

SUPPORTING STATEMENT: PART A

OD2A: LOCAL Linkage to and Retention in Care Surveillance

OMB# 0920-24AZ

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ATTACHMENTS

- A. AUTHORIZING LEGISLATION: PUBLIC HEALTH SERVICE ACT
- B. OD2A: LOCAL TECHNICAL GUIDANCE FOR LTC SURVEILLANCE
- C. OD2A: LOCAL LTC DATA ENTRY FORM
- D. OD2A: LOCAL LTC DATA IMPORT TEMPLATE
- E. PUBLISHED 60-DAY FEDERAL REGISTER NOTICE (FRN)
- F. PUBLIC COMMENT TO 60-DAY FRN
- G. APLICABILITY OF PRIVACY ACT
- H. RESEARCH DETERMINATION

ACROYNMS

CoC	Cascade of Care
DOP	Division of Overdose Prevention
ED	Emergency departments
EMS	Emergency Medical Services
LTC	Linkage to and Retention in Care
MOUD	Medications for Opioid Use Disorder
NCIPC	National Center for Injury Prevention and Control
OD	Opioid Use Disorder
SUD	Substance use disorder
StUD	Stimulant use disorder

SUMMARY TABLE

- **Goal of the study** – Establish a surveillance system to measure linkage to and retention in care for substance use disorder (SUD). This goal will be accomplished by funding 12 jurisdictions (local health departments) that will collect and share standardized data with CDC to inform and enhance regional and national linkage to care efforts. Linkage to and retention in care surveillance at the local level complements prevention-focused activities by providing a better understanding of the cascade of care (CoC) for SUD, including referral to, initiation of, retention in, and loss to follow-up in evidence-based treatment for SUD, harm reduction services, and other related supports, especially among people at higher risk of overdose and/or historically underserved.
- **Intended use of the resulting data** – Improve monitoring of linkage to and retention in care for SUD at the local level and evaluate programmatic efforts to link individuals with SUD to treatment.
- **Methods to be used to collect** – Twelve local health departments were funded by CDC to collect programmatic data on linkage to care among individuals with SUD identified via key entry points to care and leverage other existing data sources. Funded health departments will collect standardized indicators of linkage to care for SUD and submit aggregate data to CDC every 6 months via REDCap.
- **The subpopulation to be studied** – Individuals with opioid use disorder (OUD) and/or stimulant use disorder (StUD) identified via key entry points to care such as nonfatal overdose identified in the ED or by EMS, other clinical care programs, harm reduction programs, criminal justice or other community-based programs.
- **How data will be analyzed** - Descriptive analyses such as frequencies, proportions, and rates. Additional analysis may be conducted (e.g., jointpoint regression) to describe trends.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), requests the Office of Management and Budget (OMB) approval for three years for a new information collection request (ICR) to collect and analyze data tracking individuals linked to evidence-based treatment, harm reduction services, and supports through the Cascade of Care (CoC) for Opioid Use Disorder and/or Stimulant Use Disorder.

Background

In the United States, opioid overdose deaths have increased significantly over the years. Drug overdose deaths in the United States increased by 14% from 2020 to 2021. Of the 106,699 drug overdose deaths in 2021, over 75% involved an opioid. Deaths involving psychostimulants, such as methamphetamine, also increased from 2020 to 2021. Scaling up prevention and surveillance activities to address substance misuse and nonfatal and fatal drug overdoses are priorities for the Centers for Disease Control and Prevention. Evidence shows that reducing drug overdoses requires increased capacity for linking people to treatment and harm reduction services and improving retention across care settings. Linking individuals with a substance use disorder to treatment and harm reduction is a key strategy for saving lives and it is crucial that jurisdictions implement surveillance strategies that can inform and improve their linkage to and retention in care activities.

In September 2023, the Division of Overdose Prevention (DOP) launched a new surveillance program as part of the *Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities* (OD2A: LOCAL) Notice of Funding Opportunity (NOFO): Linkage to and Retention in Care surveillance. Linkage to Care is a 5-year NOFO which connects individuals at risk of overdose to evidence-based treatment, services, and supports, thereby reducing future overdoses and other harms associated with substance use. Implementation of surveillance systems to collect data on standardized Linkage to and Retention in Care indicators is needed so that health departments can measure the impact of their linkage to care programs, inform overdose prevention activities, and appropriately allocate public health resources where they are most needed. 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 A).

