SUPPORTING STATEMENT: PART B

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Drug Overdose Surveillance and Epidemiology (DOSE)

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1. Respondent Universe and Sampling Methods

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. The DOSE system originally received OMB approval to collect data from 50 states, the District of Columbia and Puerto Rico, and currently captures data from 47 states and the District of Columbia. We seek to expand to all 50 states and the District of Columbia in 2023. No sampling methods will be employed. Our goal was to build a system that captured at least 75% of all non-federal ED visits in participating health department. At present (January 2022), the DOSE system captures, on average, 85% of ED visits in 47 states and the District of Columbia. The goal is 75% instead of a 100% because ongoing work with 47 state health departments and the District of Columbia found that some local rapid ED data collection do not have full participation of all EDs in their jurisdiction.

2. Procedures for the Collection of Information

The health departments participating in DOSE will share up to two types of data with CDC on an ongoing basis:

1. Counts of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses by county as well as age group, sex, and race/ethnicity. Data will be shared with CDC on a monthly basis using a standardized Excel form, the *Rapid ED overdose data form* (Att D*)*, and standard CDC case definitions of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses. Also, measures of data quality and metadata will be collected and are described in the SSA and Att D.
2. Counts of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses extracted from hospital discharge data files. Data will be shared with CDC yearly or quarterly using a standardized Excel form, the *ED discharge overdose data form* (Att E), and standard CDC case definitions of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses. Data will be aggregated by county as well as age group, sex, and race/ethnicity. Also, measures of data quality and metadata will be collected and are described in the SSA and Att E.

The specific procedures CDC will use to collect the *Rapid ED overdose data form* and the *ED discharge overdose data form* from the participating health department is described below.

Procedures for collecting the Rapid ED overdose data form (Att D) on a monthly basis

The following procedures will be used to collect the *Rapid ED overdose data form*.

Step 1: Participating health departments must choose what existing data source they will use to complete the *Rapid ED overdose data form.* The three options are:

1) *National Syndromic Surveillance Program (NSSP) BioSense Platform (OMB #0920-0824):* State and local health departments share preliminary case-level ED data in near-real time with CDC. These data include the chief complaint of the patient seeking care at the ED (e.g., "heroin overdose", "opioid poisoning", and "cocaine OD") and/or diagnosis codes, primarily the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. Chief complaints tend to be submitted within 24 hours of the ED visit while ICD-10-CM codes may take a few weeks.
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 and also work to collect data in near real-time.
3) *Hospital ED Discharge Data:* Some health departments have no or limited ED syndromic surveillance. These states, however, may 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.

Step 2: Using CDC case definitions for drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses, participating health departments collaborate with CDC to complete the *Rapid ED overdose data form* on ED visits that occurred one to two months before the reporting date (e.g., ED visits occurring in January 2022 would be reported at the beginning of March, 2022). The procedure for sharing the data with CDC varies slightly depending on the ED data source used by the health department.

1) *National Syndromic Surveillance Program (NSSP) BioSense Platform:* Using access to case-level ED data provided to CDC through the NSSP BioSense platform, CDC will complete the vast majority of the *Rapid ED overdose data form* each month including calculating the total number of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses that occurred each month by county and by age, sex, and race/ethnicity. CDC, however, will need to consult with the participating health department when completing metadata and will also share the *Rapid ED overdose data form* with the participating health department to validate the CDC analysis.
2) *State or Territorial ED Syndromic Surveillance and Hospital ED Discharge Data:* Participating health departments will be responsible for completing the *Rapid ED overdose data form* each month using CDC case definitions for suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses. CDC has reduced burden on health departments and maintained consistent application of its case definitions by supplying participating health departments SAS, R, and ESSENCE programs that states and territories can use to automatically apply the CDC definition to their data and produce required counts in a format compatible with the *Rapid ED overdose data form.*

Step 3: Participating health departments that are not sharing data with CDC through the NSSP BioSense platform will submit the *Rapid ED overdose data form* to CDC using the

