

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Public Health/Public Safety Strategies to Reduce Drug Overdose Data Collection—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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. 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. 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.

Multisector collaboration is critical to saving lives and reducing the overdose epidemic. 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. 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. 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. 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 goal of this Generic Clearance mechanism (Generic ICR, GenIC) 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 Clearance will allow for the gathering of information about PH/PS strategies to identify actions to improve responses to the overdose crisis. No mechanism 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 Clearance will be used to rapidly improve the implementation of programs enacted through these partnerships throughout the lifespan of CDC’s national programs. The estimated annual burden hours for this collection are 2,500. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health/Public Safety Strategies Data Collection Participants.	Public Health/Public Safety Strategies Data Collection Instruments.	5,000	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-23FZ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC)

has submitted the information collection request titled “Healthcare Response and Prevention Training Curriculum for Health Departments” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 16, 2023 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This

notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy

of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Healthcare Response and Prevention Training Curriculum for Health Departments—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC funds Healthcare-Associated Infection and Antibiotic Resistance (HAI/AR) programs in 64 state, local and territorial health departments. Funding is awarded through the

Epidemiology and Laboratory cooperative agreements (ELC). Funds are intended to provide critical resources to recipients in support of a broad range of healthcare infection prevention and control and epidemiologic surveillance activities to detect, monitor, mitigate, and prevent the spread of HAI/AR in healthcare settings. Recently, HAI/AR programs have experienced an increase in program size and scope through COVID-19 supplemental funds. To better support the growing programs, CDC has developed high-priority trainings requested by the health department programs with the goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks in healthcare settings, including preventing the spread of SARS-CoV-2.

The proposed training evaluation will be used to assess whether the CDC-developed trainings are reaching the intended audience and achieving the intended goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks, including COVID-19 at the individual trainee and program level. CDC requests OMB approval for an estimated 316 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Trainees	Registration	600	2	5/60
Public Health Trainees	Pre-Test	600	2	5/60
Public Health Trainees	Post-test	600	2	5/60
HAI/AR Program Leads	Public Health program impact of trainings	64	1	15/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-3370]

Post-Warning Letter Meetings Under the Generic Drug User Fee Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Post-Warning Letter Meetings Under GDUFA.” This draft guidance provides information on the implementation of the Post-Warning Letter Meeting process for certain drug manufacturing facilities, a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to the reauthorization of the Generic Drug User Fee Amendments (GDUFA), as described in “GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027” (GDUFA III commitment letter). Specifically, this draft guidance

describes the process detailed in the GDUFA III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility’s ongoing remediation efforts to current good manufacturing practice (CGMP) deficiencies described in a warning letter, how to prepare and submit a complete meeting package, and how FDA intends to conduct the Post-Warning Letter Meeting.

DATES: Submit either electronic or written comments on the draft guidance by October 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows: