SUPPORTING STATEMENT: PART A

Public Health/Public Safety Strategies to Reduce Drug Overdose Data Collection

GENERIC

OMB# 0920-XXXX

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A. Justification

Summary Table

- Goal of the study: CDC requests approval for a 3-year period for this new GENERIC information collection (IC) request to collect data in response to an urgent request from a public health or safety entity (i.e., agency or program) to improve responses to the overdose crisis that involve public health and public safety sectors; or address justice-involved populations at increased risk of overdose. When a data collection meets criteria for review and approval under the Paperwork Reduction Act, approval will be sought for the data collection through this Generic Information Collection Request (ICR). The National Center for Injury Prevention and Control (NCIPC) anticipates that information will need to be collected to: (a) understand the design, implementation, and uptake of strategies that involve public health and safety sectors or target justice-involved populations at increased risk of overdose; (b) identify barriers, facilitators, and best practices associated with strategy implementation: and (c) identify disparities in access to, or the effectiveness of, these strategies among diverse populations.

- Intended use of the resulting data: The information gathered about public health/public safety strategies to reduce overdose will be used to improve the implementation of public health/public safety partnerships through the lifespan of CDC's national overdose prevention programs.

- Methods to be used to collect: Specific data collection needs will be determined by the requesting entity in consultation with CDC. CDC staff may provide technical assistance on or be deployed to assist with the investigation. To collect data, surveys, individual or group interviews, observations, and document reviews may be used. Multiple data collection modes may be employed in a single investigation. Data collection instruments and methods will be rapidly created and implemented to meet the unique needs of the situation and the agency requesting assistance, often immediately before deployment, if applicable. Revisions will often be required while data collection is underway.

- The subpopulation to be studied: Likely respondents include: public health and public safety professionals, medical examiners, individuals who use drugs or have a history of drug use or criminal legal system involvement, families and friends of individuals who use drugs or have a history of drug use or criminal legal system involvement, individuals served by policies or programs to reduce overdose, health care providers, pharmacists, and representatives of harm reduction, peer recovery, or other community organizations.

- How data will be analyzed: Although dependent on the method of collection and content, it is anticipated that data analysis will involve: (1) computing basic descriptive statistics to characterize the study population, strategies of interest, and design, implementation, uptake, and effects of strategies; and (2) coding documents or interview transcripts to identify barriers, facilitators, and best practices associated with strategy implementation.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) seeks OMB approval for this Generic information collection (IC) request for a 3-year period to conduct investigations of strategies to reduce overdose that involve public health and public safety sectors, including those intended for justice-involved populations at increased risk of overdose (hereafter referred to as "PH/PS Strategies Data Collection"). In this context:

- The public health sector includes public health, behavioral health, drug treatment and recovery, drug overdose prevention, and harm reduction
- The public safety sector includes first responders (e.g., fire, police, and emergency medical services) and criminal justice professionals (e.g., courts, jails, prisons, probation, and parole).
- Justice-involved populations at increased risk of overdose include individuals who use drugs or have used drugs in the past and have encountered the criminal legal system (e.g., interacted with law enforcement, been incarcerated in jail or prison or on probation or parole, attended drug court).
- Overdose refers to overdose from prescription drugs (e.g., oxycodone, methadone, alprazolam, dextroamphetamine) and/or illicit drugs (e.g., heroin, illicitly manufactured fentanyl, cocaine, xylazine, methamphetamines).
- Examples of PH/PS strategies include but are not limited to the following when they involve public safety partners or address justice-involved populations: naloxone distribution; provision of and linkage to evidence-based treatment for substance use disorders; diversion, deflection, and other programs that engage people in the criminal legal system and link individuals to treatment and care; drug checking and other efforts to examine the drug supply; education about drugs and overdose risk; peer support services; harm reduction services; stigma reduction campaigns; overdose fatality reviews; and overdose spike response plans, among others.

