SUPPORTING STATEMENT: PART A

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Drug Overdose Surveillance and Epidemiology (DOSE)

OMB# TBD

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- **Goal of the study –** Rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant 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 52 health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) with CDC.
- **Intended use of the resulting data -** Improve local, state, and regional situational awareness of drug, opioid, heroin, and stimulant 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 and territorial health departments. 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-two funded health departments (50 state health departments, Puerto Rico, 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 60% 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, and stimulant overdoses by county, age group, sex, 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 52 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, 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, or stimulant 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

CDC requests OMB approval for three years for this new data collection, the Drug Overdose Surveillance and Epidemiology (DOSE) system. DOSE funds 52 health departments (50 state health departments, the health department of Puerto Rico and the health department of the District of Columbia) to rapidly share existing ED data on counts of ED visits involving suspected drug, opioid, heroin, and stimulant 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.

Two circumstances make DOSE necessary. First, the rapid increase in opioid overdose deaths since 2013,[1] numerous severe fentanyl and fentanyl analog outbreaks occurring across the United States,[2,3,4,5,6] and the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017[7] have highlighted the urgent need to rapidly establish and enhance timely surveillance of suspected drug, opioid, heroin, and stimulant 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, the District of Columbia, and Puerto Rico drug overdose ED surveillance currently funded through the CDC Enhanced State Opioid Overdose Surveillance Funding Opportunity (ESOOS; CDC-RFA-CE16-1608).[8] This expansion occurs as a component of CDC's Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904), posted February 1, 2019. Initiated in 12 states in September 2016, ESOOS currently funds 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 use 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). DOSE will replace and enhance ESOOS ED data sharing.

Three key lessons from ESOOS informed the enhanced data sharing that DOSE will implement.

1. In order to collect more comparable and standardized data across the 52 participating health departments, DOSE will require participating health departments to rapidly report local ED data to CDC in a standard manner using *the Rapid ED overdose data form* and CDC case definitions. In contrast, ESOOS data sharing currently uses state-based drug overdose definitions and data sharing models (i.e., not standardized across states).
2. DOSE expands data sharing with participating health departments to include counts of ED overdose visits suspected to involve stimulants. This responds to sharp increases in deaths involving stimulants as well as increased co-use and mixing of opioids with stimulants over the past few years.[9,10]
3. 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 compare counts of drug,

opioid, heroin, and stimulant 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). Based on their local hospital discharge data collection, all participating health departments will be required to either report hospital discharge data to CDC quarterly or once a year in a standard manner using the *ED discharge overdose data form* and CDC case definitions.

The shift to requiring the use of two standard data reporting forms, *the Rapid ED overdose data form* and *ED discharge overdose data form,* and CDC case definitions requires OMB approval and is described in this form.

Background: The opioid overdose epidemic is a public health emergency

Drug overdose deaths in the United States increased by 16% per year from 2014 through 2017 and increased by 10% from 2016 to 2017 to over 70,000 deaths.[11] More than two out of three drug overdose deaths in 2017 involved an opioid,[12] and opioid overdose deaths have increased six-fold from 1999 to 2017.[13] Non-fatal opioid overdoses are on the rise as well; ED data on opioid overdoses showed a 30% increase in visits involving opioid overdoses from July 1, 2016 to September 30, 2017 that affected all US regions, age groups, and sexes.[14] 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, [15] joining at least eight states that have declared the opioid overdose epidemic a statewide emergency. [16] The opioid overdose epidemic is one of the U.S. Department of Health and Human Services (HHS) top priorities. In 2017, HHS launched a 5-point Opioid Strategy: 1) Access: Better Prevention, Treatment, and Recovery Services, 2) Data: Better Data on the Epidemic, 3) Pain: Better Pain Management, 4) Overdoses: Better Targeting of Overdose-Reversing Drugs, and 5) Research: Better Research on Pain and Addiction. [17] DOSE is a critical element of HHS's second goal to support timelier and more specific data through accelerating the speed at which CDC's reports drug overdose data.

Finally, the rapid increases in overdoses related to fentanyl and heroin coupled with multiple local and state reports of severe and oftentimes widespread opioid overdose outbreaks since 2013[18,19,20,21,22] highlight the need for more rapid, comprehensive and coordinated local, state and regional surveillance and response to emerging drug overdose trends. Due to the rapid worsening of the opioid crisis, enhanced surveillance also needs to be established quickly, within a year of funding states when feasible.