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. The NCIPC Partner's Portal will conduct automatic data quality checks on submitted files to verify that required data is submitted without major data quality issues. This process will improve data quality and reduce the need for multiple data submissions by state and local health departments. The CDC SAMS partner portal which hosts the NCIPC 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 the participating health departments.[1]

Step 4: Up to one month will be taken for CDC to collaborate with participating health departments to validate their submitted data for dissemination. Data with no significant issues are expected to be validated much quicker than a month. In contrast, data with significant issues may have to be resubmitted and/or excluded from analyses on a case-by-case basis. On average, CDC is currently able to validate data and close out each data submission within two and a half weeks. Key parts of the validation process include:

- Ensuring all required data was submitted in the correct format using the CDC case definitions on the required reporting date.
- Ensuring the data submission is internally consistent (i.e., total ED visits broken down by sex, age, and race/ethnicity match those broken down by county).
- Identify and discuss with submitting health departments large changes in total ED visits or data quality (e.g., large drop in the number of ED visits or a large drop in the number of ED visits with a valid ICD-10-CM code) identified in the metadata or review of aggregate data reported to CDC.

Step 5: CDC will convene a workgroup of participating health departments at least once every two months to identify ways to improve the data sharing process, data quality, case definitions and analytic approach of DOSE.

Procedures for collecting the ED discharge overdose data form (Att E) on a quarterly or yearly basis

The procedures for completing *the ED discharge overdose data form* are the same as discussed above for the *Rapid ED overdose data form* except for the following exceptions.

- All participating health departments able to share discharge data with CDC must complete the *ED discharge overdose data form* using CDC case definitions and using hospital discharge data (i.e., ICD-10-CM diagnosis codes). The *ED discharge overdose data form* collects counts of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses on both ED visits not resulting in hospitalizations and ED visits resulting in hospitalizations.
- The goal is to have the data reported to CDC quarterly.

Proposed analyses used on data

The following types of statistical methods will be used to analyze the data:

- Descriptive analyses such as analyzing the percent change in the rate of ED visits (number of overdose ED visits divided by total ED visits per time period multiplied by 10,000) involving drug, opioid, heroin, fentanyl, all stimulant,

cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses by US region, state/territory, county, sex, race/ethnicity, and age group.
- Long-term trends analyses using Joinpoint regression or hierarchical linear modeling.
- Latent class analyses to look at patterns in polysubstance use by sex, race/ethnicity, age group, and geographic location.
- Identifying and tracking possible outbreaks within states by working with health departments to analyze trend changes in drug, opioid, heroin, or stimulant overdoses at the county level or districts level (e.g., districts are combinations of counties within state designed by states).

Estimation Procedures

The data collection will not use statistical weighting because:
- The census will include a minimum of 75% of all ED visits (i.e., a significant portion of all ED visits). At present (January 2022), the DOSE system captures, on average, 85% of ED visits in 47 states and the District of Columbia.
- The primary goal of syndromic surveillance is to provide situational awareness and inform response. In order to achieve these goals, regional and state surveillance needs to be able to track and validate large changes in drug overdoses by examining the specific local area or hospital data driving the large change.
- The primary goal of DOSE is to detect rapid changes over time in participating hospitals instead of estimating the incidence of drug overdose through estimation procedures. Consequently, the key concern is monitoring for substantial changes in ED participation or data quality over time that would bias detection of outbreaks or changes in suspected drug, opioid, heroin, or stimulant overdoses (See **Unusual Problems** for a description for how DOSE works to track and respond to this potential bias).
- Participating hospitals are not randomly selected and limited information is available on non-participating hospitals. This coupled with the small percent of non-participating hospitals would make accurate adjustments for non-response difficult and expensive.

Degree of Accuracy

This issue does not apply to this methodology.

