



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20JE; Docket No. CDC-2020-0025]

**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 proposed and/or 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 (TOM Kits*) across U.S. Laboratories." CDC will use a brief web-based survey to collect information from laboratories submitting

requests for TOM Kits*. CDC will use this information to prioritize which laboratories will receive kits when quantities are limited.

*TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0025 by any of the following methods:

- Federal eRulemaking Portal: 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, N.E., MS-D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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; and
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.
5. Assess information collection costs.

Proposed Project

Distribution of Traceable Opioid Material* Kits (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 percent 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 percent 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.

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Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per	Average Burden per	Total Burden (in
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			Respondent	Response (in hours)	hours)
Federal Laboratories	TOM Kits* Questions	400	1	6/60	40
State, Local, and Tribal Government Laboratories	TOM Kits* Questions	400	1	6/60	40
Private or Not-for-Profit Institutions	TOM Kits* Questions	400	1	6/60	40
Total					120

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Office of Science,
Centers for Disease Control and Prevention.

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