Drug Overdose Surveillance and Epidemiology (DOSE)

The Drug Overdose Surveillance and Epidemiology (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 by the end of the three-year OMB period. DOSE will replace ESOOS.

DOSE is made possible because the vast majority of the 52 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)[23] diagnosis codes, assigned the ED visit on approximately 60% of ED visits 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 (>4,000 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, Puerto Rico, 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.[24, 25]

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, and stimulant 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

Fifty-two funded health departments (50 states, Puerto Rico and the District of Columbia) will be required to complete the *Rapid ED overdose data form* (See Attachment D) on a monthly basis using data from existing local ED data collection efforts, described above, and share with CDC.

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. While states sharing case-level ED data with CDC will accomplish this goal, some health departments using local ED syndromic systems or hospital discharge data may start by submitting quarterly reports to CDC and transition to monthly reporting overtime due to limitations in their local data collection.

2. **Key variables shared with CDC**. Key variables why they are collected is described in Table below.

Variable	Justification for collecting
Count of ED visits suspected to involve 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[26,27] or synthetic cannabinoids[28] 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 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,[29] and work in ESOOS.[30,31] • The general category of "opioids" will be tracked instead of specific types of

Variable	Justification for collecting
	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. [32, 33]
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.[34,35] • While other types of opioids proved difficult to track using ED data, work in 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 visits suspected to involve stimulants	• Recent increases in stimulant overdoses such as cocaine and methamphetamine and co-use with opioids[36,37] 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.
Sex, age group, and county level data by drug overdose indicators	Aggregating data on drug, opioid, heroin, and stimulant overdose by sex, age group 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.
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 52 participating health departments to report major changes in ED participation or data quality each month.
Three new overdose indicators	Due to the rapidly evolving nature of the opioid overdose epidemic and surveillance work, CDC anticipates the need to create three new overdose indicators during Year 1 and Year 2 of the project that capture overdoses that involve specific drugs not currently tracked (e.g., benzodiazepines) or only tracked by drug class (e.g., cocaine is

Variable	Justification for collecting
	part of the stimulant indicators).

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

The 52 funded health departments (50 states, Puerto Rico and the District of Columbia) will be required to complete the *ED discharge overdose data form* (See Attachment E) on a quarterly or yearly basis using hospital billing discharge data. 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 26 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 52 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, and stimulant 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 three-year pilot to access whether the analysis and dissemination of ED and hospitalization burden data on drug overdoses can be accelerated through targeted data sharing.

This program is authorized under section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act and section 391 (a) [42 U.S.C. 280(b)] of the Public Service Health Act (See Attachment 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" (See Attachment A2).

2. Purpose and Use of Information Collection

DOSE has the following critical public health applications:

- *DOSE will improve situational awareness of federal, state, and local health departments of emerging drug overdose outbreaks and the progression of the opioid overdose epidemic.* At a minimum, DOSE will share preliminary data with HHS and CDC leadership approximately 3 months after the end of the quarter in which the drug overdose occurred (e.g., share data on drug, opioid, heroin, and stimulant overdoses occurring between January – March, 2020 by July, 2020). State health departments will have monthly or faster access to their aggregate data. Timely preliminary ED data on suspected drug, opioid, heroin, and stimulant overdoses can be used to more rapidly detect and confirm acute state or multistate drug overdose outbreaks that require regional or national responses. A number of investigations of drug overdose outbreaks have found that ED syndromic data detected the outbreak early and could provide situational awareness of its spread.[38,39] Also, large increases in ED visits involving opioid overdoses in the Midwest during 2016-2017 found that a major factor were suspected opioid overdoses outbreaks (i.e., sharp increases in opioid overdoses over a single three-month period) affecting districts within states.[40] The ability of DOSE to analyze county data (Note: Alaska, Louisiana and Puerto Rico do not use counties but instead use borough, parish, or municipality, respectively) across the 50 US states, District of Columbia, and

Puerto Rico will make it a powerful tool to detect, confirm and respond to major outbreaks, especially those extending across state borders.