Background

The drug overdose epidemic continues to pose a serious threat to communities across the country. In March 2023, the declaration of the opioid crisis as a national public health emergency was renewed yet again.[1] Further, provisional data from the National Center for Health Statistics confirmed that the number of overdose deaths in 2022 was 109,680, which is a 0.5% increase from 2020.[2] Adding to this challenge, drug availability and overdose trends are rapidly changing, shaped by the westward expansion of fentanyl, the eastward expansion of methamphetamine, the inclusion of adulterants in the drug supply (e.g., fentanyl, xylazine), and increasing polysubstance-involved overdose.[3,4]

Justice-involved populations are particularly vulnerable to overdose risk. One study shows that the overdose risk among individuals recently released from prison is 129 times the risk of the general population.[5] Involvement in community corrections (i.e., probation and parole) can also increase overdose risk.[6] Many correctional agencies do not provide access to naloxone, medications for opioid use disorder, and other evidence-based overdose prevention strategies to individuals in custody or under supervision who need it.[7,8]

Multisector collaboration is critical to saving lives and reducing the overdose epidemic.[9] Two key sectors in this response are public health and public safety (PH/PS), as they are both on the front lines and both tasked with improving community safety and well-being. CDC demonstrates strong commitment to PH/PS partnerships through implementation of several national programs. Beginning in September 2019, CDC's Overdose Data to Action (OD2A) funds enhanced surveillance and prevention of fatal and nonfatal opioid overdoses in 47 states and 19 localities. In most of these jurisdictions, prevention activities are carried out in partnership with public safety.[10] Since 2017, CDC has supported the Overdose Response Strategy (ORS), a unique collaboration between public health and public safety partners created to help local communities reduce drug overdose and save lives.[11] Finally, CDC recently launched the Opioid Rapid Response Program, an interagency, coordinated federal effort with the HHS Office of Inspector General to help mitigate overdose risks among patients who lose access to a prescriber of opioids due to law enforcement actions.[12] As a relatively new and increasingly leveraged tool for overdose prevention, a greater understanding of PH/PS strategies are needed to inform these national programs. The legal justification for conducting urgent data collection can be found in the Public Health Service Act (42 USC Sec. 301 [241] (a) (Attachment A).

2. Purpose and Use of Information Collection

Purpose

The goal of this Generic information request (IC)is to collect data to improve overdose prevention efforts that involve PH/PS sectors or address justice-involved populations at increased risk of overdose. This requires practical information and experiential knowledge on current implementation of overdose prevention efforts by PH/PS. Based on previous experience, NCIPC anticipates that information will need to be collected to:

(a) understand the design, implementation, and uptake of strategies that involve public health and safety, or individuals involved in the criminal legal system who are at increased risk of overdose.

(b) identify barriers, facilitators, and best practices associated with strategy implementation; and,

(c) identify disparities in access to strategies among diverse populations or the effectiveness of these strategies in reducing overdose.

This Generic IC will allow for the gathering of information about PH/PS strategies to identify actions to improve responses to the overdose crisis. No Generic currently exists that would allow for exploration of programs, practices, and capacity among PH/PS partnerships to address overdose. The assessments conducted and information gathered through this Generic will be used to rapidly improve the implementation of programs enacted through these partnerships throughout the lifespan of CDC's national programs and more broadly. In this context, a routine IC does not suffice, as not collecting this information in a timely manner impedes CDC from responding to state or local requests for assistance and delays identifying new strategies or modifying existing ones that could lead to reduced overdose morbidity and mortality.

Need

This Generic information collection request is needed because PH/PS partnerships and the strategies implemented through these partnerships are a relatively new and increasingly leveraged tool for overdose prevention that require greater understanding. The drug overdose epidemic continues in the United States. In 2021, 106,699 drug overdose death occurred, an increase of 15% from 2020.[13] Adults aged 65 and over had the largest percentage increase in rates from 2020 to 2021. Drug overdose death rates increased for each race and Hispanic-origin group except non-Hispanic Asian people between 2020 and 2021. The rate of drug overdose deaths involving synthetic opioids other than methadone increased 22%.[14] From 2020 through 2021, the rate of drug overdose deaths increased for deaths involving cocaine and those involving psychostimulants with abuse potential.[14]

In 2022, the Drug Enforcement Administration (DEA) seized over 50 million fentanyl-laced, counterfeit prescription pills and more than 10,000 pounds of fentanyl powder. DEA laboratory testing in 2022 revealed that six out of ten fentanyl-laced, counterfeit prescription pills contained a potentially lethal dose of fentanyl. This is an increase from DEA's announcement in 2021 that four out of ten fentanyl-laced, counterfeit prescription pills contain a potentially deadly dose. In 2022, DEA seized more than double the amount of fentanyl-laced, fake prescription pills that it seized in 2021. DEA also seized nearly 131,000 pounds of methamphetamine, more than 4,300 pounds of heroin, and over 444,000 pounds of cocaine.

