



March 24, 2023

Dear Public Health Laboratory Directors:

APHL is pleased to provide guidance tools to assist you in responding to the ***“Overdose Data to Action in States (OD2A-S)”*** notice of funding opportunities. (NOFO). This new 5-year cooperative agreement opportunity [OD2A-S \(CDC-RFA-CE-23-0002\)](#) was posted on March 7, 2023. The NOFO solicits applications which focus on the complex nature of the opioid overdose epidemic and highlight the need for an interdisciplinary, comprehensive, and cohesive public health approach. Eligible jurisdictions include all state health departments including the District of Columbia.

There are two overall required components of this award, surveillance and prevention. Within these two components, there are required and optional strategies to enhance the quality and timeliness of data on overdose morbidity and mortality, and to use these data to inform and target prevention and response efforts at the state and local level.

A separate guidance tool is being provided to local laboratories for their use in responding to ***“Overdose Data to Action (OD2A): Limiting Overdose through Collaborative Actions in Localities”*** (OD2A-LOCAL, CDC-RFA-CE-23-0003).

APHL encourages our members to collaborate with their partners in injury prevention and overdose epidemiology to support public health laboratory infrastructure, enhance forensic toxicology testing and develop and or augment biosurveillance programs that characterize the nature and extent of the non-fatal overdose epidemic. By leveraging relationships, technical expertise and analytical instruments acquired through work in the Laboratory Response Network for Chemical Threats (LRN-C) and previous OD2A cooperative agreements, public health laboratories are poised to provide critical, currently limited information regarding the pharmaceutical and illicit drugs resulting in overdose. This funding opportunity also provides technical and financial resources to support laboratories interested in, but not yet engaged in, drug overdose surveillance.

Laboratory Directors and appropriate technical staff should contribute to the relevant sections of the grant proposal. Laboratory Directors are asked to share this guidance with appropriate technical staff. **The OD2A-S application must be submitted by May 8, 2023.**

If you need assistance, please feel free to contact the APHL staff below.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker".

Scott Becker, MS  
Executive Director

## APHL Staff Contacts

Subject Area	Staff Contact	Email	Telephone
Biosurveillance OD2A -States	Julianne Nassif	<a href="mailto:julianne.nassif@aphl.org">julianne.nassif@aphl.org</a>	240-485-2737
LRN-C and Biomonitoring	Jennifer Liebreich	<a href="mailto:jennifer.liebreich@aphl.org">jennifer.liebreich@aphl.org</a>	240-485-3829
Informatics	Michelle Meigs	<a href="mailto:michelle.meigs@aphl.org">michelle.meigs@aphl.org</a>	240-485-2771

## Overdose Data to Action – States (OD2A-S)

### Important Dates

Optional Letter of Intent: March 27, 2023  
Application Due: May 8, 2023  
Anticipated Award Date: August 1, 2023

### Key Points:

- *Funding is to support recipients in getting high quality, comprehensive, and more timely data of overdose morbidity and mortality, and to use those data to inform prevention.*
- *Anticipated number of awards – 51, all states (including the District of Columbia) averaging \$3,753,774 will be made for each year of the five-year cooperative agreement.*
- *Laboratory related opportunities include funding for public health laboratory infrastructure, enhanced forensic toxicology testing to aid medical examiners and coroners in investigating fatal overdoses and optional and competitive awards (up to 20) for biosurveillance of non-fatal overdoses.*
- *APHL suggests that you include activities that will improve integration with your health department partners, which will improve the quality and timeliness of laboratory testing and will provide impactful data for public health practice.*

## Surveillance Component:

Three surveillance core strategies are required of all recipients (Surveillance Infrastructure, Morbidity Surveillance, and Mortality Surveillance) and two surveillance optional and competitive strategies will be awarded to up to twenty states (Biosurveillance and Data Linkage).