- *DOSE will enhance public awareness of the progression of the opioid overdose epidemic and other emerging drug overdose threats in their area:* Limited timely local and state data is available on nonfatal and fatal drug overdoses. Currently, the National Center of Health Statistics publishes preliminary drug overdose death data from the death certificate with a 7-month delay.[41] These data, however, are only available at the state level, report 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 are available from the Health Care Utilization Project (HCUP) with a two to three year delay and not available for all states.[42] DOSE will address these gaps in the following ways:
    - DOSE will publish to the web at least twice a year changes in ED visits suspected to involve drug, opioid, heroin and stimulant overdoses by state as well as changes by sex and age group. In its first two years of operation, ESOOS has demonstrated the value of timely ED data by helping identify a stabilization of opioid overdoses rates in the second half of 2017 and highlighted that some states are still experiencing increases.[43] This trend has been confirmed in other data sources.[44,45]
    - DOSE will also monitor trends in suspected drug, opioid, heroin, and stimulants overdose across states in order to identify large changes and identify suspected outbreaks. This will further speed the identification and response to drug overdose outbreaks or trends shifts.
    - With the goal of monitoring at least 75% of all non-federal ED visits for suspected drug, opioid, heroin, and stimulant overdoses, DOSE also will work to build state and local health department capacity to increase public awareness of drug overdose trends in their community (e.g., county or city), especially drug overdose outbreaks.
- *DOSE will enhance local health department surveillance of suspected drug, opioid, heroin and stimulant overdoses.* A growing number of jurisdictions are implementing alert systems that use CDC national and state drug, opioid, heroin, and/or stimulant definitions to detect drug overdose outbreaks within their states. DOSE will continue to improve these definitions in collaboration with the 52 participating health departments. Also, data sharing work with CDC is helping identify issues within state ED data collections that support more accurate local monitoring of outbreaks.
- *Assist states in mandatory reporting requirements of overdose*. Over the past few years, states have begun to consider legal statutes requiring the reporting of nonfatal drug overdoses treated in EDs to state health departments.[46] The foundation laid by ESOOS and the continued work with DOSE will enable state health departments to be ready for such circumstances. For example, states can use the standard CDC definition to identify suspected drug overdoses to be included in their mandatory reporting system. Specifically, two funded ESOOS states (New Mexico and Tennessee) have integrated some aspects of the CDC case definition in their process for identifying reportable drug overdoses.

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 4,000 hospitals and around 60% of ED visits in the US is currently shared with CDC through the NSSP BioSense platform. 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 33 health departments (32 state health departments and District of Columbia) will provide CDC access to their ED data within the NSSP BioSense platform using ESSENCE. 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 19 health departments (18 state health departments and Puerto Rico) not expected to share case-level ED data with CDC through NSSP BioSense, DOSE will:
    a. Develop 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, and stimulant 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. 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:
        i. 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 52 funded state health departments (50 state health departments, the Puerto Rico health department, and the District of Columbia health department) will share hospital discharge data with CDC quarterly or yearly 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.[47] 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 Unintentional Injury Prevention (DUIP) 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 and stimulant overdoses by leveraging the approximately 60% of ED visits in the US that are shared by local health departments or their partners with CDC through the NSSP BioSense Platform. The collaborative effort between DUIP and DHIS includes the following elements:

1. State and local health departments participating in CDC NSSP BioSense have the opportunity to share ED data on specific illnesses and injuries with CDC through NSSP BioSense collaborative projects. In 2016, DUIP launched a NSSP BioSense collaborative project to enhance state health departments sharing of ED data on suspected drug, opioid, and heroin overdoses with CDC. This collaborative data sharing agreement is covered by an existing OMB PRA (National Syndromic Surveillance Program BioSense Platform - OMB #0920-0824) and will be expanded from 18 health

departments currently sharing as part of ESOOS to an estimated 33 health departments in DOSE by the end of 2019. CDC will complete the *Rapid ED overdose data form* for the 33 health departments and share the results with the health department for verification.