State and local agencies are responsible for tracking and controlling local overdose epidemics by implementing prevention and response strategies that increasingly include both public health and public safety sectors. However, state and local agencies often require assistance and support from CDC to inform implementation of these strategies. Often, data collection and analyses are needed to meet complex and immediate demands for information. These agencies rely on CDC to respond quickly to their requests for short-term data collection and analysis support. NCIPC is uniquely qualified to assist in data collection and analysis on the implementation of PH/PS strategies to reduce overdose using this Generic given its oversight of national programs in this area.

The ongoing overdose crisis, heightened overdose risk among justice-involved populations, and new PH/PS partnerships forged in response support the need for this Generic. While jurisdictions continue to develop their capacity to respond to increases in drug overdose, including in partnership with public safety, some still require substantial technical assistance to address the specific needs of justice-involved individuals and work effectively across PH/PS sectors. They would benefit from data collections that examine PH/PS responses to the overdose crisis before modifying or scaling up action. Specifically, it would be helpful to know what overdose prevention strategies are currently in use by PH/PS partners, how to address implementation challenges, how to reach populations equitably and effectively, and which strategies should be prioritized at different times or in different localized contexts. In addition, overdose prevention strategies change rapidly in response to the changing overdose epidemic. Data collection to understand their use and effects demands a quicker timeline than the regular IC timeline would allow.

Circumstances
When such a data collection is conducted in response to an urgent request from a state or local public health or safety entity, and the data collection meets criteria for review and approval under the Paperwork Reduction Act, approval will be sought for the data collection through this Generic.

This Generic "PH/PS Strategies Data Collection" will address drug overdose when there is a request from state or local agency to investigate the implementation of PH/PS strategies; associated barriers, facilitators, and best practices; and disparities in access to, or the effectiveness in the community of, strategies. When assistance is requested by a state or local agency, CDC will make every effort to respond by providing data collection support to inform or improve public health action. Requests for data collection assistance are expected to emerge through direct requests to NCIPC from state or local agencies or programs that involve cross-sector partnerships or seek to address overdose risk within the criminal legal system.

When the need to collect data from 10 or more entities is indicated, the circumstances that justify an urgent "PH/PS Strategies Data Collection" include:

- Increased overdoses (e.g., increase in number of nonfatal or fatal overdoses or accelerating trends) among justice-involved populations.
- Emergence of a new overdose prevention or response strategy or expansion of an existing PH/PS strategy.
- Indication that a promising or evidence-based strategy has not been widely adopted, is not meeting its intended goals, or is not reaching all populations equitably.

The circumstances that would not justify "PH/PS Strategies Data Collection" include:

- Investigations for the purposes of program evaluation, surveillance, needs assessment, or research conducted primarily to contribute to generalizable knowledge.
- Investigations initiated by CDC, without request from an external partner.
- Investigations with data collection expected for greater than 90 days.

A Generic is best suited in this circumstance because more than one genIC using very similar methods may be conducted and NCIPC cannot determine the details of the information collections until specific requests are submitted by jurisdictions. Additionally, it is anticipated that information collections will be voluntary, low burden, and uncontroversial. Because this Generic seeks to examine current implementation of PH/PS strategies, many of which are supported by CDC funding, it is anticipated that the information collected would not be controversial. PH/PS strategies permitted in the current policy environment would be explored. Additionally, interactions between public safety and the public can be sensitive. However, the proposed processes of collecting information will not raise issues as they will not force interactions between groups or elicit conversation about unauthorized programs or policies.