(This guidance tool includes only sections relevant to the laboratory)

### **Surveillance Infrastructure - Strategy 1 (\$250,000)**

The purpose of this strategy is to build and sustain the overdose surveillance infrastructure in the jurisdiction.

Funding must not duplicate or overlap with resources provided under other federal funding sources or CDC mechanisms including, but not limited to, Epidemiology and Laboratory Capacity for Prevention and Control of infectious diseases (ELC; CDC-RFS-CK-19-1904), Data Modernization Initiative (DMI), and efforts to strengthen the overall US public health infrastructure, workforce and data systems (i.e., CDC-RFA-OE22-2203). This strategy defines specific ways in which this funding may be used:

- Enhancing emergency medical services (EMS) data and systems
- Hiring surveillance staff (FTEs or contractors)
- State-led DMI initiatives
- Enhanced analysis and dissemination of drug overdose data for overdose surveillance
- **Enhancing/modernizing public health laboratories, including increased staffing and/or laboratory equipment or supplies for testing related to non-fatal drug overdose.**

*Consider laboratory safety and security upgrades, analytical instrumentation, supplies, analytical standards and reagents and staff needed for non-fatal overdose testing.*

### **Morbidity Surveillance - Strategy 2**

There are no laboratory related activities identified for this strategy.

### **Mortality Surveillance - Strategy 3**

This strategy requires recipients to collect and enter data on the characteristics and substances detected and involved in unintentional and undetermined intent drug overdose (UUDO) deaths into the State Unintentional Drug Overdose Reporting System (SUDORS). There are 8 requirements for this surveillance strategy with only one relevant to forensic toxicology laboratories.

6.(page 23 of 111) Clearly indicate in the budget the amount of funding allocated to support enhanced toxicology testing of opioid and stimulant overdose deaths by their medical examiner or coroner community. Testing guidance is provided in Appendix 4 and budget guidance in Appendix 5 of the NOFO. The funding may be provided directly to forensic toxicology laboratories or directly to medical examiners and coroners.

*Forensic toxicology laboratories should compare their current testing related to opioids and stimulant deaths as compared to the CDC guidance in Appendix 4 of the NOFO. These tests include a Primary Toxicology Drug Screen, an Enhanced Toxicology Drug Screen, Comprehensive Novel Psychoactive Substances (NPS) Testing and if economically feasible further examination of suspected mixtures. The testing guidance will be updated based on regional and emerging threat data. If enhanced forensic toxicology testing is appropriate, prepare a budget request using the state specific anticipated funding levels provided in Appendix 5, as a guide.*

*Consider staffing, instrument purchase, instrument service, supplies reagent, data management and*

*contractual (courier, shipping etc.) needs when crafting your budget.*

*Consider the use of [traceable opioid material kits](#) to improve the detection of synthetic opioids and other novel substances.*

If current forensic toxicology testing is consistent with the enhanced testing outlined in Appendix 4 AND, with approval from CDC, funding may be used to:

1. Improve forensic investigation of overdose deaths
2. Reimburse medical examiners and coroners for SUDORS-related work
3. Support general medical examiners/coroner staffing needs
4. Projects approved by the CDC project and science officer

### **Optional and Competitive Surveillance Strategy: Biosurveillance - Strategy 4 (\$350,000) Up to 20 awards**

The primary goal of this surveillance strategy is to gather a standard set of laboratory data from biological specimens from suspected overdoses in the emergency department (ED). These data will be used to enhance existing CDC's Drug Overdose Surveillance and Epidemiological System (DOSE) data by providing more contextual information for ED visits that can be used to identify trends in drugs contributing to overdose.

