Pharmacy-based Methadone: Analysis of Current Laws and Regulations

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PHARMACY-BASED METHADONE: ANALYSIS OF CURRENT LAWS AND REGULATIONS

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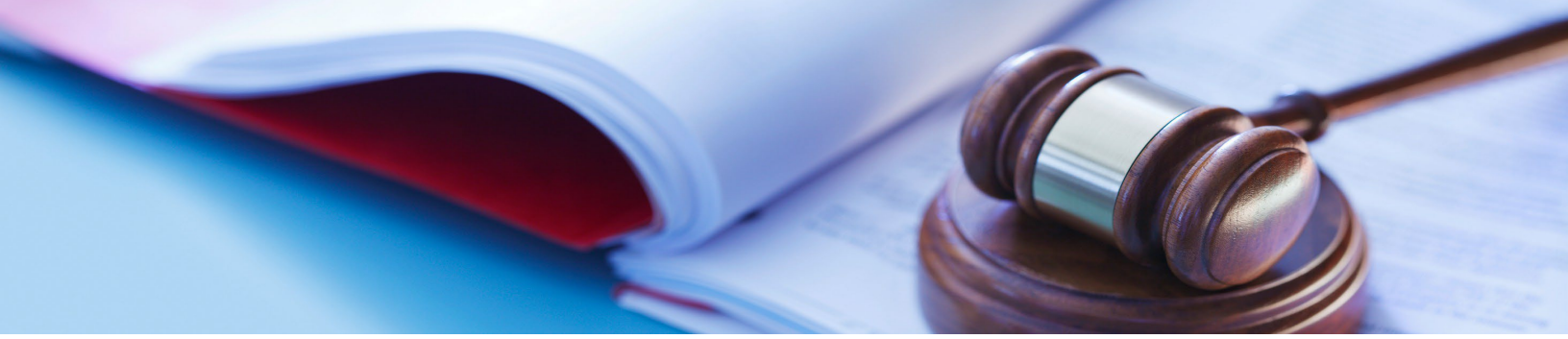


Executive Summary

An entity that provides methadone for opioid use disorder (OUD) treatment in the United States is subject to multiple levels of laws and regulations. These include federal laws, federal regulations, state laws, state regulations. Subject to a few exceptions, as these laws and regulations exist today, opioid treatment programs (OTPs) are the only entity allowed to provide methadone for OUD treatment. In contrast, methadone prescribed for pain treatment is not subject to the OTP limitation and can be dispensed by pharmacists from a pharmacy.[1]

This written analysis results from the underlying project's directive to conduct a rigorous review of the laws and regulations currently applying to methadone for OUD treatment to determine the types of laws and regulations that need to change to support pharmacy-based methadone treatment. At the outset of this project, the project's research team identified three specific pharmacy-based methadone delivery models for express consideration in this analysis. These three models are:

(1) A pharmacy partners with an OTP to operate a medication unit[2] in the pharmacy;
(2) A pharmacy allows an OTP to park a mobile medication unit at or near the pharmacy parking lot; and
(3) A pharmacy dispenses methadone for OUD like any other controlled substance after being prescribed by a physician or other authorized prescriber (called the prescriber-enhanced delivery model within this analysis).

For each of these three models, this analysis poses the following questions:

- Are any federal law or regulation changes required before this delivery model can commence?
- Are any state law or regulation changes required before this delivery model can commence?
- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

[1] Unless otherwise specified, references to "pharmacy" in this analysis mean a "community pharmacy," which is also known as a "retail pharmacy."
[2] As described in more detail below, a "medication unit" is an entity that is part of an already-established OTP, but located geographically separate from it.

Answering these questions requires a comprehensive understanding of laws and regulations, as they exist today, that directly apply to methadone for OUD treatment or could be implicated by one of the three identified pharmacy-based methadone delivery models. To provide this understanding, prior to considering the questions, this analysis:

- Introduces the federal and state entities/agencies that play important roles in governing methadone for OUD treatment, which include Congress, the U.S. Drug Enforcement Administration (DEA), the Substance Abuse and Mental Health Services Administration (SAMHSA), state legislatures, state controlled substance authorities, and the state opioid treatment authority (SOTA);
- Provides a detailed glossary of defined terms used in the laws and regulations examined and highlights the fact that different federal agencies use different terminology;
- Explains the provision in the federal Controlled Substances Act (21 U.S.C. § 823(h)) that creates a joint DEA/SAMHSA regulatory scheme for methadone for OUD treatment;
- Describes SAMHSA's regulations that govern how OTPs must provide methadone for OUD treatment and authorizes OTPs to establish a medication unit in a separate geographic location;
- Describes DEA's regulations governing the narcotic treatment program (NTP) registration that is required for an OTP to provide methadone for OUD treatment and how methadone must be secured and stored;
- Introduces other federal laws that could be relevant to pharmacy-based methadone delivery models including fraud and abuse laws and disclosure of substance use disorder (SUD) treatment records to prescription drug monitoring programs; and
- Summarizes the general types of state laws and regulations that place additional restrictions on methadone for OUD treatment or govern areas not addressed by DEA or SAMHSA, and explains how those laws and regulations may potentially limit or prevent pharmacy-based methadone delivery models.