2. 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. To expand the use of NSSP BioSense by the 19 participating health departments expected to not share data through NSSP BioSense as well as improve the quality of NSSP BioSense data, CDC is supporting two efforts:
    a. CDC funded efforts to expand and improve the NSSP BioSense platform as part of CDC's emergency response to the opioid overdose epidemic. The FY 2018 Consolidated Appropriations Act and Accompanying Report includes an increase in funding appropriated to Centers for Disease Control and Prevention (CDC) to "advance the understanding of the opioid overdose epidemic and scale up prevention activities across all 50 States and Washington, D.C." Responding to this goal, CDC activated CDC-RFA-TP18-1802 Cooperative Agreement for Emergency Response: Public Health Crisis Response funding to those affected by the opioid overdose epidemic.[48] Jurisdictions applying for this funding had the opportunity to use the one-year funding to expand hospital participation in NSSP BioSense and improve their capacity to use timely and comprehensive syndromic surveillance data on non-fatal opioid overdoses.
    b. In CDC's Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904) posted February 1, 2019, DUIP strongly encourages all 52 eligible health departments to share ED data with CDC through NSSP BioSense. Specifically, participating health departments that propose to share case-level ED data on suspected drug, opioid, heroin and stimulant overdoses through NSSP BioSense will be funded at higher levels than health departments sharing ED data from other sources (e.g., local ED syndromic systems or hospital discharge). This should over time encourage more data sharing through NSSP BioSense.
3. DOSE staff is collaborating with NSSP BioSense staff to optimize the use of ESSENCE to share and analyze data on ED visits involving suspected drug, opioid, heroin and stimulant overdoses. The collaboration involves intensive communication, limited detailing of NSSP BioSense staff to this project and funding to enhance the NSSP BioSense platform. Deliverables of this collaboration include:
    a. Providing state and local health department access to standardized improved national definitions of suspected drug, opioid, heroin and stimulant overdoses that can be applied to their data in real-time to better detect local drug overdose outbreaks.
    b. Creating tools to assess and improve NSSP BioSense ED data quality at the local, state, and national levels.
    c. Enhance DUIP's ability to analyze suspected drug, opioid, heroin and stimulant overdoses in NSSP BioSense.

DUIP took a number of actions to identify and contact other federal programs collecting ED data to ensure coordination and avoid duplication. First, CDC had preliminary conversations about

this data collection effort with OMB in the summer of 2018. During the phone call, OMB recommended contacting and coordinating with a number of other federal agencies including NCHS and SAMHSA that are already collecting ED data. As recommended by OMB, DUIP conducted outreach and held conversations with these agencies in fall 2018 and into early 2019 (see below for detail on what was learned). Finally, CDC has created the Opioid Response Coordinating Unit (ORCU) to ensure coordination of CDC's responses related to the opioid overdose epidemic.

Through the conversation with OMB and ORCU as well as DOSE planning work, 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 system	Description	Time lag	Purpose of ED system	Additional Value of DOSE	Recent contact
Health Care Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS)[49] 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.	• DUIP regularly analyzes HCUP data through the CDC data hub[50] 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)[51] 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.	• DUIP regularly analyzes HCUP data through the CDC data hub[52] as part of our efforts to understand the opioid overdose epidemic • Review of HCUP materials
The Drug	In fall 2018,	Reporting	The new DAWN is	• DOSE will provide	• Multiple phone

ED data system	Description	Time lag	Purpose of ED system	Additional Value of DOSE	Recent contact
Abuse Warning Network (DAWN) operated by SAMHSA[53] OMB # 0930-0078	SAMHSA restarted the DAWN surveillance system after a 7 year period of inactivity. Trained abstractors employed by the DAWN data contractor will mine existing hospital electronic health record (EHR) systems. DAWN will begin data abstraction in mid-2019 with a 25 hospitals, and will grow to a total of 50 hospitals in DAWN's second year. The new DAWN will be 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.	frequency is still be determined, but likely will be monthly to quarterly.	bringing in hospitals in three categories: 1) hospitals purposively selected from areas with high drug overdose burden; 2) hospitals 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.	timely local and regional situational awareness because it will monitor at least 75% of ED visits across all 50 states, Puerto Rico, and the District of Columbia, or over 4,000 hospitals. • DOSE will include data from all communities, regardless of overdose burden.	conversations have been held between summer 2018 and winter 2019. Future phone calls are planned. • Frequent email conversation continues with key SAMSHA, DAWN staff • Key contact person: Elizabeth Crane, Division of Surveillance and Data Collection, CBHSQ, SAMHSA.
National Electronic Injury Surveillance System -- Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project conducted by	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	~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	• 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	• Ongoing discussions because DUIP contributes and collaborates on the data collection. • Key Contact Person: Dan Budnitz, Division of Healthcare Quality

