SUPPORTING STATEMENT: PART A

Drug Overdose Surveillance and Epidemiology (DOSE)

OMB #0920-1268

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SUMMARY TABLE

- **Goal of the study –** This is a revision request for the currently approved Drug Overdose Surveillance and Epidemiology (DOSE) to continue data collection efforts. Revisions are requested to revise the number of eligible jurisdictions and revise burden. The purpose of the Drug Overdose Surveillance and Epidemiology (DOSE) system is to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug overdoses at the local, state, and regional level. This goal will be accomplished by standardizing and enhancing sharing of existing ED data locally collected by health departments with CDC.**Intended use of the resulting data -** Improve local, state, and regional situational awareness of all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine, overdose trends and response to acute local and multi-state drug outbreaks.
- **Methods to be used to collect –** The project, Drug Overdose Surveillance and Epidemiology (DOSE) system will leverage ED syndromic data, as well as line-level emergency department (ED) and inpatient hospitalization 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. DOSE system funds 50 health departments (49 state health departments and the health department of the District of Columbia; ND is the only state not funded of the 50 states). For DOSE Syndromic Surveillance (SyS) data, 48 health departments (OK and CA do not participate in SyS) will rapidly share existing ED data with CDC on a monthly basis.
- **The subpopulation to be studied –** Individuals who visit an ED to receive treatment for all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdose.
- **How data will be analyzed -** Descriptive analyses will be conducted, such as frequencies and changes in the rate of ED visits involving all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine 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 ED syndromic surveillance and ED and inpatient hospitalization 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 09/30/2025. CDC is requesting OMB approval for an additional 3 years to continue data collection efforts. The DOSE system currently captures data from 49 states (ND is the only state that did not apply for funding of the 50 states) and the District of Columbia. DOSE captures two types of data. First, DOSE Syndromic Surveillance (SyS) data, 48 health departments (OK and CA do not participate in SyS) that rapidly share existing Emergency Department (ED) data on counts of ED visits involving eight required nonfatal drug overdose indicators (suspected all drug, all opioid, heroin, fentanyl, benzodiazepine, all stimulant, methamphetamine, and cocaine overdoses), plus the number of total ED visits of any cause, using *the Rapid ED overdose data form* (Attachment D) and standard CDC case definitions. Second, DOSE ED and Inpatient Hospitalization Discharge Surveillance (Discharge) data, 35 jurisdictions (34 states (OK and CA participate in Discharge only) and the District of Columbia) participate – 32 jurisdictions submit both ED and Inpatient Hospitalization discharge data, while 3 jurisdictions only submit Inpatient Hospitalization discharge data. The submission requirement include line-level .csv format containing discharge/billing data on ED visits and/or inpatient hospitalizations involving a drug poisoning (i.e., line-level data on visits with any T36-T50 ICD-10-CM code, including all intents and encounters, underdosing, and adverse effects), in a CSV data form. Funded jurisdictions receive discharge data from a state hospital association. Jurisdictions submitting discharge/billing data also submit aggregate data on total ED visits and/or inpatient hospitalizations (of any cause) using the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E). For both SyS and Discharge data, CDC provided SAS/R programs that populate the data forms.

Revisions noted below are for two purposes: (1) to revise the number of eligible recipients from current and future data collection efforts and (2) to revise burden estimates. Based on current data sharing from states we have decreased our burden estimate to 655 from 975 hours previously approved.

Several circumstances make DOSE necessary. First, there have been rapid increases in opioid overdose deaths since 2013[1] and numerous severe fentanyl and fentanyl analog outbreaks occurring across the United States[2-6]. In addition, the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017[7] 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 occurred 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. In September 2023, Overdose Data to Action in States (OD2A-S, CDC-RFA-CE23-002) funding supported the expansion of DOSE from 47 states to 49 states and the District of Columbia. To differentiate the DOSE from OD2A funded in 2019 with the one funded in 2023, hereinafter the former and the latter will be referred to as DOSE 1.0 and DOSE 2.0, respectively. OD2A-S funding expires in September 2028, thus, we are requesting three additional years for DOSE 2.0 data collection.

Over the past several years of implementing DOSE 1.0 and the first year of DOSE 2.0, 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. CDC developed 8 syndrome definitions for the 8 required drug indicators for DOSE 2.0 data submission[9-16].
2. Using the forms [the "*Rapid ED overdose data form"* (Attachment D)" and "*ED/Inpatient Hospitalization discharge overdose data form*" (Attachment E)"] has improved CDC data processing time. CDC has developed SAS/R programs for states to use to analyze the data and populates results into the forementioned data forms, which has reduced state data processing time.
3. Some states are unable to share syndromic surveillance data, thus allowing flexibilities for sharing of ED/Inpatient hospitalization discharge overdose data using the form [the "*ED/Inpatient Hospitalization discharge overdose data form*" (Attachment E)] has been beneficial. Other jurisdictions participating in SyS can also share ED/hospital discharge data. 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 2.0 will continue to compare counts and rates of all drug, all 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 ED/Inpatient hospitalization discharge overdose data files (the current public surveillance standard used to assess the burden of drug overdoses treated in EDs/hospitals).
4. Working closely with the states that have participated in DOSE 1.0 ED/Inpatient hospitalization discharge data submission, CDC learned that the states already receive ED or Inpatient hospitalization discharge data from their Hospital Associations regularly. Therefore, in DOSE 2.0, CDC added an optional opportunity for the states to submit line-level .csv file on all drug overdose-related ED and/or inpatient hospitalization visits, encompassing all intents, encounter types, and substances (including underdosing and averse effects). The line-level data covers a comprehensive range of drug overdose cases, as defined by ICD-10-CM codes T36-T50.
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 (Attachment D and Attachment E) and will require OMB approval.