Definitive toxicological testing, such as with liquid chromatography-tandem mass spectrometry (LC/MS/MS) may be used to identify (and quantify) specific substances. Biosurveillance data will allow for a more comprehensive picture of specific drugs implicated in overdoses and will assist communities in responding to the latest drug trends. Data collected will include race, ethnicity, age, sex and geographic location of the patients which will allow for granular assessment of specific assessment affecting groups that may be disproportionately affected by overdose. As with DOSE, variables collected are limited to those included in the hospital HER system; however, county of patient residence will be collected, which would allow for triangulation of these data with county-level variables to better understand social determinants of health (e.g., reduced economic stability; limited healthcare access, including those who have been historically underserved or are underinsured) and also people experiencing certain social or physical health conditions that may place them at disproportionate risk of nonfatal drug overdose (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration).

*See p.90-92 of the [NOFO for biosurveillance plan requirements, expectations, and application scoring criteria](#). Several resources are available on the APHL [website](#) to assist laboratories in responding to this biosurveillance opportunity. APHL strongly encourages the review of the following documents, webinars, and videos:*

#### Documents

- [Model Opioids Biosurveillance Strategy for Public Health Practice](#)
- [Fundamentals of Fentanyl Safety in Public Health Laboratory Settings](#)
- [DEA Registration Checklist](#)

#### Webinars

- [APHL Model biosurveillance Strategy for Public Health Practice](#)
- [Fentanyl Safety in Laboratory Settings](#)

## Video

- [Fentanyl Safety in Laboratory Settings](#)

*APHL's Opioids Community of Practice is an online message board and monthly teleconference focused on facilitating communication between government laboratories and their public health partners. The Community of Practice meets monthly to discuss technical issues, challenges, strategies, and best practices. Subject matter experts present on a variety of topics of interest to the community. To join the Community of Practice (CoP), send an email to [eh@aphl.org](mailto:eh@aphl.org) with "Opioid CoP" in the subject line.*

*The APHL Overdose Biosurveillance Task Force (OBTF), a multi-disciplinary group of subject matter experts in analytical chemistry, toxicology, and epidemiology is currently drafting guidance for public health laboratories engaged in polysubstance identification used for nonfatal drug overdose biosurveillance. The group is also providing quality management recommendations for use with high-resolution mass spectrometry (HRMS) when used in nonfatal drug overdose biosurveillance. This document will be published in the fall of 2023.*

*Consider staffing, instrument purchase, instrument service, supplies, reagents, data management and contractual (courier, shipping etc.) needs when crafting your budget.*

*Consider the use of [traceable opioid material kits](#) to improve the detection of synthetic opioids and other novel substances.*

Recipients of this award must meet the following six requirements:

1. By the start of Year 2, the recipient will have established systematic sampling of available remnant biological specimens presenting to EDs with suspected nonfatal overdose and identified a partner laboratory (**with a preference for state or regional public health laboratories**) to perform definitive testing for a standardized panel of drugs. Results from definitive testing will be shared with CDC in a routine and standardized fashion that will utilize existing data systems where possible.

*Determine your jurisdiction's legal authority to collect and analyze specimens for nonfatal biosurveillance ensuring human subjects review and informed consent needs are considered prior to program implementation. Authority and requirements vary considerably by state. (These steps may not be required if the activity is determined to be public health surveillance.*

*Examples of successful strategies for obtaining specimens may be found on the APHL CoP under "Resources". These include regulations, letters of intent and memoranda of understanding that may be useful to your jurisdiction in order to develop and or refine a sampling approach.*

- 1.1 Line-level data will be reported quarterly for all new tests performed by the date. Mechanism for submission will be specified and will build upon existing reporting systems as much as possible (LRN-C messaging or SAMS upload).

*APHL recommends that you highlight your laboratory's experience with electronic laboratory reporting via various data systems such LRN-C messaging or SAMS upload.*

*Initiate discussions with your public health and information technology partners regarding the*

*implementation of electronic laboratory reporting for chemical testing if that capability does not currently exist. The following resources may help to inform that discussion:*

[APHL Informatics Resources](#)

[CDC Guidance on ELR](#)

- 1.2 Recipient agrees to meet data preparation and submission requirements, including but not limited to specimen ID, patient ID, specimen collection date, test date, test(s) performed, result(s) and limited patient data (age, sex, race, ethnicity, patient residence location, and clinical presentation information (if available)). Optional data, such as quantitative results will also be accepted but not required.