Scope of data collection
To initiate data collection, a request for assistance would come from a lead investigator at a jurisdictional agency or set of agencies (e.g., state public health department, or local sheriff's

office and health department jointly). CDC staff may provide technical assistance with developing questionnaires, interview guides, and a data collection and analysis plan. CDC staff may assist in some or all the operations of the investigation by deploying to the field or carrying out these functions remotely. This can include conducting training, determining sampling frames, and collecting data. CDC staff may analyze the data (either locally or remotely) and assist in report writing and presenting the final report to the local jurisdiction. The overarching goal when providing support is to offer actionable best practices, based on the findings from the investigation, for implementing, improving, or scaling up PH/PS strategies.

The information collected will vary depending on the nature of the strategy under investigation and the jurisdiction. Based on previous experience, NCIPC anticipates that requests will be based on the need to (a) understand the design, implementation, and uptake of strategies that involve public health and safety or address justice-involved populations at increased risk of overdose; (b) identify barriers, facilitators, and best practices associated with strategy implementation; and (c) identify disparities in access to, or the effectiveness of, strategies among diverse populations.

To satisfy the urgent nature of these requests and rapidly changing drug overdose landscape, data collection instruments and methods must be uniquely created and implemented to meet the needs of request, often immediately before deployment, with needed revisions identified while investigators are in the field. Specific questions might change, or new questions could evolve during the investigation as new information is revealed. The choice of data collection mode may be influenced by what is already known about the strategy; the nature of PH/PS partnerships in the area; the location, size, and characteristics of the strategy beneficiaries; and resources available to local authorities and the team in the field.

Examples of data collection modes that could be employed during a "PH/PS Strategies Data collection" include:

- document review (e.g., review of program's screening or reporting forms to explore program components)
- observation
- face-to-face interview
- remote interview
- web-based questionnaire
- self-administered questionnaire

Multiple data collection modes can be employed in a single investigation. It is anticipated that the most common data collection modes will include web-based questionnaires and remote interviews.

Respondent type will vary by investigation. Likely respondents include:

- Public health professionals
- Public safety professionals (i.e., police officers, correctional staff, emergency medical personnel, fire, and rescue)
- Medical examiners
- Individuals served by policies or programs to reduce overdose

- Individuals who use drugs or have a history of drug use or criminal-legal involvement
- Families and friends of individuals who use drugs or have a history of drug use or criminal legal involvement
- Health care providers, including substance use service providers
- Pharmacists
- Representatives of harm reduction, peer recovery drug prevention or other community organizations

Data could be collected in multiple cities, counties, or even states depending on the type of the strategy under investigation. For example, some strategies may be implemented differently in different locations and cross-site comparisons will be needed to understand variations in practice and their localized effects. It is anticipated that there will be no more than 53 requests per year (one per state, District of Columbia, Puerto Rico, and US Virgin Islands).

Proposed Data Use
The information gathered through this Generic will be used to improve the implementation of PH/PS partnerships throughout the lifespan of CDC's national programs and to others implementing these partnerships. The data will largely be used to develop programmatic reports, tools, and implementation guides for the purposes of program improvement. The information collected will not be used to make generalizable statements about the population of interest. However, in collaboration with the agencies that request and participate in information collection, other dissemination tools such as webinar, abstracts, presentations, and manuscripts may be developed.

Report on requests developed under this Rapid Response Suicide Investigation Data Collection during the period of OMB approval

This is a new request and does not have an associated data collection. However, CDC will report to the OMB Desk officer all the Generic requests under this "Public Health/Public Safety Strategies to Reduce Overdose Data Collections" Generic mechanism through the future revision of the ICR.

3. Use of Improved Information Technology and Burden Reduction

During rapid data collections, there often is not enough time to develop, test, and launch electronic systems for the collection of data. However, online, or electronic submission of responses will be used when feasible. If this mode is utilized, it will be password-protected. To minimize burden, document reviews about strategy implementation will be used when available.