DOSE background

In 2022, a total of 107,941 drug overdose deaths occurred, corresponding to an age-adjusted rate of 32.6 per 100,000 population, quadruple from the 2002 rate (8.2)[17]. From 2021 to 2022, the synthetic opioid-involved death rate other than methadone increased 4.1%, from 21.8 to 22.7 per 100,000. The psychostimulant-involved age-adjusted death rate increased more than 34 times, from 0.3 in 2002 to 10.4 in 2022[18]. Two states had a significant increase in non-fatal overdoses between 2023 and 2024 (DOSE dashboard). 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[7]. 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[19]. The ONDCP's 2024 National Drug Control Strategy includes these four strategic priorities as well as a priority to focus on "Chapter 8: Building Better Data Systems and Research" [20]

DOSE 2.0 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[21]. DOSE 2.0 data collection integrates, expands, and enhances previous data sharing efforts with public health departments initiated under ESOOS and DOSE 1.0. The goal of DOSE 2.0 is to conduct surveillance of approximately 80% of all ED facilities in a given jurisdiction for drug overdoses through the end of the OD2A-S cooperative agreement in 2028. In 2023, OD2A-S provided funding for 90 jurisdictions; 49 states and the District of Columbia share data with DOSE 2.0. Though we had hoped to capture data from all 50 states and the District of Columbia, only 49 states and the District of Columbia applied for this funding announcement. We describe our progress to date in more detail in Section 2.

DOSE 2.0 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 and other respiratory illnesses, heat-related illness, and hurricane-related health issues. DOSE 1.0 ensured participating jurisdictions use their data to track suspected overdoses by providing participating jurisdictions standardized definitions of ED visits involving all drug, all opioid, heroin and all stimulant overdoses. To further advance overdose surveillance, for DOSE 2.0, CDC added 4 additional drug indicators – fentanyl, cocaine, methamphetamine, and benzodiazepine. This facilitates rapid identification and tracking of ED data on a total of 8 drug overdose indicators.

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 ED/inpatient hospital discharge overdose data files. DOSE 2.0 integrates data across these three types of ED surveillance to quickly build a national surveillance system while leveraging existing ED data collection efforts. DOSE 2.0 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 2.0 is provided below:

1. *CDC National ED Syndromic Surveillance:* The Detect and Monitor Division in the Office of Public Health Data, Surveillance, and Technology (OPHDST) 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)[22] diagnosis codes, assigned the ED visit on approximately 80% 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 *4. 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. *ED/Inpatient Hospitalization Discharge Overdose Data:* Some health departments have no or limited syndromic surveillance of ED visits. These health departments, however, may be able to leverage line-level ED and/or Inpatient Hospitalization discharge overdose data that is routinely collected by most states. ED/Inpatient Hospitalization discharge data are collected for billing purposes, use 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 many states have access to line-level ED/inpatient hospitalization discharge data that meet the requirements of DOSE 2.0.

Key advantages to DOSE 2.0 compared to initiating a new ED data collection are:

1. DOSE 2.0 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 2.0 ensures state and local health departments ED syndromic efforts are integrated into national surveillance instead of duplicated.
3. DOSE 2.0 leverages instead of duplicating existing CDC work through CDC NSSP and DOSE 1.0 to rapidly share state and local health departments' ED data with CDC.
4. DOSE 2.0 ensures that state and 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[22,23].

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 (Attachment 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" (Attachment A2).

2. Purpose and Use of Information Collection

All data shared between CDC and health departments in DOSE 2.0 can be categorized into two type of data: 1) DOSE Syndromic Surveillance data using the standardized Rapid ED overdose data form (Attachment D) and 2) DOSE ED and inpatient hospitalization discharge surveillance (Discharge) data using line-level discharge/billing data involving a drug poisoning in a .csv format and the standardized ED/Inpatient Hospitalization discharge overdose data form (Attachment E). CDC developed standardized syndrome definitions of all drugs, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine. The justification of the two types of data and the key variables they collect is described in detail below.

DOSE Syndromic Surveillance data

Health departments able to share syndromic surveillance data with CDC will be required to complete the *Rapid ED overdose data form* (Attachment 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 and why they will continue to be collected are described in the table below.

Table 1: Key variables shared with CDC for Syndromic Surveillance:

Variable	Justification for collecting
Count of ED visits suspected to involve all drug overdoses	• Detect emerging drug overdose problems that would not be detected by variables tracking specific drug classes such as opioids. For instance, overdose outbreaks involving fentanyl analogs[5,25] or synthetic cannabinoids[26] may not be identified in 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 visits suspected to involve all opioid overdoses	• More than 2 out of 3 drug overdose deaths involves an opioid and recent severe drug overdose outbreaks involve opioids. • Collection of ED data on opioid overdoses was found to be feasible and useful in pilot studies, response to outbreaks[27], and work in ESOOS[28].

