. This is a four year project.

15. Explanation for Program Changes or Adjustments

This serves as a revision request for the currently approved package (Drug Overdose Surveillance and Epidemiology (DOSE) – OMB# 0920-1268, expiration date 08/31/2022). Funding for DOSE has been extended by one year (new end date: September 2023) and we are requesting an additional three years of data collection. Revisions are requested to revise the number of eligible states, change the data collection template (see Attachment D-2), and revise burden. No additional burden has been added; however, based on current data sharing from states we have decreased our burden estimate to 975 from 1272 hours (i.e., we estimated 19 states would be sharing data outside NSSP when in fact, only 10 states are sharing data outside NSSP).

16. Plans for Tabulation and Publication and Project Time Schedule

Monthly, quarterly, and yearly trends in ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses at the state level will be reported publicly on an ongoing basis by CDC. Additional analyses examining data by age group, sex, race/ethnicity and county will also be conducted as well as comparison of ED trends with other data sets such as drug overdose mortality. These additional analyses will be released in CDC publications such as *MMWR* or in other peer-reviewed publications as well as available every six months on the CDC nonfatal drug overdose website (https://www.cdc.gov/drugoverdose/nonfatal/index.html). A project time schedule is presented below.

Table 5. Time Schedule

Task	Time Period				
Ongoing processing of monthly reports of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses submitted by public health departments to CDC (i.e., <i>Rapid ED overdose data form</i>)					
Receive on a monthly basis <i>Rapid ED overdose data form</i> (i.e., Data form 1) from the jurisdiction	1 – 2 month delay from when the overdose ED visit occurred (e.g., overdoses occurring in January 2020 will be reported to CDC in March 2020).				
Final analysis files validated within 1 month of receipt of data from jurisdiction. Preliminary data is shared with participating health department and CDC/HHS leadership	2 – 3 month delay from when the overdose ED visit occurred (e.g., analytic file for overdoses occurring in January 2020 will be completed by CDC by the end of April 2020 or earlier)				
At least twice a year, quarterly or monthly changes in ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses will be posted on the web for public access*	6 – 12 months (e.g., quarterly changes in drug and opioid overdoses occurring from January – March, 2020 to April – June, 2020 will be reported to the web in December, 2020).				
Publish surveillance reports and epidemiologic and	alyses of DOSE data to support public				
health prevention efforts Analyze trends in ED visits to identify important patterns to inform public health action and improve syndromic ED definitions of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses	At least three articles per year will be published, starting 1 year after the DOSE system begins operating.				
Conduct analyses to support improved data collection and analysis					
Conduct ongoing comparisons of ED data collected on the <i>Rapid ED overdose data form</i> with ED data collected on the <i>ED discharge overdose data form</i> to inform improvements to both data collections	These analyses will start 6 months after the DOSE system begins operating and sufficient data is available to compare across data sources.				

^{*}Data are posted here: https://www.cdc.gov/drugoverdose/data/nonfatal.html .

Initial publications focused on:

- Identifying patterns of polysubstance use among individuals treated in the ED for drug overdoses and how this patterns varies across demographic groups in order to better target interventions.
- Determining the extent to which geographically concentrated opioids outbreaks versus gradual changes in opioid overdose contribute to large increases in ED visits involving suspected opioid overdoses. This can inform public health interventions and help identify and respond to emerging public health outbreaks.
- Comparing state and country trends in ED visits involving suspected drug, opioid, heroin,

and stimulant overdoses with trends observed in drug, opioid, heroin and stimulant overdose deaths. This will help validate and improve the current data collection as well as provide insight into whether efforts to decrease fatal opioid overdoses by enhancing response are working.

• Comparing the data sources collected – syndromic and discharge – to better understand strengths and weaknesses of the two different, yet connected data sources.

Future publications will focus on:

- Exploration of trends in other drug types such as fentanyl, benzodiazepine, cocaine, and methamphetamine (separate from all stimulants)
- Assessment of relationships between health inequities and social determinents of health and suspected drug overdose.

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

There are no standard paper data collection forms to be used in this data collection. Instead, the participating health departments share the requested ED data with CDC using two Excel files, the *Rapid ED overdose data form* and the *ED discharge overdose data form*. The OMB number will be displayed on the *Rapid ED overdose data form* and the *ED discharge overdose data form* distributed to state and local health departments.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

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