DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1313; Docket No. CDC–2022–0109]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Distribution of Traceable Opioid Material* Kits and Emerging Drug Panel Kits across U.S. and International Laboratories. CDC will collect information from domestic and international laboratories submitting requests for TOM Kits* and EDP Kits, and will use this information to prioritize which laboratories will receive kits when quantities are limited.

DATES: CDC must receive written comments on or before November 15, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0109 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Distribution of Traceable Opioid Material* Kits and Emerging Drug Panel Kits across U.S. and International Laboratories (OMB Control No. 1313, Exp. 12/31/2022)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In response to the Health and Human Services (HHS) Acting Secretary's 2017 and ongoing public health emergency (PHE) declaration on opioids, the Centers for Disease Control and Prevention (CDC) has led 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 the U.S. Drug Enforcement Agency (DEA) Emerging Threat Reports. For example, the DEA 2018 data indicated that fentanyl and fentanyl-related compounds accounted for approximately 76% of their opioid identifications.

TOM Kits* are not intended for diagnostic use and are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains. The CDC collects information on laboratories when they apply for test kits. This information is 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 (2) equitably distribute test kits based on the analysis techniques and matrices used by the recipient laboratory.

The CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for a Revision information collection request (ICR) titled ''Distribution of Traceable Opioid Material* Kits and Emerging Drug Panel Kits across U.S. and International Laboratories'' (OMB Control No. 0920–1313; Expiration Date 12/31/2022). As part of the proposed revisions, CDC will be expanding its program to include both TOM Kits* and the new Emerging Drug Panel (EDP) Kits. For the EDP Kits, non-opioid compounds will be identified and updated by searching recent lists put out by the DEA and the Center for Forensic Science Research and Education (CFSRE). These lists provide data on all classes of drugs that were recently identified in the field and provide recommendations on which drugs should be included in testing. They are updated several times a year and keep up with the changing drug landscape in the United States. For the current round, EDP Kits will include synthetic cannabinoids, stimulants, hallucinogens, and benzodiazepines.

CDC will distribute TOM Kits* and EDP Kits through a single vendor. The CDC vendor will distribute these kits to domestic laboratories, as previously approved, and as a revision, to

international laboratories in partnership with the United Nations Office on Drugs and Crimes (UNODC). The CDC vendor will bulk ship these kits to UNODC for international distribution, or the vendor may direct ship these kits to select international laboratories upon UNODC request.

Over the past three years, CDC has received 1,472 requests from interested laboratories (approximately 490 requests per year) and has distributed 3,007 TOM Kits*. Based on this experience and with the addition of EDP Kits, we anticipate that up to 600 domestic laboratories will request test kits per year. Given that each application will take six minutes, the annual time burden for 600 domestic laboratories will be 60 hours.

We will add 30 additional annual burden hours for the international distribution of test kits. We estimate that 300 international partner laboratories will apply for test kits per year with UNODC, assuming the same six minutes per application. The UNODC will compile and report this information to CDC twice a year (15 burden hours per response).

We estimate a total time burden of 90 hours per year, which is a decrease of 30 hours over the previously approved 120 hours. There is no cost to the respondents other than their time to participate.

** 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)	Total burden (in hours)
U.S. Federal Laboratories	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
State, Local, and Tribal Government Laboratories.	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
Private or Not-for-Profit U.S. Institutions.	Test Kit Application and Questions for U.S. Laboratories (online).	200	1	6/60	20
United Nations Office on Drugs and Crimes (UNODC).	Test Kit Distribution Report for International Laboratories.	1	2	15	30
Total	.....	.....	.....	.....	90

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30Day–22–22AW]

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 ''NCEH DLS Laboratory Quality Assurance Programs'' 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 December 27, 2021, to obtain comments from the public and affected agencies. CDC received four non-substantive 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

NCEH DLS Quality Assurance Programs—Existing Collection in Use Without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Laboratory quality assurance (QA) encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods, instrumentation, analytes, source materials, and the volume of specimens tested. The Centers for Disease Control and Prevention (CDC),