Variable	Justification for collecting
	• The general category of "opioids" will be tracked instead of specific types of opioids (e.g., oxycodone or fentanyl) because: 1) EDs may not test for specific types of opioids, 2) ED chief complaint text often only lists "opioid overdose", and 3) patients may not know the specific opioid that they took due to purchasing counterfeit prescription drugs or using adulterated illicit drug products[4,29].
Count of ED visits suspected to involve heroin	• The sharp increases in heroin overdoses since 2010 coupled with the adulteration of heroin with fentanyl highlight the need to track heroin overdoses[1,30]. • While other types of opioids proved difficult to track using ED data, work in ESOOS and DOSE 1.0 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 visits suspected to involve fentanyl	• Fentanyl is a synthetic opioid that is 50 to 100 times stronger than morphine. Illegally made fentanyl is a growing problem in the United States. Fentanyl is often mixed with other drugs[31]. • Overdose deaths involving synthetic opioids such as fentanyl have risen sharply in the last decade[32]. • A new ICD-10-CM code for poisoning by fentanyl and fentanyl analogs was introduced in October 2020, allowing surveillance of nonfatal fentanyl-involved overdoses specifically. Most nonfatal synthetic opioid-involved ED visits in recent years involve fentanyl[33].
Count of ED visits suspected to involve all stimulants	• Recent increases in stimulant overdoses such as cocaine and methamphetamine and co-use with opioids[3,34] have highlighted the need to implement surveillance of stimulant overdoses. • ESOOS has shown the feasibility of tracking stimulant overdoses and a CDC definition is currently available in NSSP BioSense for health departments to use.
Counts of ED visits suspected to involve cocaine	• Rates of fatal cocaine-involved overdoses have risen rapidly since 2018. More than 1 in 5 overdose deaths involved cocaine in 2020. It also is essential to account for overdoses coinvolving cocaine and opioids, given public health and law enforcement warnings in recent years regarding the increased mixing of fentanyl with cocaine.
Counts of ED visits suspected to involve methamphetamine	• This definition was developed to help public health practitioners track and understand trends of nonfatal methamphetamine-involved overdoses treated in EDs in near real-time. • Understanding trends in methamphetamine-involved nonfatal overdoses is important for the development of evidence-based prevention strategies.
Counts of ED visits suspected to involved benzodiazepine	• Opioids and benzodiazepines have complex drug interactions with each other and, when used in combination, can increase risk for synergistic respiratory depression[35]. Persons experiencing this symptom are more likely to receive care at EDs. It is important to consider that persons treated for benzodiazepine-involved overdoses in EDs may have co-used other drugs.
Sex, age group, race/ethnicity, and county level data by drug overdose indicators	Aggregating data on all drug, all opioid, heroin, and all stimulant overdose by sex, age group, race/ethnicity, and county is critical to assist CDC as well as state and local health departments target interventions on demographic groups and geographic areas impacted by drug overdoses outbreaks or large changes.

Variable	Justification for collecting
Percent of ED visits with chief complaint text and diagnosis codes	ED visits involving drug overdose are primarily identified by analyzing patient's chief complaint and diagnosis codes fields, primarily ICD-10-CM diagnosis codes. Thus, important data quality indicators are the percent of ED visits with chief complaint data and the percent of ED visits with diagnosis codes.
Median word length of the chief complaint	The median word length of the chief complaint is tracked because the ability to identify suspected drug overdoses is impacted by the length and quality of text data entered into the chief complaint text field. Based on previous experience working with 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 maximum number of diagnosis codes	The mean and maximum of diagnosis codes, primarily ICD-10-CM diagnosis codes, collected by jurisdiction s varies (e.g., one jurisdiction may allow hospitals to enter 10 codes while another allows 16 codes). Since CDC drug overdose case definitions 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 surveillance systems	Local ED data systems may experience major changes that impact data quality (e.g., ED data sharing delayed due to the implementation of a new EHR system). In order to effectively identify and address these types of changes, DOSE will ask all participating health departments to report major changes in ED participation or data quality each month.

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

DOSE ED and inpatient hospitalization discharge surveillance data

Health departments able to share discharge data with CDC will be required to submit line-level discharge/billing data on ED visits and/or inpatient hospitalizations involving a drug poisoning (i.e., line-level data on visits with an ICD-10-CM code between T36-T50, including all intents, encounter types, substances, underdosing, and adverse effects), annually in a CSV data format. There is no template for the line-level data, but jurisdictions are provided with a data dictionary and technical guidance specifying which variables to include. In addition, jurisdictions will complete the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E) on a yearly basis, which includes data on total ED visits/inpatient hospitalizations by various strata, as well as metadata. The content in the .csv line-level file and the *ED/Inpatient Hospitalization discharge overdose data form* is described below.

1. **Frequency that this data form is reported to CDC.** The goal of the program is to have health departments submit annual reports to CDC following a standardized Excel template for aggregate data (i.e., for total ED/inpatient hospitalization visits), metadata, as well as a .csv file with line-level data. 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. Therefore, to reduce the burden as compared to DOSE 1.0 (where jurisdictions submitted data quarterly, with a 3.5-mo lag), health departments will submit annual data with 6-month lag following a standard CDC data dictionary and technical guidance. Those health departments submitting both ED and inpatient hospitalization data may experience approximately 50% increased burden compared to ED visit or inpatient hospitalization data alone in terms of data processing for submission.

Table 2: Key variables shared with CDC: Required Line level data for Discharge Surveillance

Variable	Justification for collecting
Type of record (ED or inpatient hospitalization)	Historically, emergency department and hospitalization discharge data have been the standard for tracking, monitoring, and comparing the burden of nonfatal drug overdoses across states and localities. State may choose to submit ED data, inpatient hospitalization data or both.
State jurisdiction where visit occurred	Data on all drug, all opioid, heroin, and all stimulant overdose by state of visit is critical to assist CDC and state and local health departments to prioritize interventions for geographic areas impacted by drug overdoses outbreaks or large changes.
State jurisdiction, county, and five-character FIPS code of patient residence	• While drug-induced mortality rose across the United States during 2013–2020, disparities by region, state, and county have been observed[36]. Crude death rates due to fentanyl were highest in the Northeast region, while death rates due to methamphetamines were highest in the Western region[37]. Disparities also persist in terms of treatment availability. Over 75% of U.S. counties lack opioid treatment programs, and approximately 30% of counties lack clinicians who administer buprenorphine[38]. • Data on all drug, all opioid, heroin, and all stimulant overdose by state and county of patient residence is critical to assist CDC and state and local health departments to prioritize interventions for geographic areas impacted by drug overdoses outbreaks or large changes.
Date of discharge	As discharge data is shared annually, the date of discharge will provide the timing to monitor trends and may be used with the admission date to estimate severity in terms of the duration of hospitalization.
Patient sex and patient age at admission	• The rate of drug overdose deaths in the United States during 2021–2022 was greatest among patients aged 35–46, followed by 45–54, 25–34, 55-64[32]. • Drug overdose deaths have remained greater among men compared to women over the past 20 years, although steady increases have been observed over that period for both groups[32]. • Data on all drug, all opioid, heroin, and all stimulant overdose by sex and age is critical to assist CDC and state and local health departments to prioritize interventions for demographic groups impacted by drug overdoses outbreaks or large changes.
Patient race and ethnicity based on Office of Management and Budget Standards	• Data on all drug, all opioid, heroin, and all stimulant overdose by race is collected and reported according to the U.S. Office of Management and Budget's 1997 Standards for Maintaining, Collecting, And Presenting Federal Data on Race and Ethnicity (Statistical Policy Directive No. 15)[39.] • This guidance recommends the use of 2 minimum ethnicity categories (Hispanic or Latino and Not Hispanic or Latino) and 5 minimum race categories (American Indian or Alaska Native, Asian, Black or African