Unusual Problems

ED syndromic systems are designed to collect rapid preliminary data on changes in illness and injuries such as drug overdose. These systems, however, may not provide an accurate estimate of the full burden of illnesses and injuries because they are based on preliminary data. DOSE addresses this limitation in the following ways:
1. CDC analyses will primarily focus on detecting outbreaks and rapid changes in drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses to inform response. Consequently, public health departments can share data from different ED data sources because the key data requirement is the ability to detect change over time within each jurisdiction (e.g., data consistently collected within the same

jurisdiction overtime) and not comparing absolute counts and rates of overdose across participating health departments (e.g., one jurisdiction may report a slightly higher opioid overdose rate than another jurisdiction because it captures 95% of ICD-10-CM codes on ED visits within a month of the date of the ED visit compared to the other jurisdiction which captures only 60%).

   a. CDC will not compare numbers or rates of suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses calculated using data from *Rapid ED overdose data form* across jurisdictions (e.g., say one state has a higher overdose rate than another state) because the data sources and data quality vary across jurisdictions (e.g., one jurisdiction may report a higher heroin overdose rate than another jurisdiction because it EDs commonly describe patient's chief complaint with two to three sentences compared to another jurisdiction where chief complaints are commonly described with two or three words).
   b. CDC will not analyze rates (e.g., ED visits suspected to involve opioid overdoses divided by total number of ED visits in a state) with fewer than 20 cases in the numerator (e.g., number of ED visits suspected to involve opioid overdoses) because of possible statistical instability of rate estimates. For instance, CDC will not report the percent change in suspected opioid overdose rates from January to February 2022 if only 19 ED visits were suspected to involve an opioid overdose in January 2022.

2. CDC will monitor the preliminary ED data submitted on the *Rapid ED overdose data form* by each jurisdiction for large monthly changes in hospital participation or data quality (e.g., percent of ED visits missing chief complaint and/or ICD-10-CM diagnosis information). This is critical to identify and respond to major changes in ED syndromic systems such as transmission delays associated with the implementation of new EHR system by a major health care provider or a large health care provider joining or exiting the local ED surveillance. Responses to the these types of problems will be customized and could include delaying submission of data until a problem is resolved or suppressing data from counties or state(s) if the data has major and/or multiple data quality problems. Other steps may be investigated if major variation in the percent of ED visits missing data on chief complaint and diagnosis codes (e.g., ICD-10-CM diagnosis codes) is found to consistently occur over time in a significant number of counties or states.
3. Using the *ED discharge overdose data form* and standard CDC case definitions, DOSE requires that the participating health departments, when able, submit hospital discharge data (i.e., ICD-10-CM codes) on ED visits and hospitalizations suspected to involve drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses on a quarterly or yearly basis. Hospital discharge data is the current standard for estimating the burden of drug overdoses treated in EDs. In addition to allowing DOSE to estimate the burden of drug overdose related to ED visits, the hospital discharge counts of drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses reported on the *ED discharge overdose data form* will be compared against the counts captured in *Rapid ED overdose data form* to improve and assess the validity of the rapid ED data collection.

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

Two primary issues pose challenges to conducting rapid overdose surveillance of all ED visits in the US.

1. The participating health departments rely on at least three different systems for conducting rapid ED surveillance of overdoses (i.e., NSSP BioSense, local ED syndromic, and hospital discharge). Consequently, none of these three systems provide national coverage.
2. Not all EDs participate in their local rapid ED surveillance. Current DOSE estimates show that, on average, health departments currently receive data on around 85% of ED visits in their jurisdiction. These gaps can occur for a variety of reasons including a major health system not choosing to cooperate with a local ED data collection, the local ED data collection focusing on a subset of counties or ED data collection driven at the county or city instead of state-level.

CDC has engaged in three strategies to improve the coverage of the DOSE system and address these two issues. DOSE coverage is defined as the percent of non-federal ED visits reported to CDC in the *Rapid ED overdose data form*.