ED data system	Description	Time lag	Purpose of ED system	Additional Value of DOSE	Recent contact
CDC in collaboration with FDA and Consumer Product Safety Commission.[54] OMB #: 3041-0029	overdose. In 2017, NEISS-CADES began collecting ED visits involving prescription opioid overdoses as well as ED visits involving adverse events. NEISS-CADES has abstractors manually review targeted ED visits		related to illicit opioids such as heroin or illicitly-made fentanyl or allow for state estimates.	heroin or illicitly-made fentanyl	Promotion, NCEZID, CDC
SAMHSA Emergency Department Surveillance System (SEDSS) leverages data from the National Center for Health Statistics (NCHS) National Hospital Care Survey (NHCS). [55] OMB #: 0920-0212	SEDDS draws EDs from the NHCS nationally representative sample of ~500 acute care hospitals. Of this sample, around 200 EDs participate in SEDDS. While not nationally representative, work continues to become nationally representative. SEDDS automatically receives data from hospitals' electronic health records (EHR) and currently uses diagnostic and procedural codes from the UB-04 administrative claims data to identify and describe drug-related ED visits.[56] Approximately 1,000 acute care hospitals outside the NHCS sample have expressed interest in the program, but are not sending data at this time.	The current time lag in reporting is 3 years, with the most recent data from 2015. The electronic infrastructure of the system, however, lends itself to rapid data sharing over time.	SEDSS collects data electronically and in the future may be able to produce national estimates. Also, SEDSS collects identifiable patient information that can be used to link SEDSS to other datasets (e.g., the National Death Index) or track the same patient overtime.	• DOSE will provide timely local and regional situational awareness because it will monitor at least 75% of ED visits across all 50 states, Puerto Rico, and the District of Columbia, or over 4,000 hospitals. • DOSE data will be rapidly available (within one month of ED visit) and thus can inform more rapid response to changes in drug overdose patterns. • DOSE gathers data from local surveillance systems ensuring local health departments and CDC are using the same data to track outbreaks and trends. This is a critical element of syndromic surveillance.[57]	• Phone conversations 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, DUIP 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, and stimulant overdoses.

- If a DAWN hospital reports an outbreak or is located in an area identified by DOSE as experiencing a drug, opioid, heroin or stimulant outbreak, 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, the District of Columbia and Puerto Rico 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. [58,59,60,61,62] Also, the nature and complexity of drug overdoses continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl,[63] cocaine products laced with fentanyl,[64] increasing overdoses involving synthetic cannabinoids[65] and large increases in overdose deaths involving methamphetamines and cocaine.[66] 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.[67] 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.[68]
- 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, and stimulant 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. [69,70,71,72,73] Also, the nature and complexity of the drug overdoses continues to rapidly evolve with distribution of counterfeit prescription pills laced with fentanyl, [74] cocaine products laced with fentanyl, [75] increasing overdoses involving synthetic cannabinoids[76] and large increases in overdose deaths involving methamphetamines and cocaine. [77] 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 33 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, and stimulant 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 2, 2019. Vol. 84. No. 63, pp. 12610 (Attachment B). CDC received and responded to one substantive public comment (Attachment B1). The substantive public comments

expressed appreciation for the collection and the way done. No changes were made to the data collection.

B. Efforts to Consult Outside the Agency

DUIP, NCIPC is currently receiving feedback from 32 state public health departments and the District of Columbia on improving rapid ED surveillance of suspected drug, opioid, and heroin overdoses who are participating in the ESOOS program. Secondly, intensive consultation with Ohio,[78] Massachusetts, and Rhode Island[79] 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.

DUIP, 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. DOSE is housed within the NCIPC Partner's Portal web-based system. The Partner's Portal system has a current Authorization to Operate. The Privacy Impact Assessment (PIA) is attached (Attachment F1). Also, the Privacy Impact Assessment (PIA) for the DOSE data templates (i.e., Rapid ED overdose data form and ED discharge overdose data form is attached (Attachment F2).

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

1. State health departments, the District of Columbia and Puerto Rico (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 a subset of 33 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 52 participating health departments.[80]

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 (Attachment C).

12. A. Estimates of Annualized Burden Hours and Costs

This data collection includes two data forms:

- *Rapid ED overdose data form (Form 1)* supports rapid monthly ED surveillance of suspected drug, opioid, heroin and stimulant overdoses to detect outbreaks and provide situational awareness (See Attachment 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 and stimulant overdoses that occurred each month by county and by age and sex. 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). Although the goal is monthly reporting, some jurisdictions may only be able to share data quarterly due to limitations in their existing local ED data. These jurisdictions over time will be expected to shift to monthly reporting. 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.
    - *Health departments sharing data with CDC through NSSP BioSense:* CDC expects at least 33 of the 52 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 and stimulant overdoses that occurred each month by county and by age and sex. 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 198 burden hours across the 33 responding health departments.