	American, Native Hawaaiian or Other Pacific Islander, and White), and more than one race category (multiple race) may be selected. • While updates to the standard have been recently released, we maintain the standards that are currently being utilized by jurisdictions and the hospital associations that gather the data. • Overdose deaths are disproportionately greater among some racial and ethnic minority groups; Non-Hispanic Black and African Americans had the greatest rates of overdose deaths in 2020, with 39 per 100,000 deaths, followed by Non-Hispanic American Indian, Alaskan Native populations with 36 per 100,000 deaths[40]. • Data on all drug, all opioid, heroin, and all stimulant overdose by race and ethnicity are critical to assist CDC and state and local health departments to prioritize interventions for demographic groups impacted by drug overdoses outbreaks or large changes.
Patient race and ethnicity combined (if applicable)	Some jurisdictions may be limited to providing race and ethnicity as a combined category due to the way that data is gathered by hospital associations or aggregated at the state level. We allow for submission of a joint patient race and ethnicity variable in those instances.
All discharge diagnosis codes	Discharge data are often used as a reliable means to estimate disease burden because of the use of standardized discharge diagnosis codes, specifically the International Classification of Diseases10th Revision, Clinical Modification [ICD-10-CM]). ICD-10-CM codes differentiate by encounter type, including the initial encounter, subsequent encounter and related sequelae; They may also provide details on the manner of injury or intent, critical information to confirm overdose diagnoses[41].
Procedure codes	Procedure codes are standardized in the ICD-10-CM and can provide details on the medical procedures performed during the hospital visit, potentially indicating severity or treatment received by the patient[42].

Line-level data that are not required but strongly recommended to be collected by states: 1) admission date, 2) admission source, 3) discharge status, 4) expected primary payer, 5) admitting or initial diagnosis code. This data will provide more detail on the circumstances of a person's admission to inpatient treatment or ED treatment, as well as insurance status at the time of the encounter. Admitting or initial diagnosis codes provided at the time of admission, which are required for inpatient admissions may also be present for ED visits. The admitting diagnosis code may not be confirmed after the patient is evaluated in the hospital and may differ from the eventual discharge diagnosis.

Aggregate data: CDC will also collect aggregate data on total ED visits/hospitalizations: a) by jurisdiction, month/year, sex, age group, race and ethnicity; and b) by jurisdiction, month/year, and county. Additionally, the aggregate template (Attachment E) has metadata questions that ask about topics such as facility coverage and data quality.

2. **CDC use of the discharge/billing data.** This data will be used in two ways:
    a. Hospital discharge data are the current standard for tracking drug overdose burden associated with ED visits and inpatient hospitalizations. Consequently, comparing trends in ED visits involving drug overdoses calculated using ED discharge data with trends in suspected drug overdoses 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. These comparisons

are 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 inpatient hospitalization data on drug overdoses from hospital discharge files is approximately two years. This inhibits response and assessment of the overall burden of drug overdose. The previous OD2A NOFO demonstrated that states can successfully submit more timely discharge/billing data compared to publicly available data sources such as the Healthcare Cost and Utilization Project (HCUP).

To date, the DOSE 2.0 system has been extremely successful at meetings its stated objectives. Currently, DOSE 2.0 operates in the 49 states and the District of Columbia currently funded by OD2A-S (ND is the only state that did not request CDC funding in the current cycle but may for the next funding cycle in 2028). Of these 50 health departments, 47 share syndromic data with CDC monthly and 35 share ED/hospital discharge data. **Figure 1** depicts the requested state data sharing for DOSE 2.0, which includes 49 states and the District of Columbia with 48 health departments sharing syndromic and 35 sharing discharge data. Access to this timely data have 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.

