



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17ACE; Docket No. CDC-2017-0043]

**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 "Evaluation of Medication-Assisted Treatment (MAT) for Opioid use disorder." CDC will use the collection to conduct an

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 over a two-year follow up period.

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-2017-0043 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, N.E., 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, 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 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

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

Background and Brief Description

CDC seeks a three-year OMB approval to collect evaluation information for Medication-Assisted Treatment (MAT) for Opioid use disorder.

About 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 evaluation is to conduct an epidemiologic, mixed-methods evaluation of OUD treatment in real-world outpatient settings. The study aims to have 3,000 participants from real-world outpatient settings to better understand the relationship between type of MAT and individual, provider, and contextual characteristics related to retention in treatment and abstinence from opioid use. The sites will be located across 10 diverse metropolitan statistical areas (MSAs) with four sites in each MSA. At each site, about 75 participants are expected to participate for a total of 300 per MSA. Across all MSAs, the study will aim to have 750 client participants in each of the four treatment conditions (MMT, BUP, NAL, and COUN).

The study will use 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. The only cost to respondents will be time spent responding to the survey/screener.

Estimated Annualized Burden Hours

Type of Respondents	Instrument Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden (hours)
Provider site staff	Client Permission Form	15	100	5/60	125
	Visit Form	15	525	10/60	1,313
	Site Director Questionnaire	15	2	1	30
	Focus Groups	27	1	90/60	41
Client respondents	Client Screener	1,333	1	5/60	111
	Client Check-in	1,000	2	15/60	500
	Client Questionnaire	2,412	1	49/60	1,978
	Focus Groups	27	1	90/60	41
Total					4,139

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.

[FR Doc. 2017-12736 Filed: 6/16/2017 8:45 am; Publication Date: 6/19/2017]