This collection acknowledges the notice from the Office of Management and Budget (OMB) announcing revisions to Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), effective March 28, 2024. We have updated the race categories that will be collected to more closely align with the new minimum categories. However, it is unknown if the funded local health departments that submit data to CDC will be able to comply with the new standards at this time; reasons are provided below on A.2.

A.2. Purpose and Use of Information Collection

Funded local health departments will be tasked with the collection and sharing of standardized Linkage to and Retention in Care indicators with CDC, as part of this effort. Local health departments are uniquely suited to implement surveillance systems for standardized Linkage to and Retention in Care (LTC) indicators due to their proximity to the communities they serve and access to data from local linkage to care programs and activities. Following an extensive environmental scan and with input from local and state overdose prevention and response programs, the CDC defined a substance use disorder cascade of care (CoC) and a set of minimum standard measures to assess local LTC efforts. The overarching goal of this initiative hinges on generating actionable data that jurisdictions can leverage to enhance and fine-tune their linkage to and retention in care programs. Linkage to and Retention in Care surveillance will also foster a robust foundation for deriving insights into disparities, unmet needs, and optimal practices across the CoC.

Standardized LTC indicators include identification of need, engagement by linkage to care programs, referral to care and treatment, linkage to care/treatment initiation, and treatment retention status. The data collection procedures and instruments include:

- The **Technical Guidance document** includes detailed instructions for collecting standardized indicators on linkage to and retention in care to funded jurisdictions. It provides detailed indicator case definitions, how to report and submit aggregate data, and information on reporting timelines. Version 1.0 of the Technical Guidance is provided as Attachment B.
- Jurisdictions will have the option to submit indicator data to CDC via REDCap using one of two methods:
 1. Directly entering data into the **OD2A: LOCAL Linkage to and Retention in Care Data Entry Form** (indicator questions from the data entry form are included in Attachment C), or
 2. Entering data into the **OD2A: LOCAL Linkage to and Retention in Care Data Import Template** (Attachment D) and using the data import feature in REDCap. The **data import template** is a tool that provides a structured framework for jurisdictions to report standardized aggregate data on linkage to and retention in care indicators. A Data Dictionary is included as a separate tab in the Data Import Template document, which includes the name, description, field type, and values for each variable.
- Jurisdictions will submit answers to metadata questions via the OD2A: LOCAL Linkage to and Retention in Care Data Entry Form in REDCap (metadata questions from the data entry form are included in Attachment C).

This approach will help standardize data processes to drive data-to-action decision making and improve intra-jurisdictional comparisons over time to drive better health outcomes. Ultimately, a standardized approach ensures that a greater number of individuals access the care they require and drives meaningful change in how individuals are connected to care.

To more closely align with the recent OMB requirements for collecting data on race and ethnicity, we have added “Middle Eastern or North African” as an additional race category in the data import template. This will allow CDC to analyze and report data by the minimum race and/or ethnicity categories required by OMB. However, since CDC is not collecting primary data for this data collection activity, our ability to report accurate data for the required categories is dependent on the data sources utilized by local health departments. Many of the funded health departments are using data from administrative data sets (eg, billing or claims data, emergency department data) to calculate the indicators and stratify the data by racial and ethnic categories. Thus, they will only be able to abstract racial/ethnic categories that are collected by these data systems, and their ability to comply with the new OMB standards will be dependent on updates within relevant data systems to align with the new standards. This will likely take several years to fully implement at the local level across data sharing partners. CDC will provide information on the new standards and the required timeline for coming into compliance to OD2A: LOCAL recipients, and we will encourage recipients to communicate these requirements to their data sharing partners.

A.3. Use of Improved Information Technology and Burden Reduction

CDC will be leveraging an established CDC web-based data collection tool, called REDCap, to collect the standardized indicator data. REDCap will minimize burden on local health departments in three critical ways. First, REDCap automatically and quickly identifies data errors when the recipient submits data to CDC. This will allow recipients to quickly fix errors on submission instead of engaging in extended data quality discussions with CDC over days. Also, REDCap is a mature data collection tool that is stable and accessible. This will prevent local health departments losing time due to instabilities or programming issues often associated with new systems. Finally, the system is integrated with CDC security protocols widely used at CDC which makes access familiar to many local public health staff and easy to use for staff at local health departments. Many OD2A: LOCAL recipients use REDCap for data collection in their jurisdictions and are already familiar with the system, further decreasing burden associated with having to learn a new platform.