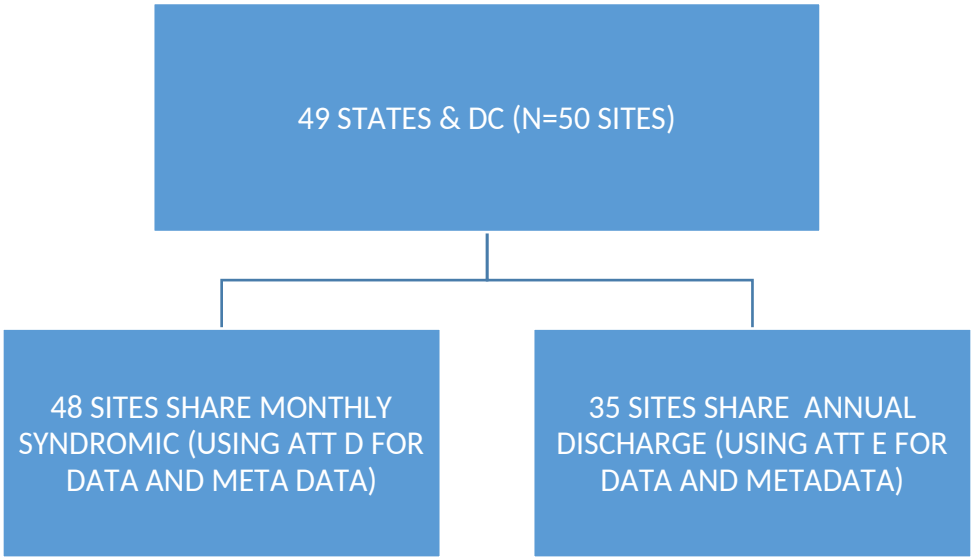

Figure 1: Current state data sharing for DOSE 2.0

Data from the DOSE 2.0 system have also raised public awareness of the progression of the drug overdose epidemic in their area. As recently as June 2024, we have updated two areas of CDC's website using data from DOSE Syndromic Surveillance data (https://www.cdc.gov/overdose-prevention/data-research/facts-stats/dose-dashboard-nonfatal-surveillance-data.html) and DOSE ED and Inpatient Hospitalization Discharge data (https://www.cdc.gov/overdose-prevention/data-research/facts-stats/dose-dashboard-nonfatal-discharge-data.html).

DOSE 1.0 and 2.0 data have also been used in in 14 peer-reviewed and MMWR publications (Attachment G) and was featured in a special supplement in *Public Health Reports* (https://journals.sagepub.com/toc/phr/136/1_suppl).

In addition to reporting out on drug overdoses, CDC DOSE staff have provided extensive technical assistance to health departments participating in DOSE 2.0. At present (July 2024), the DOSE syndromic surveillance system captures 90.6% of ED facilities in 44 states and the District of Columbia. As of July 2024, the DOSE ED Discharge data surveillance system captures 95.7% of ED facilities in 21 states, and the DOSE Inpatient Hospitalization Discharge data surveillance system captures 94.3% of inpatient hospital facilities in 26 states. 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. All funded state health departments will be asked to share ED and/or inpatient hospitalization discharge data with CDC yearly (N=35) by submitting a line-level .csv file with data on drug overdose-related visits, plus the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E), which has aggregate data on total ED visits and/or inpatient hospitalizations. Similar to the *Rapid ED overdose data form* (Attachment D), the ED/Inpatient hospitalization discharge overdose data form is in an Excel template.
2. Participating health departments will share the *Rapid ED overdose data form* (Attachment D), *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E), and *a line-level .csv file* 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[43]. 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 2.0 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 ED or inpatient hospitalization discharge data that the health departments are already collecting. In addition, DOSE continuously communicate on an ongoing basis with other federal collections of ED data.

DOP has taken 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.

Table 3: Emergency Department Data Systems and Characteristics

ED data system	Description	Time lag	Purpose of ED system	Additional Value of DOSE	Recent contact
Health Care Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS)[44] administered by the Agency of Healthcare Research and Quality (AHRQ) OMB #: 0935-0206	40 states contribute data to NEDS. In 2021, the database contains a sample of around 30 million ED visits that can be used to make national estimates of ED visits involving specific illnesses and injury. Key data include ICD-9-CM and ICD-10-CM diagnosis and procedure codes and medical charges as well as geographic, hospital, and patient characteristics as well as descriptions of the nature of visits.	~ 3 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[45] • Review of HCUP materials.
Health Care Utilization Project (HCUP) State Emergency Department Databases (SEDD)[46] 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 41 participating data organizations from 31 states. Data and access conditions vary across state. As of July 10, 2024, 15 states provided access to 2022 data, 13 states provided access to 2021 data, and 1 state provided access to 2016 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 provides 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 timelier and more 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[45] as part of our efforts to understand the opioid overdose epidemic • Review of HCUP materials.
The Drug Abuse Warning Network	In fall 2018, SAMHSA restarted the DAWN surveillance system	Reporting frequency is still be determined,	DAWN samples hospitals from three categories: 1) 10 high priority	• DOSE will provide timely local and regional situational awareness because	• Multiple phone conversations were held between

ED data system	Description	Time lag	Purpose of ED system	Additional Value of DOSE	Recent contact
(DAWN) operated by SAMHSA[47] OMB # 0930-0078	after a 7-year period of inactivity. in DAWN, hospital electronic health record (EHR) are collected from a selection of non-federal, short-stay, general surgical, and medical hospitals with at least one ED open 24 hours a day, 7 days a week and more than 100 visits per month. DAWN conducted data abstraction in 2022 from 53 participating hospitals. DAWN is an early warning system that detects increases in drug-related 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.	but likely will be monthly to quarterly.	sentinel hospitals that were specifically selected to enhance drug-related ED visit surveillance.; 2) a systematic random sample of eight rural and suburban hospitals located in counties with the highest rates of five-year combined drug-related overdose deaths.; and 3) is a systematic random sample of 32 hospitals from counties not included in Part B. This design provides a framework suitable for sentinel surveillance and for national estimation	it will monitor visits from at least 80% of ED facilities across all 50 states and the District of Columbia, or over 6,000 hospitals. • DOSE will include data from all communities, regardless of overdose burden.	summer 2018 and winter 2019 with original DAWN program staff. • Frequent email conversation continued through 2020 with key SAMSHA, DAWN staff. • Connected with DAWN staff at several conferences in 2024. • Key contact person: Sean Lynch, Division of Surveillance and Data Collection, CBHSQ, SAMHSA.