Based upon the understanding gained from the comprehensive look at current laws and regulations, this analysis reaches numerous conclusions about each of the three identified pharmacy-based methadone delivery models.

Pharmacy partners with an OTP to allow the OTP to operate a medication unit in the pharmacy. This is allowed under current federal laws and regulations. The lack of medication units across the country, however, suggests that current laws and regulations cause enough logistical, administrative, and financial difficulty that OTPs rarely try to establish them. The analysis concludes that several types of changes to federal laws/regulations would encourage medication units at pharmacies, including: (1) streamlining and simplifying the DEA and SAMHSA approval processes for a medication unit; (2) allowing operators of medication units at pharmacies to obtain and store methadone in the same manner that the pharmacy already uses for all other controlled substances dispensed at the pharmacy; and (3) allowing operators of medication units at pharmacies to use the inventory, recordkeeping, and reporting systems already in place for all other DEA schedule II controlled substances dispensed at the pharmacy.

For this model, the need for change to state laws/regulations varies depending on the individual state. States with restrictions on medication unit locations may need to change those laws/regulations before a medication unit can operate out of a pharmacy. In addition, states with restrictions on opening OTPs generally (even where the laws/regulations do not expressly mention medication units) are also problematic because a medication unit requires an OTP. As a result, state decisionmakers could view a proposed medication unit as a proposed OTP location, particularly if the state's laws/regulations do not contain provisions expressly addressing medication units. One particular type of state restriction that can apply to OTPs is the requirement that an entity seeking to establish an OTP submit a certificate of need. Certificate of need laws are mechanisms for approving major capital expenditures and projects for certain healthcare facilities. These mechanisms generally require that a health planning agency or other entity approve the creation of new healthcare facilities or the expansion of an existing facility's services in a specified area. Because the petitioning process takes significant time, costs a lot of money, and open the request to challenge from competitors and those opposed to the proposal, these requirements act as barriers to equitable and accessible healthcare.

State action to encourage pharmacy-based medication units should create a clear, express process for the approval and siting of such units. Federal laws already provide for layers of approval by DEA, SAMHSA, and SOTA, so there is little need for additional state regulation. However, a lack of laws and regulations expressly addressing medication units at all is also problematic. In the absence of an express provision that a medication unit in a pharmacy is both *allowable and will be allowed* if certain conditions are met, state and local decisionmakers may place roadblocks (intentionally or unintentionally) that delay or prevent implementation.

Pharmacy allows an OTP to park a mobile medication unit at or near the pharmacy. As with the first model, this is allowed under current federal laws/regulations and the analysis of required and desired changes to federal and state laws/regulations is largely the same. Just like with fixed medication units, streamlining and simplifying the DEA and SAMHSA approval processes for a mobile medication unit would assist in making this delivery model more attractive. However, because the mobile medication unit would exist wholly outside of the pharmacy's walls, the fact that DEA and SAMHSA require methadone storage, security, recordkeeping, and reporting requirements different from typical pharmacy operations should create fewer administrative and logistical issues to the pharmacy itself. Likewise, states should craft clear, express provisions about mobile medication units that provide a simple and streamlined process for approval and indicate such approval will be granted if conditions are met.