CDC is also working to further reduce burden over the 5-year NOFO in two ways. First, CDC will provide local health departments **SAS and/or R statistical programming code** that will assist them in quickly and automatically formatting and loading data into REDCap. This reduces the burden on health departments by helping them automate the process of translating their data into the format required by CDC. Second, CDC will work with a contractor to explore other technological ways to automate and streamline data submission. Specifically, in 2024, CDC will review and pilot the reporting process with a few jurisdictions to identify opportunities to reduce burden and improve data quality.

A.4. Efforts to Identify Duplication and Use of Similar Information

There is no similar ongoing surveillance system in existence, and currently no standardized surveillance data to understand linkage to and retention in care for substance use disorder. Additionally, this surveillance system differs completely from the other state-level surveillance systems in OD2A-S (e.g., DOSE, SUDORS).

Information about overdose-related emergency department admissions is reported to CDC under OMB No. 0920-1268 (exp. 9/30/2025), Drug Overdose Surveillance and Epidemiology (DOSE). This information collection allows CDC and participating jurisdictions to 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.

Information about overdose-related mortality is reported to CDC under OMB No. 0920-1128 (exp. 2/28/2026), in the State Unintentional Drug Overdose Reporting System (SUDORS). This information collection allows CDC and participating jurisdictions to detect state and local community changes in unintentional and undetermined intent drug-related overdose deaths. It also collects information about risk factors for fatal drug overdose deaths that can inform the selection and targeting of interventions.

Information about linkage to care (LTC) was previously reported to CDC under OMB No. 0920-1283 (exp. 8/31/2023) Strategy 3 “Implement innovative surveillance to support NOFO interventions.” Funded health departments for Strategy 3 were required to implement linkage to care (LTC) as part of their prevention activities and were also required to select an innovative surveillance project, one of which could be tracking LTC. However, jurisdictions were able to select their own indicators to

report, and flexibility was given to recipients with reporting requirements for innovative surveillance. Also, many recipients were not conducting surveillance of their required LTC projects, which impeded their implementation and evaluation. Due to an expressed interest from jurisdictions funded under Strategy 3 for more guidance on which indicators to collect and a desire for a more standardized approach, CDC developed standardized indicators to be used across all jurisdictions to better understand outcomes for LTC. A standardized approach aims to better track referral and linkage to and retention in care and to evaluate prevention activities focused on these efforts. Expanding surveillance of linkage to and retention in care will complement prevention-focused activities and support public health agencies' efforts to evaluate linkage to and retention in care programs.

On March 4, 2022, NCIPC staff provided OMB an overview of the proposed data collection for linkage to and retention in care. Staff gave a presentation which included background on the current state of linkage to care surveillance efforts, an overview of the OD2A: LOCAL cooperative agreement, goals of the proposed data collection, and the preliminary reporting schedule. OMB provided guidance on the timeline required for each step in the OMB approval process, including the 60-day and 30-day FRN. NCIPC staff mentioned that the data collection would include some optional data fields, and asked if the optional fields should be included in the OMB package. OMB staff advised that the package should include both required and optional fields, with the instrument notated to indicate which fields are optional. Given that OD2A: LOCAL is a 5-year cooperative agreement, OMB advised NCIPC staff that they would need to submit a revision at least every 3 years. OMB staff also stated that the same OMB control number could be used for future funding that collected linkage to care surveillance data; in other words, the OMB approval follows the data collection activity, not necessarily the funding source.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

While overdose death rates have increased across demographics in the U.S., recent increases (2020) were highest among certain racial/ethnic minority populations, including non-Hispanic Black (44%) and Native Hawaiian/Other Pacific Islander persons (39%).¹ Systemic racism and its impacts on social determinants of health have resulted in disparities in access to, linkage to, and retention in care for substance use disorders, compounding risk in certain populations. A better understanding of linkage to and retention in care among priority populations (e.g., persons at increased risk of overdose) is needed to address disparities in access to and outcomes for linkage to and retention in care.

CDC's Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities (OD2A: LOCAL), Component C is the first time a surveillance system will be established to measure linkage to and retention in care for SUD among individuals at increased risk of overdose. The first year of funding for Component C, September 2023 – September 2024, is a planning year. During the planning year, CDC and a subcontractor will work with recipients to refine Component C program requirements and iteratively address challenges and opportunities so that data collection can begin by

September 2024. Aggregate data for standardized LTC indicators will be submitted to CDC every six months, and each data submission should include two quarters of aggregate data.