Data collection protocols will be designed to be as unobtrusive as possible, and only the minimal information necessary will be collected to reduce burden to the respondent. The specific data collection protocol will be tailored to meet the immediate needs of the request.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches and discussions with local authorities will initially be conducted to determine the extent of existing information. If found, previous information will be used, whenever appropriate, to contribute to an investigation. However, an urgent request for assistance generally requires the collection of data specific to a particular strategy in a particular context. Strategies to reduce overdose that involve PH/PS or target justice-involved populations are not widely documented in the literature.

NCIPC has confirmed with other Centers within CDC that they have not already collected the type of information covered by this data collection. NCIPC has also reached out to the Substance Abuse and Mental Health Services Administration to ensure the proposed data collection is not duplicative of any of their efforts in working with states. NCIPC consulted with The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). NCIPC provided an overview of the proposed information collection request, including background, need, proposed data collection and proposed data use. OIRA was supportive of NCIPC moving forward with this Generic Information Collection Request

The NCIPC OMB-IRB coordinator serves in the role of the Information Collection Request Liaison (ICRL) for this Generic. The ICRL will be responsible for maintaining a data collection instrument library, which will include the final data collection instruments administered under this Generic. In the event a genIC is requested from a CDC program, the ICRL will require the program to determine whether the information already exists, and to use data collection instruments (or components of such instruments) that have already been approved in previous data collections.

5. Impact on Small Businesses or Other Small Entities

Every effort will be made to minimize the burden on all respondents during the collection of information during investigations. Information collected is held to the absolute minimum required to identify new actions or improving existing ones to control the overdose crisis to ease impact on small businesses or entities. No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This Generic involves one-time, rapid data collection efforts related to understanding the design, implementation, uptake, and effects of overdose prevention strategies that change quickly with the evolving nature of the drug overdose crisis. Not collecting this information in a timely manner impedes CDC from responding to state or local requests for assistance and delays identifying new strategies or modifying existing ones that could lead to reduced morbidity and mortality associated with overdose.

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

Often, data need to be collected within days or weeks of the request made by the jurisdictional agency. Given the need for rapid data collection to minimize threats to public health, respondents are asked to respond to requests for data in fewer than 30 days.

To ensure that data on PH/PS strategies to reduce overdose are collected in a timely manner, allowing for the rapid identification of new recommended actions that can save lives, "PH/PS Strategies Data Collection" will adhere to the following timeline and processes:

1. At the request of the state or local authority and after consultation with our external partners, NCIPC will decide to organize and deploy a team to provide data collection assistance to our partners. If appropriate, this data collection assistance may also take place virtually.
2. Through Information Collection Review Office (ICRO) at CDC, the OMB Desk officer is notified of the information collection request immediately via e-mail from CDC, followed by receipt of the genIC "Request for Public Health/Public Safety Strategies to Reduce Overdose Data Collection." The genIC will include the protocol for the investigation (see **Attachment C**, the investigation protocol template). The protocol describes the circumstances, purpose, case definition (if applicable), study population, variables of interest, respondents, anticipated burden hours, data analysis plan, synthesis of results, and draft data collection instruments.
3. The OMB desk officer responds with comments on the proposed genIC within 4-6 weeks. If no response is received within 6 weeks, the team assumes that the information collection is cleared.
4. While in the field, minor modifications may be needed to data collection instruments or number of respondents based on new information about the strategy under investigation, context, or available data sources. At the completion of the data collection, the investigators must submit the final data collection instrument(s) and associated burden to the NCIPC NCIPC OMB-IRB coordinator using the "burden memo" (see **Attachment D**).
5. CDC maintains a library of data collection instruments that includes all final data collection instruments conducted under this Generic ICR.
6. CDC will report to the OMB Desk officer all the Generic requests under this "Public Health/Public Safety Strategies to Reduce Overdose Data Collections" Generic mechanism through the revision of the ICR.

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 June 9 ,2023 vol. 88 No. 111, pp. 37885 (Attachment B). There were no comments to the 60-day Federal Register Notice.

B. Efforts to Consult Outside the Agency

The following are the individuals we consulted with to inform the development of this package. There were no major problems that could not be resolved during the consultation.