*APHL recommends capturing and retaining the following additional information: specimen type (i.e., whole blood, serum, urine), test method, analytical platform and detection limit and reporting limit for quantitative assays.*

- 1.3 Metadata will also be required to facilitate proper interpretation and aggregation of data, including but not limited to submitter information, sampling scheme, testing panel and information about the testing laboratory.

*CDC will provide additional information regarding metadata requirements to awardees and options for sampling schema and testing panels.*

- 1.4 Coverage = testing of a minimum of 20 specimens (from unique overdose events)/per week/per initial pilot hospital or hospital partner system partners. This may expand if the number of submitting hospital facilities expand and laboratory capacity allows.

*PHLs should collaborate with public health partners, leverage relationships developed between acute care hospitals, chemical threat coordinators and regional poison centers to acquire remnant specimens from patients presenting with suspected nonfatal drug overdoses. Estimate weekly laboratory standing capacity to analyze and report polysubstance data and advise partners accordingly.*

- 1.5 Letters of Support from definitive laboratory testing partner (e.g., state public health laboratory) that is evidence of agreement to perform the required activities.

*Public health laboratory directors **must** provide a Letter of Support to health department principal investigator agreeing to provide definitive laboratory testing for polysubstance biosurveillance and related required activities.*

*Label the document "S4 Partner Testing Lab LOS" and upload as a pdf.*

- 1.6 Demonstration of proficiency from the identified laboratory.

*PHLs should describe current biosurveillance activities (if appropriate), including an overview of the quality management system, participation in relevant external proficiency testing or quality assessment programs.*

*Laboratories who are not currently performing biosurveillance should summarize experience in other toxicology testing – chemical threat response (LRN-C), human biomonitoring, forensic toxicology - and how demonstration of proficiency was achieved and maintained for assays in those programs.*

*Describe relevant laboratory certifications and accreditations, including but not limited to, CLIA certification with a toxicology subspecialty, ISO/IC -17025, or College of American Pathologists.*

2. Recipients must provide a narrative description of experience in conducting overdose biosurveillance testing; **preference will be given to laboratories who demonstrate good working relationships with hospitals and the ability to receive specimens routinely from hospitals.**

*PHLs should summarize current experience with definitive biosurveillance testing including details regarding specimen acquisition, volume and number of clinical partners providing specimens. Additionally, laboratories should provide a description of the physical space, analytical instrumentation, safety, security and diversion control practices, staffing and collaborative relationships with partners in injury prevention, epidemiology, clinical medicine and poison control.*

*Experienced laboratories should highlight publications and presentations related to biosurveillance as well as involvement in the APHL Community of Practice, Overdose Biosurveillance Task Force or other relevant professional partnerships and organizations.*

3. Letters of Support/Agreement from partner hospitals must be provided to demonstrate that partner hospitals have been identified who will share a subset of patient specimens definitive testing along with required data.

*Work with public health partners to secure the necessary Letters of Support for biosurveillance. Chemical threat coordinators often have established relationships with emergency departments and hospital laboratories that can facilitate an introduction to discuss biosurveillance.*

*Label as “S4 Partner Hospital LOS” (number if there is more than one) and upload as a PDF.*

4. By Year 3, recipients must produce or contribute to at least two data products per year using biosurveillance data. These can include sharing results with internal partners (such as epidemiologists) or external data products showing analyzed results (e.g., contributing data to an overdose dashboard, external reports, or alerts, etc.) Recipients must describe plans to share and disseminate data, including for use in local overdose prevention activities and to partner hospital sites.