As DOSE 2.0 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 all drug, all 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 all drug, all 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 2.0 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[2-5,32]. Also, the nature and complexity of drug overdoses continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl[49], cocaine products laced with fentanyl[3], increasing overdoses involving synthetic cannabinoids[26] and large increases in overdose deaths involving methamphetamines and cocaine[34]. 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[50]. 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[51].
- Local health department surveillance and response to suspected, all drug, all opioid, heroin and all 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

Under the current revison request this data collection will not be able to comply with the updated OMB's Satisitcal Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. DOSE receives data through the state health departments from Electronic Health Records. Therefore, DOSE will need to continue collecting race and ethnicity using the previous standards to effectively compare the progress of the programs. DOSE will not be able to enforce the new OMB standards during this funding period, which ends in September 2028, but will implement the new standards in the next round of funding.

This data collection will require monthly reporting of aggregate ED data on suspected all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses using the *Rapid ED overdose data form* (Attachment D). This is more rapid than quarterly data sharing recommended by OMB. Monthly sharing of ED data is critical to fulfill the mission of DOSE 2.0, which is timely response to drug overdose outbreaks and identify changes in drug overdose trends. 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 illegally manufactured fentanyl and fentanyl analogues have sharply increased in recent years and been accompanied by multiple local and state reports of severe and often widespread opioid overdose outbreaks since 2013[2-6]. Also, the nature and complexity of the drug overdose epidemic continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl[49], cocaine products laced with fentanyl[3], increasing overdoses involving synthetic cannabinoids[26], and large increases in overdose deaths involving methamphetamines and cocaine[34]. Increases in benzodiazepine-involved overdoses, both with and without opioids, have also recently occurred from 2019-2020[52]. 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 2.0 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 fulfilling two types of DOSE data – Syndromic Surveillance data and ED/Inpatient Hospitalization discharge overdose data by completing required data sharing forms, the *Rapid ED overdose data form* and *ED/Inpatient Hospitalization discharge overdose data form*, and providing a line-level .csv file on a monthly basis and yearly basis, respectively.
2. Providing substantial technical assistance to participating health departments in completing reports. This includes:
    a. For DOSE Syndromic Surveillance data, CDC developed SAS, R and ESSENCE programming code that allows the participating health department to identify suspected all drug, all 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* (Attachment D). This will substantially reduce the burden of completing the form.

b. For DOSE ED/Inpatient Hospitalization discharge data, CDC developed SAS and R code that will populate the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E).

c. For DOSE ED/Inpatient Hospitalization discharge overdose data, CDC developed a data dictionary and technical guidance document that provides instructions on how to pull line-level data in a .csv format on visits with any T36-T50 ICD-10-CM code, including all intents and encounters, underdosing, and adverse effects.

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 Nov. 7, 2024, vol. 89, No. 217, pp. 88774-6 (Attachment B). For this notice CDC received no public comments.

B. Efforts to Consult Outside the Agency

DOP, NCIPC receives annual feedback from state public health departments and the District of Columbia on improving both Syndromic and ED/Inpatient hospitalization discharge overdose data to track suspected drug overdoses who are participating in DOSE 2.0. Secondly, intensive consultation with Ohio[27], Massachusetts, and Rhode Island[53] 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 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. (Attachment 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 share with CDC aggregate data collected on two standardized forms, the *Rapid ED overdose data form* (Attachment D) and the *ED/Inpatient Hospitalization discharge overdose data form*

(Attachment E), as well as a line-level .csv file. These aggregate forms and line-level CSV file do not include any PII

2. Participating health departments will submit the *Rapid ED overdose data form* (Attachment D), the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E), *and line-level .csv file* 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[43].
3. Only selected staff working in the DOSE program will have access to aggregate data entered into the *Rapid ED overdose data form* (Attachment D) and the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E) 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 (Attachment C).

12. A. Estimates of Annualized Burden Hours and Costs

This data collection includes Syndromic surveillance (one data form) and Discharge surveillance (one data form and one line-level .csv file):

- **Syndromic Surveillance**: *Rapid ED overdose data form* (Attachment D) supports rapid monthly ED surveillance of suspected all drug, all opioid, heroin and all stimulant overdoses to detect outbreaks and provide situational awareness. The *Rapid ED overdose data form* (Attachment D) asks jurisdictions to use existing local ED data to calculate the total number of suspected all drug, all 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* (Attachment D) will vary across two groups: 1) health departments using the NSSP BioSense Platform and thus completing the *Rapid ED overdose data form* (Attachment D) using CDC provided SAS/R program and technical guidance document and 2) health departments not using the NSSP BioSense

Platform and completing the *Rapid ED overdose data form* (Attachment D) with minimal CDC assistance. The burden for these two groups is described below.

- *Health departments using NSSP BioSense:* CDC identified 45 of the funded health departments complete the *Rapid ED overdose data form* (Attachment D) using the NSSP BioSense Platform (OMB #0920-0824). Based on CDC collaborative work with health departments using the NSSP BioSense Platform and downloading data via SAS or R code, the burden will be 0.5 hours per monthly report per jurisdiction. Thus, the annual burden per health department will be 6 hours (0.5 hours x 12 months) or a total of 270 burden hours across the 45 responding health departments.
- *Health departments accessing local syndromic ED data:* CDC identified 3 of the funded health departments (i.e., the health departments not using CDC NSSP BioSense) to complete the *Rapid ED overdose data form* (Attachment D) using local ED syndromic 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. 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 108 annual burden hours across all 3 responding health departments.