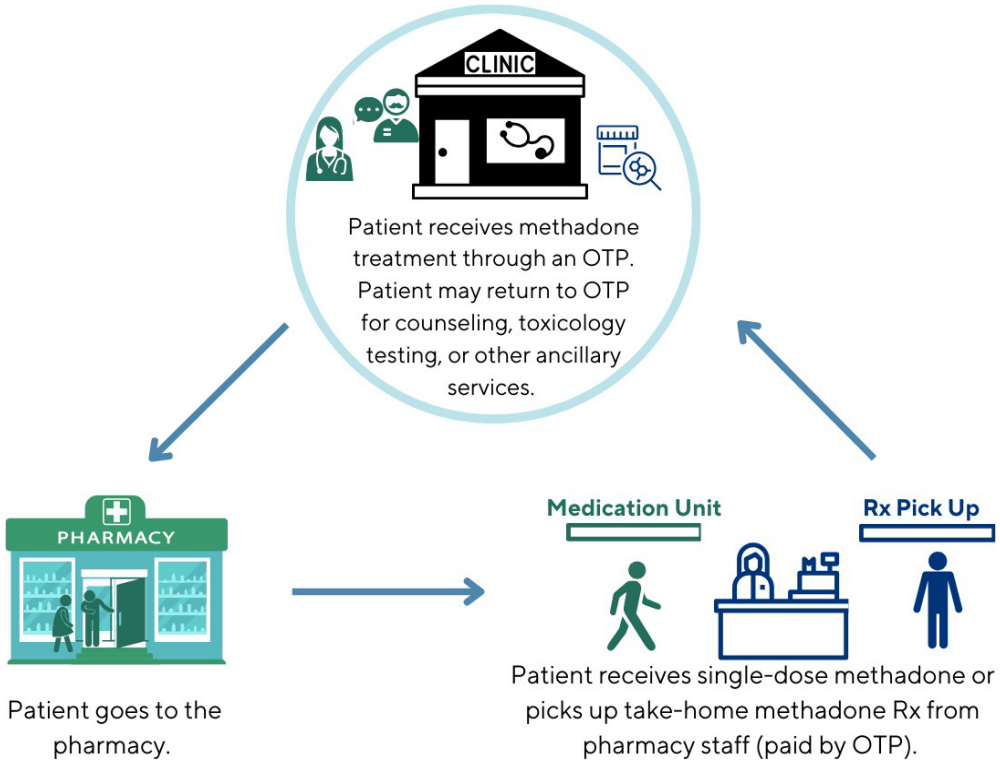
Pharmacy dispenses methadone for OUD like any other controlled substance after being prescribed by a physician or other authorized prescriber. The third delivery model analyzed, also called the prescriber-enhanced model within this analysis, involves a pharmacy dispensing prescribed methadone like any other controlled substance. This model is not allowed under current federal laws or regulations. As the CSA, DEA regulations, and SAMHSA regulations prevent implementation of this delivery model now, action by Congress, DEA, and SAMHSA is needed to put the necessary changes in place. While the final product of the necessary changes is clear—allowing practitioners to prescribe methadone for OUD and allowing retail pharmacies to dispense it—there are many paths that Congress, DEA, and SAMHSA could take to achieve the desired result. Moreover, assuming Congress acts, subsequent revisions to DEA and SAMHSA regulations greatly depend on how Congress changes the law. One possible way Congress could act is by passing the "Modernizing Opioid Treatment Access Act" (MOTAA), introduced in both the Senate and House of Representatives in March 2023.

Among other things, MOTAA proposes to: (1) waive provisions of the CSA that require qualified practitioners to obtain a separate registration from DEA to prescribe and dispense methadone for OUD treatment; (2) direct the DEA to register certain practitioners to prescribe methadone that is dispensed through a pharmacy for an individual's unsupervised use; (3) require those qualified practitioners to be licensed or authorized to prescribe controlled substances, and to either work for an OTP or be a physician or psychiatrist with a specialty certification in addiction medicine; and (4) allow a state to ask the DEA to stop registering such practitioners in its jurisdiction.

