

Research Protocol for Medication-Assisted Treatment with Methadone (MAT) Laws

Prepared by Legal Science

November 2016

MEDICATION-ASSISTED TREATMENT WITH METHADONE LAWS

November 2016

Research Protocol

- I. **Date of Protocol:** November 30, 2016
- II. **Scope:** Compile federal and state laws regulating medication-assisted treatment with methadone (MAT) laws, including statutes and regulations. MAT is an approach using FDA-approved drugs for the treatment of opioid disorders. This dataset limited research to MAT with methadone. Federal law establishes the minimum standards for MAT with methadone and outpatient Opioid Treatment Programs (OTPs), but many states have established further restrictions and regulations on the use of MAT with methadone at OTPs. This dataset began as a cross-sectional dataset and is now valid through October 1, 2016.
- III. **Primary Data Collection**
 - a. **Original Project Dates:** June 1, 2016 – November 30, 2016
 - b. **Original Dates Covered in Dataset:** July 8, 2016 – October 1, 2016
 - c. **Data Collection Methods:** The team building this dataset consisted of three legal researchers (“Researchers”) and one supervisor (“Supervisor”). The Supervisor identified the federal law covering medication-assisted treatment with methadone and conducted preliminary background research on state MAT with methadone laws. The Researchers conducted background research on the key areas of variance between the state and federal law. They eventually focused their research on the two more restrictive states, California and New York. They assisted the Supervisor in drafting coding questions to be entered into the MonQcle. Through this research and question drafting, the team developed the inclusionary and exclusionary scoping criteria described below.
 - d. **Databases Used:** Searches were conducted using WestlawNext and state-specific legislature websites. Full text versions of the laws collected were pulled from legislature websites.
 - e. **Search Terms:** MAT, medication assisted treatment, opioid treatment programs, narcotic treatment programs, methadone, methadone treatment, drug abuse treatment
 - i. The Researchers supplemented key word searches by examining the table of contents of each relevant section of the state law that they identified.
 - f. **Initial Returns and Additional Inclusion or Exclusion Criteria:** Included laws covering medication-assisted treatment using methadone only. The federal law was built into each state record to specifically highlight the states that went beyond the federal law and mandated more restrictive policies on OTPs. This dataset also specifically contains laws on outpatient OTPs.
 - i. Excluded laws pertaining exclusively to buprenorphine treatment programs as well as residential drug abuse treatment programs that did not use methadone treatment.
 - ii. Specific inclusion and exclusion criteria for coding questions is described below.

IV. Coding

- a. **Development of Coding Scheme:** The team met with Holly Catania, JD, an expert on medication-assisted treatment to discuss areas of variance between federal and state laws. The team decided to construct a dataset that would provide a general overview of MAT laws and OTP regulations while specifically highlighting areas where states tended to go beyond the federal law, as identified by the expert. Once the coding questions were finalized, the Supervisor entered the questions into the MonQcle.

This dataset requires the overlay of federal law. The federal law provides the minimum standards for which an opioid treatment program must comply. Here, we have inserted the applicable federal law, 42 C.F.R. § 8.12 Federal opioid treatment standards, into each entry to show how the federal law applies. The federal law requires all opioid treatment programs to be certified by an accreditation body specific to each state.

- b. **Coding Methods:** The Researchers were responsible for researching, building, and coding all state records. The Supervisor researched, built, and coded the federal record. The Supervisor reviewed the research and coding for each of the records as they were completed. The Supervisor also added new answer choices as needed, based on the different responses found in state laws. Our team coded the standards for adult patients and caution noted key differences for patients under the age of 21 where appropriate. The team did not note differences for other specific patients, such as pregnant patients, where the standards may differ. A future version of this dataset may address these different standards. Specific coding criteria by question are described below:
- i. For the question, “**Does the jurisdiction require a central registry of OTP patients?**”, the Researchers coded “Yes” for programs that must submit information about each patient explicitly to a central registry for methadone and/or OTP patients. This registry is separate from a prescription monitoring program and is more than collecting the record of each patient at each program location. The purpose of the central registry is to track whether a patient is going to more than one program location.
 - ii. For the question, “**Is random toxicology testing required?**”, the toxicology requirement is often referred to as drug testing. If the statute requires drug testing, the Researchers coded “Yes” for this question. Additionally, if the question mentions random testing that is monthly, the Researchers coded “12” here. For states that required a certain number of tests initially or for the first few months of treatment, then required a certain amount for the remainder of the year (typically monthly), the Researchers coded that remainder amount and caution noted the testing requirements for the initial months of treatment.
 - iii. For the question, “**Is treatment planning for admitted patients required at OTPs?**”, treatment planning includes what some states refer to as an “individualized service plan” for each patient.
 - iv. For the questions, “**Is physician evaluation required for new patient admission?**” and “**How soon must the physician evaluate the patient?**” the Researchers are looking in state laws for a requirement similar to the standard laid out in 42 C.F.R. § 8.12(f)(2) which states that OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. That full medical examination must be completed within 14 days following admission.

- c. Quality Control:** The Supervisor assigned the first 10 states for redundant coding by the Researchers. The divergence rate was 5.7%. All divergences were discussed and resolved accordingly. Another 10 states were assigned for redundant coding and the divergence rate fell to 1.7%. Subsequent rounds of redundant coding yielded divergence rates of 0% throughout the quality control process. The Supervisor then did a final coding check for each state and finalized the data for publication.