- **Discharge surveillance:** *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E) supports yearly hospital discharge surveillance of ED and/or inpatient hospitalization visits involving drug poisoning (i.e., any visit with a T36-T50 ICD-10-CM code, including all intents, encounters, and sequelae, including underdosing and adverse effects) to evaluate rapid ED surveillance and assess drug overdose burden (Attachment E). The preliminary ED data captured by the *Rapid ED overdose data form* (Attachment D) needs to be compared and validated against ED discharge data that uses ICD-10-CM codes, currently the standard for tracking ED visits. In addition, inpatient hospitalization data provide more information about the context and burden surrounding nonfatal drug overdoses. All health departments participating in discharge data surveillance will be asked to complete the *ED/Inpatient Hospitalization discharge overdose data form* using ED and/or inpatient hospitalization discharge data already routinely collected in their jurisdiction.

  Specifically, participating health departments will submit line-level data on drug overdoses involving drug poisoning (i.e., any visit with a T36-T50 ICD-10-CM code, including all intents, encounters, and sequelae, including underdosing and adverse effects) (via a CSV file, following the CDC Data Dictionary); submit aggregate data on total ED visits and/or inpatient hospitalizations by county and by age, sex, and race/ethnicity (in an aggregate Excel template, Attachment E); and provide metadata such as coverage of the ED/hospital discharge surveillance system (e.g., percentage of all ED facilities captured by the jurisdiction's ED surveillance) (in the same aggregate Excel template, Attachment E). A total of 35 health departments are participating in DOSE discharge data submission/surveillance; 32 are sharing both ED and inpatient hospitalization data, and 3 are sharing inpatient hospitalization data only. The burden associated with each of these groups is described below.
  - 35 jurisdictions are sharing ED and/or inpatient hospitalization discharge data yearly, including 32 jurisdictions that contribute both ED and inpatient hospitalization data

and 3 states the contribute inpatient hospitalization data only. Based on optional experiences of health departments completing similar templates, the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E) will take a jurisdiction 3 hours to complete and will be completed yearly, for an annual burden per jurisdiction of hours (3 hours x 1 submission every year) or a total of 96 annual burden hours across 32 jurisdictions, and 3 states will complete the inpatient hospitalization data only at an estimated time burden of 2 hours (2 hours x 1 submission every year), or 6 hours across 3 jurisdictions.

- All 35 jurisdictions participating in discharge surveillance will submit line-level discharge/billing data on ED visits and/or inpatient hospitalizations involving a drug poisoning (i.e., line-level data on visits with any T36-T50 ICD-10-CM code, including all intents and encounters, underdosing, and adverse effects), in a CSV data form. There is no template for the line-level data, but the jurisdictions are provided with a data dictionary and technical guidance specifying which variables to include. After working with jurisdictions with varying degree of data size (e.g., some smaller states have fewer cases compared to other larger states), on average, the annual burden has been estimated at approximately 5 hrs to generate .csv file. Therefore, to generate a line-level .csv data form will take a jurisdiction 5 hours to complete and will be completed yearly, for an annual burden per jurisdiction of hours (5 hours x 1 submission every year) or a total of 175 annual burden hours across 35 jurisdictions.

Overall, burden associated with providing required data elements for DOSE ED/Inpatient Hospitalization Discharge surveillance (the *ED/Inpatient Hospitalization discharge overdose data form* + line-level csv file) results in a total 655 estimated burden of hours across all 35 jurisdictions annually. Furthermore, the revision request will result in an overall reduction in the currently approved total annual burden from 975 hours in 2023 to 655 hours, while decreasing the annual burden costs from $29,123 in 2023 to $25,211.

Table 4. 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 NSSP BioSense (OMB #0920-0824)*	Rapid ED overdose data form (Att. D)	45	12	30/60	270
Participating health departments sharing aggregate data from local syndromic data file	Rapid ED overdose data form (Att. D)	3	12	3	108
Participating health department sharing finalized ED and inpatient hospitalization aggregate data on total ED/inpatient hospitalization visits,	ED and hospitalization discharge overdose data form (Att. E)	32	1	3	96

and metadata on a yearly basis					
Participating health department sharing finalized aggregate data on total inpatient hospitalization visits, and metadata on a yearly basis	Inpatient hospitalization discharge overdose data form (Att. E)	3	1	2	6
Participating health department sharing line-level ED/inpatient hospitalization discharge data	Inpatient hospitalization discharge overdose data form (Att. E)	35	1	5	175
Total					655

* 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 ($38.49) as estimated by the Bureau of Labor Statistics (https://www.bls.gov/oes/current/999001.htm#00-0000 , accessed on 26Jul2024) was used to estimate burden costs.

Table 5. Estimates of annualized respondent burden costs

Type of respondent	No. of respondents	No. of responses per respondent	Total annual burden (hours)	Hourly wage rate	Total respondent cost
Participating health departments sharing aggregate data from NSSP BioSense	45	12	270	$38.49	$10,392
Participating health departments sharing aggregate data from local syndromic data file	3	12	108	$38.49	$4,157
Participating health department sharing finalized ED and inpatient hospitalization aggregate data on total ED/inpatient hospitalization visits, and metadata on a yearly basis	32	1	96	$38.49	$3,695

Participating health department sharing finalized aggregate data on total inpatient hospitalization visits, and metadata on a yearly basis	3	1	6	$38.49	$231
Participating health department sharing line-level ED/inpatient hospitalization discharge data (.csv) on drug overdose-related visits (i.e., any visit with an ICD-10-CM code between T36-T50, including all intents, encounters, underdosing, and adverse effects.	35	1	175	$38.49	$6,736
Total					$25,211

* 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 one senior data manager (100%)	$227,242
Contract to fund four data managers (100%)	$624,872
Other Direct Costs	

Subcontractors	$0
Travel and subsistence	$0
Total Estimated Contract Costs	**$852,114**