- *Health departments sharing local syndromic ED data or hospital discharge data:* CDC expects about 19 of the 52 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. 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 684 annual burden hours across all 19 responding health departments.

- *ED discharge overdose data form* (Form 2) supports quarterly or yearly hospital discharge surveillance of ED visits involving suspected drug, opioid, heroin and stimulant overdoses to evaluate rapid ED surveillance and assess drug overdose burden (See Attachment 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 52 participating health departments (50 state health departments, the District of Columbia and Puerto Rico) 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 and stimulant overdoses by county and by age and sex 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). Due to variations in the collection of local ED hospital discharge data across jurisdictions, CDC expects up to 26 health departments to submit data quarterly and at least 26 health departments to submit data yearly. The burden associated with each of these groups is described below.

    - CDC estimates that up to 26 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 312 annual burden hours across 26 jurisdictions.
    - The remaining 26 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 78 annual burden hours across 26 jurisdictions.

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	Rapid ED	19	12	3	684

departments sharing aggregate data from local syndromic or hospital discharge file	overdose data form (Att. D)				
Participating health departments sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920-0824)*	Rapid ED overdose data form (Att. D)	33	12	30/60	198
Participating health department sharing finalized hospital discharge data on a quarterly basis	ED discharge overdose data form (Att. E)	26	4	3	312
Participating health department sharing finalized hospital discharge data on a yearly basis	ED discharge overdose data form (Att. E)	26	1	3	78
Total					1,272

* 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 ($27.34) as estimated by the Bureau of Labor Statistics (https://www.bls.gov/oes/current/999001.htm#00-0000 , accessed on 10Sept2018) 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	19	12	684	$27.34	$18,700

Participating health departments sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920-0824)*	33	12	198	$27.34	$5,413
Participating health department sharing finalized hospital discharge data on a quarterly basis	26	4	312	$27.34	$8,530
Participating health department sharing finalized hospital discharge data on a yearly basis	26	1	78	$27.34	$2,133
Total					$34,776

* 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 data manager (50%)	$ 43,750
Other Direct Costs	

Subcontractors	$0
Travel and subsistence	$0
Total Estimated Contract Costs	**$43,750**

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 52 participating health departments completing the *Rapid ED overdose data form* and the *ED discharge overdose data form.* • Responsible for data quality checking in approximately 10 jurisdictions each, including addressing problems with data submitted in the *Rapid ED overdose data form* and the *ED discharge overdose data form.* • Enhance national overdose definitions, data quality and data sharing protocols used in DOSE. • Conduct rapid surveillance of suspected drug, opioid, heroin, and stimulant 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
3 Data managers • 1 manager (100%) • 2 managers (80%)	• 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.	$270,400

Indirect costs for staff (25%)		$222,922
Sub-total		$1,114,611
Contract Costs		$43,750
Total		$1,158,361

Total annual contractual and government staff costs are approximately $1.2 million. This is a three year project.

15. Explanation for Program Changes or Adjustments

This is the first time this data collection has been reviewed.

16. Plans for Tabulation and Publication and Project Time Schedule

Monthly, quarterly, and yearly trends in ED visits involving suspected drug, opioid, heroin and stimulant overdoses at the state level will be reported publicly on an ongoing basis by CDC. Additional analyses examining data by age group, sex, 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. 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, and stimulant overdoses submitted by public health departments to CDC (i.e., *Rapid ED overdose data form*)	
Receive on a monthly basis *Rapid ED overdose data form* (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 and opioid 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).

Support response to severe and/or large drug overdose outbreaks	
Support at least 2 rapid responses to severe and/or large drug overdose outbreaks per year. CDC is launching opioid response teams in 2019 to provide intensive support to states impacted by the opioid overdose epidemic.[81]	Once data sharing begins, DOSE will support CDC, state, and local drug overdose outbreak response activities on an as needed basis.
Publish surveillance reports and epidemiologic analyses 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 and stimulant 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 *Rapid ED overdose data form* with ED data collected on the *ED discharge overdose data form* 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 will posted in a manner similar to reports published by ESOOS at https://www.cdc.gov/drugoverdose/data/nonfatal.html .

Initial publications will focus 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.
- Determine 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.

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 52 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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