DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–20JE]

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 ''Distribution of Traceable Opioid Material (TOM) Kits across U.S. Laboratories'' 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 February 28, 2020 to obtain comments from the public and affected agencies. CDC received four comments 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

Distribution of Traceable Opioid Material (TOM) Kits across U.S. Laboratories—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For the first time in U.S. history, a drug class has been declared a national public health emergency; each day more than 140 Americans die from drug overdoses, 91 specifically because of opioids. Since 2013, there have been significant increases in overdose deaths involving synthetic opioids—particularly those involving illicitly-manufactured fentanyl. The U.S. Drug Enforcement Administration (DEA) estimates that 75% of all opioid identifications are illicit fentanyls. Laboratories are routinely asked to confirm which fentanyl or other opioids are involved in an overdose or encountered by first responders, as it is critical to identify and classify the types of drugs involved in an overdose, how often they are involved, and how that involvement may change over time. By understanding which drugs are present, appropriate prevention and response activities can be implemented.

The Centers for Disease Control and Prevention (CDC) is leading the development of Traceable Opioid Material* Kits (TOM Kits*) to support detection of emerging opioids. CDC maintains the contents of the TOM Kits* based on new needs identified, in part, through DEA Emerging Threat Reports. The DEA 2018 mid-year data indicate that fentanyl and fentanyl-related compounds account for approximately 75% of their opioid identifications. These kits are reference materials and do not eliminate the need to meet analytical method requirements of other federal agencies. TOM Kits* are not intended for diagnostic use. The kits are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains.

To equitably distribute these TOM Kits*, the CDC conducted an emergency information collection, titled ''Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories,'' under the Health and Human Services (HHS) Secretary's Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver mechanism for the period from 03/20/2019 to 05/10/2019. From 05/10/2019, CDC continued distributing kits using a generic information collection (GenIC) under ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' (OMB Control No. 0923–0047; expiration date 01/31/2022). To continue this collection, the CDC is currently requesting a three-year PRA clearance for a new information collection request (ICR) under the same title.

CDC is currently distributing a product line of TOM Kits*. Examples of products in this line include the: (1) Opioid Certified Reference Material Kit (Opioid CRM Kit); and (2) Fentanyl Analog Screening Kit (FAS Kit). Respondent laboratories requesting the TOM Kits* can be from any sector (academic, public, or private), must be located in the U.S., must have a verifiable business address, must have a current DEA registration, must comply with respective state and local regulations, and must submit requests directly to the respective vendor.

As the number of laboratories requesting TOM Kits* is high, the information collection will be used to prioritize which laboratories will receive kits when quantities are limited. The brief six-minute web-based survey will allow the CDC to (1) determine what service the recipient laboratory performs and the volume of samples the laboratory processes, and to (2) equitably distribute TOM Kits* based on the analysis techniques, matrix, and sample size used by the recipient laboratory.

The annual number of respondents (n=1,200) was based on the number of 2019 requests. The total time burden requested is 120 hours per year. There is no burden on the respondents other than their time. **TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.*

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Federal Laboratories	TOM Kits* Questions	400	1	6/60
State, Local, and Tribal Government Laboratories	TOM Kits* Questions	400	1	6/60
Private or Not-for-Profit Institutions	TOM Kits* Questions	400	1	6/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–0260]

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 Health Hazard Evaluations/Technical Assistance and Emerging Problems 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 February 10, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments 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

Health Hazard Evaluations/Technical Assistance and Emerging Problems (OMB Control No. 0920–0260, Exp. 10/31/2020)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In accordance with its mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, NIOSH responds to requests for HHE to identify chemical, biological or physical hazards in workplaces throughout the United States. Each year, NIOSH receives approximately 250 such requests. Most HHE requests come from workplaces in the following industrial sectors: Services, manufacturing, health and social services, transportation, and construction.

A printed HHE request form is available in English and in Spanish. The form is also available on the internet and differs from the printed version only in format and in the fact that it can be submitted directly from the website. The request form takes an estimated 12 minutes to complete. The form provides the mechanism for employees, employers, and other authorized representatives to supply the information required by the regulations governing the NIOSH HHE program (42 CFR 85.3–1). NIOSH reviews the HHE request to determine if an on-site evaluation is needed. The primary purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. For 25% of the requests received NIOSH determines an on-site evaluation is needed.

In about 70% of on-site evaluations, employees are interviewed in an informal manner to help further define concerns. Interviews may take approximately 15 minutes per respondent. The interview questions are specific to each workplace and its suspected diseases and hazards. However, interviews are based on standard medical practices. In approximately 30% of on-site evaluations questionnaires are distributed to the employees (averaging about 100 employees per site). Questionnaires may require approximately 30 minutes to complete. The survey questions are specific to each workplace and its suspected diseases and hazards, however, items in the questionnaires are derived from standardized or widely used medical and epidemiologic data collection instruments.

About 70% of the on-site evaluations involve employee exposure monitoring in the workplace. Employees participating in on-site evaluations by wearing a sampler or monitoring device to measure personal workplace exposures are offered the opportunity to get notification of their exposure results. To indicate their preference and, if interested, provide contact information, employees complete a contact information post card. Completing the contact card may take five minutes or less. The number of employees monitored for workplace exposures per