B) Government costs

Table 6. Cost to government - Government

Personnel	Tasks	Avg. cost/yr
2 Senior scientists (50%)	Program oversight and strategic direction	$ 135,591
9 Epidemiologists (50%)	• Direct technical assistance to participating health departments completing the *Rapid ED overdose data form* (Attachment D), the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E), *and line-level .csv file.* • Responsible for data quality checking in approximately 8 jurisdictions each, including addressing problems with data submitted in the *Rapid ED overdose data form* (Attachment D), the *ED/Inpatient Hospitalization discharge overdose data form* (Attachment E), *and the line-level .csv file.* • Enhance national overdose definitions, data quality and data sharing protocols used in DOSE. • Conduct rapid surveillance of suspected all drug, all 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	$524,538
9 Public health advisors (5%)	Programmatic, budgetary, administrative management and oversight of DOSE 2.0 as part of OD2A NOFO	$45,489
2 Data managers (100%)	• Manage and curate monthly data submitted in the *Rapid ED overdose data form* (Attachment D), the *ED/Inpatient hospitalization discharge overdose data form* (Attachment E), and line-level .csv file. • Implement system to rapidly and automatically	$250,000

	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.	
Indirect costs for staff (25%)		$955,618 + $238,904
Sub-total		$1,194,522
Contract Costs		$852,114
Total		$2,046,636

Total annual contractual and government staff costs are approximately $2.05 million. The remainder to complete this project is 3 years.

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 09/31/2025). Funding for DOSE 2.0 has been awarded in September 2023 and we are requesting an additional three years of data collection to match the OD2A-S NOFO (CDC-RFA-CE-23-0002) funding period. Revisions are requested to revise the number of eligible states, change the data collection template (see Attachment D-2), and revise burden. Based on current data sharing from states we have decreased our burden estimate to 655 from 975 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

Monthly, quarterly, and yearly trends in ED visits involving suspected all drug, all 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 DOSE website (https://www.cdc.gov/overdose-prevention/data-research/facts-stats/about-dose-system.html). A project time schedule is presented below.

Table 7. Time Schedule for Syndromic and Discharge Data Surveillance Activities

Task	Time Period
Ongoing processing of 1) monthly reports of ED visits involving suspected all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and	

other emerging drug overdoses captured via syndromic surveillance and submitted by public health departments to CDC (using *Rapid ED overdose data form* (Attachment D), and 2) annual reports of ED visits and/or inpatient hospitalizations for all drug-involved overdoses (i.e., visits with ICD-10-CM codes T36-T50) captured via discharge data surveillance and submitted by public health departments to CDC (using CSV file for line-level data and *ED/inpatient hospitalization discharge overdose data form* for aggregate data (Attachment E))	
Syndromic: Receive on a monthly basis *Rapid ED overdose data form* (Attachment D) from the jurisdiction **Discharge:** Receive on an annual basis *ED/inpatient hospitalization discharge overdose data form* (Attachment E) and line-level CSV file from the jurisdiction	**Syndromic:** 1 – 2 month delay from when the overdose ED visit occurred (e.g., overdoses occurring in January 2024 will be reported to CDC in March 2024). **Discharge:** Jurisdictions submit ED/inpatient hospitalization data from the previous year each July, with a 1–2 month delay for processing the data (e.g., 2023 data submitted in July 2024).
Syndromic: 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. **Discharge:** Analysis files are validated within 1–2 month(s) of receipt of data from jurisdiction.	**Syndromic:** 2 – 3 month delay from when the overdose ED visit occurred (e.g., analytic file for overdoses occurring in January 2024 will be completed by CDC by the end of April 2024 or earlier) **Discharge:** Data from the previous calendar year (e.g., Jan – Dec, 2023) will be uploaded in the fall of each year (e.g., October, 2024) (less than 12 month delay from end of previous calendar year) as well as data from prior years if updated historic data was submitted by the jurisdiction.
Syndromic: At least monthly: yearly and monthly changes in ED visits involving suspected all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine overdoses will be posted on the web for public access* **Discharge:** Annually: counts and rates from participating states and local jurisdictions will be posted on the web for public access, including ED visits and/or inpatient hospitalizations involving suspected all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine overdoses.**	**Syndromic:** 2 – 3 month delay from when the overdose ED visit occurred (e.g., analytic file for overdoses occurring in January 2024 will be completed by CDC by the end of April 2024 or earlier) **Discharge:** Data from the previous calendar year will be uploaded in the fall of each year (less than 12 month delay from end of previous calendar year) as well as data from prior years if updated historic data was submitted by the jurisdiction.
Publish surveillance reports and epidemiologic analyses of DOSE data to support public	

health prevention efforts	
Syndromic: Analyze trends in ED visits to identify important patterns to inform public health action regarding all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses	**Syndromic:** At least one article per year using ED syndromic data will be published, starting 1 year after the DOSE system begins operating.
Discharge: Analyze trends in ED visits and/or inpatient hospitalization visits to identify important patterns to inform public health action regarding all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses.	**Discharge**: At least one article per year using ED and/or inpatient hospitalization data will be published, starting 1 year after the DOSE system begins operating.
Conduct analyses to support improved data collection and analysis	
Syndromic / Discharge: Conduct ongoing comparisons of ED data collected on the *Rapid ED overdose data form* (Attachment D) with ED data collected on the *ED/inpatient hospitalization discharge overdose data form* (Attachment E) to inform improvements to both data collections	**Syndromic / Discharge:** 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/overdose-prevention/data-research/facts-stats/dose-dashboard-nonfatal-surveillance-data.html.

**Data are posted here: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/dose-dashboard-nonfatal-discharge-data.html

Initial publications focused on:

- Identifying patterns of polysubstance use among individuals treated in the ED for drug overdoses and how this pattern 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 all drug, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, and benzodiazepine overdoses with trends observed in all drugs, all opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine 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 determinants 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/Inpatient Hospitalization discharge overdose data form*. The OMB number will be displayed on the *Rapid ED overdose data form* and the *ED/Inpatient Hospitalization 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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