*Discuss potential data products with public health partners, consider those with the greatest potential to inform public health action locally and nationally. Contribute to the development and dissemination plan for the biosurveillance data products. In addition to the data products listed above, consider submitting manuscripts to peer-reviewed publications and presenting at national meetings to share information widely for greatest impact.*

5. Describe how you will work with local jurisdictions on this project.

*Collaborate with public health partners to ensure that local jurisdictions are represented in this*

*biosurveillance project with attention to historically underserved areas and populations. Assist in identifying clinical and hospital partners in local jurisdictions.*

6. Recipients must participate in CDC-hosted workgroup for this strategy.

*Public health laboratories apply for this optional surveillance strategy should express interest in participating in the biosurveillance work group.*

Additionally, recipients may opt to use these strategy funds for additional biosurveillance activities, provided core requirements above are met. Activities such as testing for outbreak response, pooling specimens to analyze for emerging drug threats, or analyzing point of care testing data are examples of additional activities that can be supported by this funding.

### **Optional and Competitive Surveillance Strategy: Data Linkage – Strategy 5 Up to 20 awards**

There are no direct laboratory opportunities related to this strategy.

## **Prevention Component**

(This guidance tool includes only sections relevant to the laboratory)

### **Collaborations** (pages 47-53 of the NOFO)

The complex and changing nature of the overdose epidemic highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. To accomplish the work under this funding opportunity, recipients will need to engage in coordinate with and leverage various partnerships.

#### **Required collaborations with other CDC programs are as follows:**

(Only laboratory related collaborators are included)

If proposing biosurveillance activities performed in a public health laboratory, collaboration with the Laboratory Response Network for Chemical Threats (LRN-C), funded through the Public Health Preparedness (PHEP) cooperative agreement is required. A Letter of Support from your state LRN-C lead showing that there is support for cross-training, equipment sharing, and other resources to support the activities proposed is required, and the ability to report data through LRN-C electronic reporting (ELR) or other LRN-C reporting will strengthen your application.

*Label the document “S4 LRN C Lead LOS” and upload as a PDF.*

**If proposing activities for the optional biosurveillance strategy**, a LOS must be written by the state PHL that is evidence of an agreement to perform the required activities.

*Label the document S4 Partner Testing Lab LOS” and upload as a PDF.*



Partner hospitals: demonstrating that the hospitals identified will share a subset of specimens from patients presenting with overdose for definitive testing along with required data.

*Label the document "S4 Partner Hospital LOS" (number if multiple hospitals are participating) and upload as a PDF.*

**Additional key partners and agencies**

Regardless of strategies selected, applicants are strongly encouraged to describe other strategic partnerships and collaborations with organizations that will make this work more robust and impactful or may have a role in achieving the outcomes and proposed activities (e.g., traditional and social media, non-government organizations, non-profit agencies, public health and public safety communities and the business community.)

*Consider including Memoranda of Understanding and/or Letters of Support that support these collaborations.*

***Data Use Agreements or MOUs related to hospitals providing specimens for biosurveillance will strengthen your application.***

**Budget Narrative**

*Collaborate with partners on the development of the budget and narrative related to laboratory activities including those relevant to surveillance infrastructure, enhance toxicology testing (if applicable) and biosurveillance (if applicable).*

<i>Total Surveillance Infrastructure (including PHLs)</i>	<i>\$250,000</i>
<i>Enhanced Toxicology Testing</i>	<i>(See Appendix 5 for state specific allocations)</i>
<i>Biosurveillance</i>	<i>\$350,000</i>

**Funding Restrictions** (p.81-82)

(There are many)

Funding may not be used for research.

Funding may not be used for equipment beyond what is detailed in the budget.

**Surveillance Unallowable Activities**

Funding may not be used for neonatal abstinence syndrome (NAS), or HepC/HIV surveillance.

Funding may not be used for wastewater/sewage testing.

Funding may not be used for drug testing for deaths due to motor vehicle crashes.

**Details of the review and selection process are provided in p. 85-96.**

*Laboratories are strongly encouraged to read and understand the application evaluation process and criteria to ensure the development of complete and competitive proposals.*