

Background and Brief Description

Overdose deaths involving prescription opioids and heroin have reached epidemic levels in the U.S. and continue to rise. To address the prescription drug/opioid overdose crisis, the federal government has recently allocated funding to improve access to treatment for opioid use disorders, reduce opioid related deaths, and strengthen drug misuse prevention efforts. One program resulting from the federal government’s efforts to address the opioid crisis is, the Substance Abuse and Mental Health Services Agency (SAMHSA) Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO/naloxone grant). This collection will be to evaluate the Substance Abuse and Mental Health Services Agency (SAMHSA) Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths.

This evaluation will seek to describe and understand the scope and impact of the program on overdose. To address the prescription drug/opioid overdose

crisis, the federal government has recently allocated funding to improve access to treatment for opioid use disorders, reduce opioid related deaths, and strengthen drug misuse prevention efforts. One program resulting from the federal government’s efforts to address the opioid crisis is, the Substance Abuse and Mental Health Services Agency (SAMHSA) Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO/naloxone grant). Through this program, SAMHSA awarded funding to 12 states. The funding is aimed at reducing the number of prescription drug/opioid overdose-related deaths and adverse events among individuals 18 years of age and older through educating and training first responders and other key community sectors on the prevention of prescription drug/opioid overdose-related deaths, including the purchase and distribution of naloxone. SAMHSA is funding the grant and CDC is responsible for conducting the grantee evaluation.

The intended use of the resulting data is to increase CDC and SAMHSA understanding of the scope and impact of the program on overdose fatalities and how program effectiveness may vary among different sub-populations and settings, and to increase knowledge of barriers and facilitators to program implementation. Key informant interviews and focus groups with participants in the activities enacted by the twelve state grant recipients will be methodology used. This will include state administrators of the grant and other PDO/Naloxone stakeholders including advisory council members, first responders, social service providers, laypersons including end users and their family and friend. All focus groups and interviews will be analyzed through qualitative content analysis, including utilization of a systematic coding scheme.

Total burden in hours for this collection is 381. There are no costs 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)	Total burden (in hours)
PDO/Naloxone Advisory Committee Members and Grantees.	Focus Group Discussion Guide	140	1	1.5	210
PDO/Naloxone Grantees	Individual Interview Discussion Guide for Grantees.	36	1	1	36
PDO/Naloxone Stakeholders and Partners.	Individual Interview Discussion Guide for Partners.	84	1	1	84
PDO/Naloxone Laypersons	Individual Interview Discussion Guide for Laypersons.	24	1	1	24
All participants (PDO Naloxone grantees, advisory committee, stakeholders and partners, laypersons).	Recruitment contact script	284	1	5/60	24
PDO/Naloxone Grantees	Key Informant Selection Tool	12	1	15/60	3
Total	381

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-1054; Docket No. CDC-2017-0055]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of

its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection entitled “Drug Overdose Response Investigation (DORI) Data Collections.” CDC will use the information collected to respond to urgent requests from state and local health authorities to provide epidemiological information that allows

for the selection of interventions to curb local epidemics of drug overdose.

DATES: Written comments must be received on or before September 15, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0055 by any of the following methods:

- *Federal eRulemaking Portal:*

Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson,

Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Drug Overdose Response Investigation (DORI) Data Collections (OMB control number 0920-1054, Expiration 03/31/218)—Extension—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2015, CDC received OMB approval (OMB control number 0920-1054) for a new OMB generic clearance for a three-year period to collect information to respond to urgent requests from state and local health authorities to provide epidemiological information that allows for the selection of interventions to curb local epidemics of drug overdose. CDC seeks OMB approval for an extension of this generic plan for another three-year period.

