



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-1218; Docket No. CDC-2020-0091]

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 "Evaluation of Medication-Assisted Treatment (MAT) for Opioid use disorder." CDC will use the collection to continue the epidemiologic study to assess the type of MAT (methadone maintenance; buprenorphine; naltrexone; or, counseling, no MAT), and the contextual, provider, and individual factors that influence implementation and improved patient wellbeing.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0091 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 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, 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

Evaluation of Medication-Assisted Treatment (MAT) for Opioid use disorder - Revision - National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks a one-year OMB approval to continue collecting data for Medication-Assisted Treatment (MAT) for Opioid use disorder. Approximately 2.4 million people aged 18 or older have opioid use disorders (OUDs) in the United States. At any given time, only half of these people receive some form of treatment, which may include medication-assisted treatment (MAT) or abstinence-based psychotherapy or self-help treatments (i.e., counseling without medication [COUN]). The rise in opioid overdose deaths, up from 2014-2015 due partly to a 72% rise in synthetic opioid overdose deaths alone, shows that engaging and retaining clients in OUD treatment is an urgent public health need. Only a few studies are available to help clients and providers make informed decisions about the risks and benefits associated with the different types of MATs. This information is

crucial because even though each MAT drug helps prevent withdrawal symptoms and decreases cravings, differences in treatment approach and settings influence how people respond to the medication and, thus, their long-term treatment success.

The purpose of this study is to conduct an epidemiologic, mixed-methods evaluation of OUD treatment in real-world outpatient settings. Client recruitment for this study was originally scheduled to take place between 5/1/2018 and 8/31/2019, however patient recruitment levels were lower than originally anticipated. The recruitment period was extended to 11/30/2019 to enable to recruit additional patients. Because the follow-up period for this study is 18 months, patients recruited during the extended recruitment period (8/31/2019 to 11/30/2019) will need to complete their final 18-Month Patient Questionnaire between 2/28/2021 and 5/31/2021, which is after the current OMB expiration date. The extended time period is only needed for one of the data collection instruments, thus there is a reduction in burden of 3839 hours.

The study uses a mixed-method approach using quantitative methods such as multilevel latent growth models, propensity score matching, latent class analysis and advance mediation analysis and qualitative methods such as interactive coding and analysis for common themes. There are no costs to respondents other than their time. The only cost to respondents will be time

spent responding to the survey/screener. CDC requests approval for 300 annualized burden hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Patients	Client Questionnaire 18-Month Follow-up	400	1	45/60	300
Total					300

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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