Evaluation of Medication- Assisted Treatment (MAT) for Opioid Use Disorders Study

(OMB no. 0920-1218 exp. date 02/28/2021)

Proposed Changes: Justification and Overview
11/30/2018

Justification

This non-substantial change request is related to the ICR entitled, "Evaluation of Medication-Assisted Treatment (MAT) for Opioid Use Disorders Study," OMB control number 0920-1218.

This Non-Substantive change request does not include changes to the currently approved burden and/or costs.

This Non-Substantive change request is to add three metropolitan statistical areas (MSAs) to the already approved MSAs in the ICR. In order to have the power needed to conduct analysis by study arms and sub-population, it is necessary to expand from 11 MSAs to 14 MSAs, adding Boston, Raleigh/Durham, and Denver. Based upon our analysis of the National Survey of Substance Abuse Treatment Services (N-SSATS) data set, we conservatively estimate that the addition of these MSAs will yield approximately 8-15 additional treatment sites, and will yield enough patients to meet the original study goals.

This change does not represent any change in burden; the same number of participants will be surveyed using the approved instruments. The same sampling methods will be used in the new MSAs as in the existing MSAs. This Non-Substantive change request does not include changes to the currently approved instruments or surveys.

Project Description

The U.S. Food and Drug Administration has approved three classes of medications for the treatment of an Opioid Use Disorder (OUD): methadone maintenance therapy (MMT), buprenorphine (BUP), and naltrexone (NTX). Few studies are available to help patients and providers make informed decisions about the risks and benefits associated with the different MATs. Understanding the outcomes associated with different types of MAT is crucial because differences in pharmacological characteristics and routes of administration across medications,

patients' physiological responses to medication, patients' underlying or co-occurring conditions, and provider or site characteristics all influence how patients respond to the treatment and, thus, their long-term treatment success. Recently, there has been a concerted federal effort to expand use of and access to MAT. This includes expanding the use of MAT within opioid treatment programs, increasing the number of physicians who can prescribe buprenorphine in the office-based setting, and expanding the use of long-acting injectable naltrexone.

Aligned with CDC's role in advancing public health practice, NCIPC requested approval from OMB for this ICR. This observational cohort study will yield important information about MAT implementation and the patient, provider, and site factors that can influence MAT outcomes. The study is heavily informed by and expands upon the MAT randomized controlled trials conducted by the National Institute on Drug Abuse (NIDA), and builds upon the practice-based efforts of the Substance Abuse and Mental Health Services Administration (SAMHSA) to evaluate the impact of their programmatic funding.

To help understand the factors involved in successful treatment, the CDC is conducting a study of 60 OUD treatment facilities and four primary care facilities located in 11 MSAs across the United States. The study aims to enroll 3,560 patients across all sites. Data will be collected over a two-year period from patients with OUD enrolled in MAT (MMT, BUP, or NTX) or counseling without medication treatment, regardless of retention in treatment. Data will also be collected from staff at participating treatment facilities such as site administrators, doctors, clinicians, nurses and counselors; treatment facilities may select the type of staff who participate in data collection activities.

The purpose of this mixed methods study is to follow a cohort of participants receiving MAT over a two-year period to better understand the relationship between MAT implementation and outcomes. The Study will extend previous research by 1) assessing the treatment, individual, and contextual factors that influence implementation and outcomes in real-world settings; 2) targeting a larger sample size (n=3,560) than previous studies; and, 3) providing a longer follow-up window (i.e., 24-month follow-up period with patients) than previous studies so that we can collect data on short- and longer-term outcomes and relapses. Outcomes from this study are not designed to identify or guide policy. CDC has collaborated with other relevant federal agencies to avoid duplication and maximize efficiencies in data collection.

Proposed Changes

Based upon power calculations, the approved methodology included recruitment of 60 OUD treatment facilities in 11 metropolitan statistical areas (MSAs) across the United States in order to enroll 3,560 patients across all sites. Unfortunately, despite extensive efforts by the contractor over the past year, 47 sites have been enrolled across the 11 MSAs, and patient flow and recruitment has been substantially lower than was projected based upon data provided by the sites prior to data collection. In order to have enough power to conduct analyses among the four arms of the study as well as by race/ethnicity, we must recruit at least 3,560 patients. We have approached all eligible facilities within the existing MSAs. Thus, in order to reach the needed overall sample size, it is necessary to expand to three additional MSAs, Boston, Raleigh/Durham, and Denver. Based upon our analysis of the National Survey of Substance Abuse Treatment Services (N-SSATS) data set, we conservatively estimate that each of these MSAs will yield approximately an additional 8-15 treatment sites, and will yield enough patients to meet the original study goals and sub-population analyses.

Change to Burden or Cost

This change does not represent any change in burden; the same number of participants will be surveyed using the approved instruments. The same sampling methods will be used in the new MSAs as in the existing MSAs. This Non-Substantive change request does not include changes to the currently approved burden and/or costs.