1. DOSE can be rapidly implemented and scaled to all 50 states and the District of Columbia because it relies on sharing data already being collected by state and local health department across three types of data systems (i.e., NSSP BioSense, local ED syndromic, and hospital discharge) instead of attempting to establish a new ED data collection or relying on data from only one data source such as NSSP BioSense.
2. CDC funded efforts to expand and improve the NSSP BioSense platform which captures about 71% of all ED visits in the US – up from 60% two years ago - 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.[2] 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.
3. CDC's Overdose Data to Action Notice of Funding Opportunity (OD2A, CDC-RFA-CE19-1904) requires all participating state health departments and the District of Columbia to spend a portion of their funding to support the local ED data collection and/or analysis. Recipients may spend the funding to address their own unique data gaps (e.g., one state may hire staffing to support analysis while another may us funding to improve data quality or coverage). This funding overtime should improve the coverage and quality of data collected by DOSE.

4. Tests of Procedures or Methods to be Undertaken

Case definitions of ED visits involving suspected drug, opioid, heroin, fentanyl, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdoses have been extensively tested in the following ways:

- Under previous CDC funding (i.e., Enhanced State Opioid Overdose System or ESOOS), health departments developed state-based case definitions for drug overdoses. The commonalities across these state-based definitions have been critical in informing the development of national definitions. In addition, differences across state-based definitions coupled with intense consultations with CDC have resulted in refinements of the national definitions that enhance the ability these national case definitions to detect suspected overdoses.
- CDC has collaborated with staff of the NSSP ESSENCE team to analyze and review case-level ED visits identified by each of the case definitions. Analytic techniques have included identifying words and ICD-10-CM codes that are commonly connected within ED visit (e.g., ED visits with a chief complaint that includes the abbreviation "OD" often also include words such as "drug"). Manual review of the ED chief complaint and ICD-10-CM codes of ED visits identified by CDC staff have been critical in excluding inappropriate visits and expanding the overdose definitions (e.g., capture common misspellings) to detect previously undetected cases.
- The case definitions were informed by a review of other ICD-9-CM and ICD-10-CM drug overdose coding systems.

The design of the *Rapid ED overdose data form* and the *ED discharge overdose data form* has been informed by feedback from the 32 state health departments and the District of Columbia participating in ESOOS. Specifically, the health departments highlighted the need for a standardized form and have piloted use of a similar forms and SAS programs to support completion of these forms on an optional basis.

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

The following consulting efforts were made:

1. DOSE staff has intensely collaborated with the Division of Health Informatics (DHIS), the CDC division that operates NSSP BioSense. This collaboration includes detailing staff from NSSP BioSense on a part-time basis. A key benefit from this collaboration is the expertise of CDC staff with extensive experience analyzing syndromic ED data, including a candid assessment of its strengths and weakness.
2. As part of ESOOS, CDC convened a workgroup where CDC discussed data quality and analytic approaches with 32 state health departments and the District of Columbia on approximately a monthly basis.
3. ESOOS-funded health departments engaged with CDC staff to assist in the development of all drug, opioid, heroin, all stimulant, cocaine, methamphetamine, benzodiazepine, and other emerging drug overdose case definitions for syndromic and hospital discharge data. In addition, these funded health departments have collaborated to refine the case definitions and test developed SAS code. This work has continued with DOSE-funded states.
4. As part of DOSE, CDC convenes a quarterly workgroup meeting where CDC and funded health departments discuss data quality issues and the development of case definitions as well as data dissemination efforts.
5. CDC has also worked closely with the Council for State and Territorial Epidemiologists (CSTE) to ensure health department epidemiologists are well-

equipped with the skills to analyze ED data collected within their state by conducting regional trainings.

One CDC senior epidemiologist will supervise six CDC epidemiologists backed by two data managers to lead the analysis of the DOSE data. This includes intensive work evaluating case definitions and the quality of the preliminary ED data both internally and with state health department staff. This group can consult with another senior scientist and/or request statistical support on an as needed basis.

[1] For additional information https://auth.cdc.gov/sams/SAMSUserGuide.pdf
[2] For additional information https://www.cdc.gov/phpr/readiness/funding-crisis.htm