



**Billing Code: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-17-17ACE]**

**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 *Medication-Assisted Treatment (MAT) for Opioid Use Disorders Study* 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 June, 19, 2017 to obtain comments from the public and affected agencies. CDC received three 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 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). 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

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

This is a new Information Collection Request. CDC requests a three-year OMB approval.

About 2 million people aged 12 or older in the United States have Opioid Use Disorders (OUDs) related to prescription opioids and almost 600,000 have OUDs related to heroin use (SAMHSA, 2015). OUD is a problematic pattern of opioid use that cause significant impairment or distress characterized by unsuccessful efforts to control use and failures to fulfill obligations social, at work, or school, yet many of these people do not receive OUD treatment. Given the continued need for treatment and the urgency of the opioid epidemic, further understanding of the individual and contextual factors that may impact treatment outcomes is needed. To help address this need, the CDC is conducting a study of 60 Opioid Use Disorder (OUD) treatment facilities and four primary care facilities located in 11 metropolitan statistical areas across the United States. The respondent universe includes individuals in the United States who receive some form of OUD treatment in the 11 MSAs.

Prospective participants will be eligible if they are 18 to 64 years of age and initiating one of four primary treatments for OUD: methadone maintenance treatment (MMT), buprenorphine

(BUP), naltrexone (NTX), or counseling treatment without medication (COUN). The study aims to enroll 3,560 clients across all sites to better understand the relationship between type of Medication Assisted Treatment (MAT) and individual and treatment facility characteristics, and contextual factors.

The information gained from this data collection will help inform policy makers, communities, and providers on how individual characteristics and contextual factors may impact client outcomes. The MAT study will also provide a unique perspective for three reasons: 1) It assesses the treatment, individual, and contextual factors that influence implementation and outcomes in real-world settings; 2) its large target sample size (n=3,560); and, 3) the long follow-up window (i.e., 24-month follow-up period with clients). CDC has collaborated with other relevant federal agencies to avoid duplication and maximize efficiencies in data collection. The MAT Study design and protocols have been reviewed and shared with colleagues from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA).

Four overarching evaluation questions guide the MAT Study. These questions drive the research design, and CDC developed this data collection effort to, specifically, address these evaluation questions. This data collection effort captures a series of outcome measures including the associated benefits

(e.g., reductions in morbidity, mortality, and drug overdoses; improvements in socioeconomic outcomes and health-related quality of life [HRQOL]) and potential risks (e.g., side effects, diversion potential) of each treatment alternative.

The study will use a mixed-methods approach using quantitative methods such as multilevel latent growth models, propensity score matching, latent class analysis and advanced mediation analysis and qualitative methods such as interactive coding and analysis for common themes.

The total estimated annualized burden for this collection is 3,093 hours. The only cost to respondents will be time spent responding to the surveys.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Clients	Client Screener	1,583	1	5/60
	Client Check-In	1,187	2	15/60
	Client Questionnaire Baseline	1,187	1	52/60
	Client Questionnaire 12-Month Follow-up	930	1	45/60
	Client Questionnaire 24-Month Follow-up	744	1	45/60
	Client Focus Groups	27	1	90/60
Treatment facility	Staff Focus Groups	27	1	90/60

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