Name: Traci Green
Title: Epidemiologist; Professor; Director of the Opioid Policy Research Collaborative
Phone Number: 781-736-2609
Email: tracigreen@brandeis.edu

Name: Mallory O'Brien
Title: Epidemiologist
Phone Number: 414 955-8028
Email: mobrie54@jhu.edu

Name: Jim Cormier
Title: Overdose Response Strategy National Coordinator
Phone Number: 978.697.2917
Email: jcormier@NEHIDTA.org

9. Explanation of Any Payment or Gift to Respondents

Respondents receive no gift or payment for their participation in any information collections.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The overarching Generic ICR does not have an associated data collection. When an individual data collection is requested under this Generic ICR, the Privacy Act review and applicability will be included with each submitted request under this Generic ICR. In most collections, we do not anticipate that the Privacy Act will apply.
Data will only be collected in identifiable form when it is necessary to follow up on individuals or link data from different sources. In those cases, identifiers will be destroyed upon completion of data collection. Data are treated in a secure manner, unless otherwise compelled by law. CDC maintains respondent information by using unique, study identification numbers on all data collection forms. Data may be collected in identifiable form by state or local partners but de-linked from identifiers and subsequently retrieved by an assigned code rather than name or SSN for CDC use. The lead investigator of the local or state investigation will assign and maintain the code and linking information. Personal identifiers and their linkage to study identification numbers are maintained separately in locked file cabinets or in encrypted computer files by the state/locality. All personal identifiers are stripped from the data prior to establishing a final data analysis file. Results are published in aggregate form only.

Information collected through a "PH/PS Strategies Data Collection" will be shared in aggregate, summary format with state and local public agencies and other partners engaged in controlling the local epidemic (e.g., health care providers, law enforcement, medical examiners, and community organizations). Findings from data analysis will be used by state and local professionals to immediately improve existing overdose prevention and intervention measures or take new actions to control the overdose crisis.

Information in identifiable form (IIF) may be collected from or about members of the public by states and localities. Examples of IIF categories for which data may be collected include name, mailing address, e-mail address, phone numbers, and medical information and notes. IIF is only collected when essential to the objective of the investigation. Personal identifiers are not transmitted to CDC; thus, CDC will not be collecting data that includes IIF. IIF data will not be

disclosed unless compelled by law. In no case are IIF included in any report from the investigation.

Individuals are informed that providing information is voluntary. If the respondent participates, consent for participation and sharing of data in aggregate form is assumed.

Official, written consent is only obtained when it is determined that the data collection involves human subjects research. If research is proposed to accompany the response efforts, all efforts will be taken to ensure that the proposed research complies with all human subjects requirements, including consent requirements. All personal identifiers are stripped from the data prior to delivery of data to CDC or establishing a final data analysis file. Results are only published in aggregate form. A system of records is not being created under the Privacy Act.

Local public agency policies and procedures for data storage and security are followed during each field investigation. Though the type of access control(s) implemented vary according to local policies and procedures, examples include technical controls (e.g., password protection, storage on Virtual Private Network), physical controls (e.g., storage in locked cabinets or rooms), and administrative controls (e.g., daily offsite file back-ups, signed confidentiality agreements by staff who have access to files). Information collection is conducted according to a security plan developed in consultation with the relevant local health authorities. Only staff with approval from the study lead has access to the data. Approvals are granted based on roles or a "need to know basis."

Personal identifiers are not transmitted to CDC. CDC maintains the integrity of respondent information by using unique, study identification numbers on all data collection forms.

Data are permanent federal records and are maintained in accordance with CDC's records control schedule (https://www.archives.gov/records-mgmt/grs.html). The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events are directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

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

IRB Approval

Research is not a primary focus of a "PH/PS Strategies Data Collection," and CDC will not have access to identifiable information; however, if research is proposed to accompany the response efforts, the proposed research will comply with all human subjects requirements. All data sent to CDC will be stripped of identifiers and transmitted in aggregate format. A Determination of human subjects review applicability will be included with each submitted Generic request.