Drug Overdose Response Investigation (DORI) are to be conducted in response to urgent requests from state and local health authorities to provide epidemiological information that allows for the selection of interventions to curb

local epidemics of drug overdose. Of particular interest is response to increasing trends in, or changing characteristics of, overdose from prescription drugs (with a special interest in opioid analgesics such as oxycodone or methadone; benzodiazepines such as alprazolam) and/or illicit drugs (e.g., heroin). CDC's National Center for Injury Prevention and Control (NCIPC) is frequently called upon to conduct DORIs at the request of state or local health authorities seeking support to respond to urgent public health problems resulting from drug use, misuse, abuse, and overdose. Such requests are typically, but not always, made through CDC's Epi-Aid mechanism; in most investigations, CDC's epidemiological response entails rapid and flexible collection of data that evolves during the investigation period.

Generic clearance is requested to ensure that timely information is collected during a DORI, which allows NCIPC to maintain critical mission function by working with state and local health authorities to protect the public's health. During an unanticipated rise in nonfatal or fatal drug overdose where the substances responsible for the health event need to be identified, drivers and risk factors are undetermined, and/or subgroups at risk need to be identified, immediate action by CDC is necessary to minimize or prevent public harm. CDC must have the ability to rapidly deploy data collection tools to understand the scope of the problem and determine appropriate action. Procedures for each investigation, including specific data collection plans, depend on the time and resources available, number of persons involved, and other circumstances unique to the urgent conditions at hand. Data are collected by epidemiologists, psychologists, medical professionals, subject matter experts, and biostatisticians.

Data collected during a DORI are used to understand sudden increases in drug use and misuse associated with fatal and nonfatal overdoses, understand the drivers and risk factors associated with those trends, and identify the groups most affected. This allows CDC to effectively advise states on actions that could be taken to control the local epidemic. During a DORI, data are collected once, with the rare need for follow-up. 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)	Total burden hours
Drug Overdose Response Investigation Participants.	Drug Overdose Response Investigation Data Collection Instruments.	2,700	1	30/60	1,350
Total	1350

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspection of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces fees for vessel sanitation inspections for Fiscal Year (FY) 2018. These inspections are conducted by HHS/CDC's Vessel Sanitation Program (VSP).

VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for acute gastroenteritis. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced inspections and, when necessary, reinspection.

DATES: These fees are effective October 1, 2017, through September 30, 2018.

FOR FURTHER INFORMATION CONTACT: CDR Aimee Treffiletti, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F-59, Atlanta, Georgia 30341-3717; phone: 800-323-2132, 770-488-7070, or 954-356-6650; email: *vsp@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise

ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; 42 U.S.C. 264, "Control of Communicable Diseases"). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine whether rodent, insect, or other vermin infestations exist, contaminated food or water, or other sanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable diseases are present.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. This notice announces fees that are effective for FY 2018, beginning on October 1, 2017, through September 30, 2018.

The following formula will be used to determine the fees:

$$\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted number of annual inspections}}$$

Total cost of VSP = Total cost of operating the program, such as administration, travel, staffing, sanitation inspections, and outbreak response.

Weighted number of annual inspections = Total number of ships and inspections per year accounting for vessel size, number of inspectors needed for vessel size, travel logistics to conduct inspections, and vessel location and arrivals in U.S. jurisdiction per year.

The fee schedule was originally established and published in the **Federal Register** on July 17, 1987 (52 FR 27060). It was most recently published in the **Federal Register** on August 19, 2016 (81 FR 55460). The fee schedule for FY 2018 is presented in Appendix A.

Fee

The fee schedule (Appendix A) will be effective October 1, 2017, through September 30, 2018.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP. Inspections and reinspections involve the same procedures, require the same amount of time, and are therefore charged at the same rates.

Dated: July 12, 2017.

Sandra Cashman,
Executive Secretary, Centers for Disease Control and Prevention.

Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE

Vessel size (GRT ¹)	Inspection fee
Extra Small (<3,000 GRT)	US\$1,495
Small (3,001-15,000 GRT) ..	2,990
Medium (15,001-30,000 GRT)	5,980
Large (30,001-60,000 GRT)	8,970
Extra Large (60,001-120,000 GRT)	11,960