If Component C information is not collected, there will be a gap in local level surveillance data about the extent to which individuals at risk of overdose are linked to evidence-based treatment, services, and supports that help reduce future overdoses. This will hinder the ability of both funded jurisdictions and CDC to identify emerging challenges, assess the impact of interventions, and make timely adjustments to linkage to care strategies and programs. Furthermore, without data collection, it becomes challenging to measure the effectiveness of efforts to connect individuals at risk of overdose to evidence-based treatment, which is a crucial strategy for overdose prevention. This, in turn, limits our ability to identify and investigate barriers to treatment and identify other needed program resources for individuals lost to follow-up along the SUD CoC.

Delays in reporting LTC aggregate data every 6 months will also impede CDC's ability to provide technical assistance to help jurisdictions refine and enhance their linkage to care programs and surveillance systems and address implementation gaps and opportunities.

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

The request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.a) Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on November 14, 2023, vol. 88 No. 218, pp. 78037-78038 (Attachment E). CDC received two non-substantial comments to the 60-day Federal Register Notice, no changes were made to the collection (Attachment F).

A.8.b) Efforts to Consult Outside the Agency

DOP worked closely with a subcontractor, Kahuina Consulting, during 2021 – 2022 to develop and standardized indicators for LTC. First, a comprehensive literature review, key informant interviews, and workshops with funded OD2A jurisdictions resulted in an environmental scan summarizing the current landscape of SUD LTC surveillance efforts and future opportunities. Feedback from OD2A recipients conducting LTC surveillance projects, CSTE's Innovative Surveillance Community of Practice (CoP) workgroup members, prescription drug monitoring program (PDMP) representatives, and Health Information Exchange (HIE) experts was collected during workshops and interviews to clarify data flows and existing measures. Together with input from OD2A recipients and DOP experts, a refined set of achievable indicators was developed to measure SUD linkage to and retention in care. Kahuina Consulting was instrumental in collecting and responding to feedback from local and state health departments and other public health partners. The indicators include identification of need, engagement by linkage to care programs, referral to care and treatment, linkage to care/treatment initiation, and treatment retention status.

During 2022- 2023, Kahuina in collaboration with DOP, conducted a series of Refinement Workshops with nine OD2A jurisdictions to inform adjustments to the indicator definitions, inclusion

criteria, relevant disaggregation and terminologies, and implementation guidance detailed in the draft Linkage to and Retention in Care Surveillance Indicator Toolkit. Jurisdictions represented a mix of state and local health departments with demonstrated success in implementing linkage to care programs and tracking linkage to care outcomes. Based on workshop findings, recommended adjustments were made to definitions, measurements, and scope of implementation described in the Toolkit, technical guidance, and data submission template.

A.9. Explanation of Any Payment or Gift to Respondents

No incentives, payments or gifts will be provided to survey participants.

A.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. Component C: Linkage to and Retention in Care Surveillance is housed within the CDC REDCap web-based system. The REDCap system has a current Authorization to Operate. The Privacy Impact Assessment (PIA) for the system is attached (Attachment G).

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

1. Although the funded jurisdictions collect disaggregated data at the local level, they will only share aggregated, deduplicated¹ data with CDC. CDC will provide a template to facilitate reporting of standardized indicators and minimize data entry errors.
2. Jurisdictions will submit aggregate LTC indicator data to CDC via REDCap, which is hosted on the CDC Secure Access Management Service (SAMS) site. The CDC REDCap system is a web-based tool that can be used to securely exchange data between CDC and participating health departments.
3. Only selected staff working on the OD2A: LOCAL Linkage to and Retention in Care Surveillance program will have access to aggregate data submitted via REDCap. Any data files, including analytical files, will be stored and managed on **secure CDC servers**.
4. OD2A: LOCAL Linkage to and Retention in Care Surveillance program will follow **data suppression** rules to prevent possible identification through publication of tables combining characteristics that could be used to identify an individual (e.g., age, sex, race/ethnicity, and geographic location). This includes suppressing data for case counts ranging from 1 to 9 cases at the jurisdiction level.

Data will be kept private to the extent allowed by law.

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

IRB Approval

¹ Source: <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/deduplication.html>

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. Human participants will not be used (Attachment H).

Sensitive Questions

Although sensitive information will be collected by jurisdictions (e.g., data on individuals who experienced a nonfatal overdose, individuals identified other priority entry points to care, individuals referred to treatment and harm reduction services, individuals initiated and retained in treatment), only aggregate data will be reported to CDC.

A.12. Estimates of Annualized Burden Hours and Costs

Data collection includes reporting aggregate counts for a minimum of 13 indicators and up to 24 indicators for at least two priority entry points (nonfatal overdose and one additional entry point including other clinical setting, harm reduction programs, criminal justice setting, other community setting, and self-referral). Aggregate data will be submitted to CDC every 6 months, so jurisdictions report indicators for two quarters of data at each data submission. For each reporting period (6 months), jurisdictions will also provide responses to 8 metadata questions, including 5 questions that ask for detailed descriptive information about data sources and considerations for data coverage and quality.

Average burden per response is estimated based on comparing to a similar CDC template, the *ED discharge overdose data form* (Drug Overdose Surveillance and Epidemiology (DOSE): OMB Control No: 0920-1268), which took a jurisdiction 3 hours to complete. Based on the number of variables in the ED discharge overdose data form per data submission and comparing to the number of variables in the linkage to care data form, it is estimated that jurisdictions will need 8 hours to enter the data into the template and submit to REDCap. Using a similar approach, it is estimated that it will take jurisdictions 2 hours to complete the metadata questions.

Table 1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Participating health departments reporting aggregate data to CDC using REDCap	REDCap Data Import Template (Up to 48 indicators) Att. D	12	2	8	192
	REDCap Data Entry Form (8 metadata questions) Att C	12	2	2	48

Total	240
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A.12.b) Annual burden cost

Because staff retrieving and sharing specified data with CDC will vary substantially across jurisdictions, the mean hourly wage of federal, state, and local government employees (\$32.01) as estimated by the Bureau of Labor Statistics (<https://www.bls.gov/oes/current/999001.htm#00-0000>, accessed on September 14, 2023) was used to estimate burden costs. Public Agencies who retrieve and refile records estimate costs at [240 burden hours x \$32.01/hour] = \$7,682.40. In some cases, state health departments may subcontract with the public agencies or otherwise find a way to defray these costs.

Table 2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden (Hours)	Average Hourly Wage Rate (in dollars)	Total Cost
Participating health departments reporting aggregate data to CDC using REDCap	REDCap Data Import Template (Up to 48 indicators) Att. D	192	\$32.01	\$6,145.92
	REDCap Data Entry Form (8 metadata questions) Att C	48	\$32.01	\$1,536.48
Total				\$7,682.40

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

Respondents will incur no capital or maintenance costs.

A.14. Annualized Cost to the Government

The average annualized cost to the federal government is \$308,967.92, as summarized in Table 3.

Table 3. Estimated Annualized Cost to the Government

Type of Cost	Description of Services	Annual Cost
CDC Personnel	<ul style="list-style-type: none">• 50% GS-14 @ \$113,228/year = \$56,614• 50% GS-13 @ \$95,818.00/year = \$47,909• 15% GS-13 @ \$95,818.00/year = \$14,372.70• 15% GS-13 @ \$95,818.00/year = \$14,372.70• Benefits @ 30%, CDC Personnel = \$39,980.52 Subtotal, CDC Personnel	\$173,248.92
Contractor	Contractor	\$135,719
Total Annual Estimated Costs		\$308,967.92

A.15. Explanation for Program Changes or Adjustments

Not Applicable. This is a new collection.

A.16. Plans for Tabulation and Publication, and Project Time Schedule

CDC will disseminate results to highlight progress in establishing standardized linkage to care surveillance. Some examples include publications in peer-reviewed literature, MMWRS, published reports, data briefs, periodicals, brochures, books, and media correspondence, CDC website (e.g., dashboards), listserv, and e-mail, oral presentations, and data briefs or tables shared with CDC, HHS, and other governmental leaders in response to internal or external requests.

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

There are no standard paper data collection forms to be used by states because states will be abstracting information from electronic or paper sources and transferring to the format.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. *MMWR Morb Mortal Wkly Rep* 2022;71:940–947. DOI: <http://dx.doi.org/10.15585/mmwr.mm7129e2>.