Justification for Sensitive Questions
Questions that might be considered sensitive (e.g., regarding risk behaviors, medical history, criminal legal involvement, attitudes, or opinions) are included only when necessary for the public health response. Before administering data collections, investigators inform respondents (either verbally or in writing) that participation is voluntary, respondents can refuse to answer any questions, and that respondents are not personally identified in any published reports of the study. Participants are also informed the data are being collected to understand the design, implementation, uptake, and effects of strategies to reduce overdose, and that the information they provide will inform actionable recommendations intended to help improve strategies or identify new strategies for consideration. Social security numbers are not collected.

12. Estimates of Annualized Burden Hours and Costs

CDC estimates that approximately 5000 respondents will participate in data collections each year and the average burden per response is 0.5 hours and each respondent is asked to respond once. Therefore, the total estimated annual burden in hours is 2500. While this number may seem high, the projection is reasonable considering that drug overdose is a leading cause of death in the United States, the overdose crisis is still declared a national emergency, that PH/PS strategies are taking place nationally, and that NCIPC promote enhanced overdose prevention and efforts in partnership with public safety in many of its high priority initiatives. The actual number of respondents in each information collection will vary depending on the purpose of each individual Generic request.

Table A-12.1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Public Health/ Public Safety Strategies Data Collection Participants	Public Health/Public Safety Strategies Data Collection Instruments	5000	1	30/60	2500
				Total	2500

There are no anticipated costs to respondents other than time. The U.S. median national hourly wage for all occupations in 2022 based on data from the Bureau of Labor Statistics (available at http://www.bls.gov/oes/current/oes_nat.htm#00-0000) is $22.26. This wage is assumed for all participants because of the variety of types of participants expected.

Table A-12.2 Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden (in hrs.)	Hourly Wage	Total Respondent Cost
Public Health/Public Safety Strategies Data Collection Participants	Public Health/Public Safety Strategies Data Collection Instruments	2,500	$22.26	$55,650
Total				$55,650

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

There are no equipment or overhead costs. The cost factors considered are related to routine procedures of the investigators in planning investigations; design, preparation, printing, and distribution of questionnaires; and editing, coding, tabulation, analysis, and presentation of the information. The annual cost is estimated based on the U.S. national average hourly wage for epidemiologists in 2022 ($37.75) based on data from the Bureau of Labor Statistics (available at https://www.bls.gov/oes/current/oes_nat.htm#00-0000). On average, CDC staff and contractors contribute 200 hours per data collection, for a total annualized cost to the Government of $442,020 (see Table A-14.1).

Table A-14.1 Estimated Annualized Cost to the Government

Staff or Contractor	Average Hours per request	Average Annual requests	Average Hourly Rate	Total Annualized Cost
Epidemiologist	200	26	$ 37.75	$196,300

15. Explanation for Program Changes or Adjustments

This is a new GENERIC data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The data collected in each “PH/PS Strategies Data Collection” provides information necessary for improving or expanding immediate, effective public health and public safety responses to drug use and misuse and associated fatal and nonfatal overdose. Therefore, collecting data as

soon as possible after a data collection need is identified is critical to the analysis. The duration of the data collection varies by data collection request.

Project Time Schedule	
Activity	Time Schedule
Letter received from agency requesting assistance	Investigation initiation
Convening of health scientists, epidemiologists, etc.	Within 1 week after investigation initiation
Development of data collection instrument or selection from instrument library	Weeks 1 to 3 after investigation initiation
GenIC submission and approval	Week 3 after investigation initiation
Deployment into the field	Weeks 4 to 6 after project initiation
Data collection in the field	Weeks 4 to 10 after project initiation (staff may be in the field for up to 3 weeks)
Data analysis and report generation	Weeks 10 to 16 after investigation initiation (all data collected within 3 months)

For each "PH/PS Strategies Data Collection," the lead investigator is responsible for developing an analysis plan and conducting the data analysis. A preliminary report summarizing the early findings of the investigation is written by the lead investigator within 14 days of the completion of the investigation. Any report or publication of data derived from the data collection is subject to review by relevant state or local agencies, CDC, or collaborating federal agencies. In collaboration with agencies requesting or participating in information collection, other dissemination tools such as webinars, abstracts, presentations, and manuscripts may be developed.

CDC may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). The Agency disseminates the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public."

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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