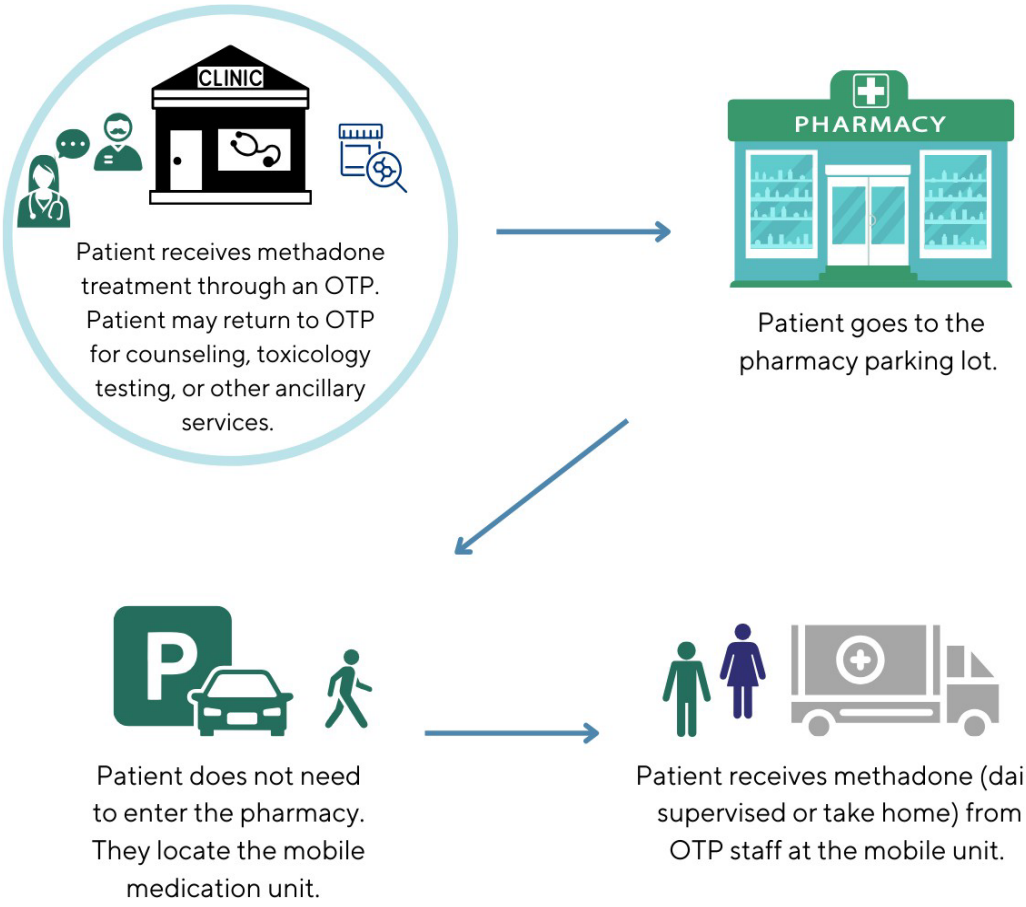
A reasonable reading of MOTAA is that the model it envisions would be completely pulled out from all current DEA and SAMHSA regulations governing OTP and NTPs. However, the requirement that DEA separately register individuals to prescribe methadone for opioid use disorder to be dispensed through a pharmacy seems to suggest (or even require) a new DEA registration category as well as, potentially, new DEA and SAMHSA regulations covering this methadone dispensing mechanism. New regulations could very well reintroduce some of the logistical and administrative challenges that OTPs/medication units face currently such as methadone storage restrictions or limitations on eligibility for take-home doses. At the state level, until the way Congress, DEA, and SAMHSA make this delivery model allowable are known, determining desirable changes to state laws/regulations is somewhat speculative. However, if federal changes give states the ability to restrict, avoid, or opt-out of this prescriber-enhanced model, the preference would be for states not to act in that respect to maximize access to methadone.

Visualizations of Pharmacy-based Methadone Treatment Delivery Models

Model 1 - Pharmacy partners with an OTP to allow the OTP to operate a medication unit in the pharmacy



Model 2 - Pharmacy allows an OTP to place a mobile medication unit in the parking lot of the pharmacy



Model 3 – Pharmacy dispenses methadone like any other controlled substance from a pharmacy after being prescribed by a physician or other authorized prescriber (the prescriber-enhanced delivery model)

Abbreviations and Acronyms

This list identifies the abbreviations and acronyms used throughout this analysis.

APQ – Aggregate production quota
CFR or C.F.R.[3] – Code of Federal Regulations
CSA – Controlled Substances Act (federal)
DEA – U.S. Drug Enforcement Administration
DOJ – U.S. Department of Justice
FDA – U.S. Food and Drug Administration
FR or Fed. Reg. – Federal Register
HHS – U.S. Department of Health and Human Services
MOTAA – Modernizing Opioid Treatment Access Act
MOUD – Medication(s) for opioid use disorder
MQ – Manufacturing quota
NTP – Narcotic treatment program
OIG – Office of Inspector General
OTP – Opioid treatment program
OUD – Opioid use disorder
PDMP – Prescription drug monitoring program
PQ – Procurement quota
SAMHSA – Substance Abuse and Mental Health Services Administration
SOTA – State Opioid Treatment Authority
SUD – Substance use disorder
USC or U.S.C. – United States Code

[3] Per *The Bluebook*, the guide for legal citation in court documents, law review articles, and legal memoranda, the longer of the two abbreviations listed is the official way to cite to the Code of Federal Regulations, Federal Register, and United States Code. The authors use these longer abbreviations most frequently in this analysis.

Glossary of Defined Terms

This analysis uses many terms and phrases defined in the Controlled Substances Act (CSA), U.S. Drug Enforcement Administration (DEA) regulations, and Substance Abuse and Mental Health Services Administration (SAMHSA) regulations. The list below contains these terms/phrases as well as their respective sources (in parentheses), precise definitions, and a link to a publicly accessible version of the federal law/regulation containing the definition. Note that the language in quotes comes directly from the statute or regulation and may not conform to terminology used today.

To highlight the existence of specific definitions when directly discussing the laws and regulations, the authors set out these terms/phrases in bold typeface in the sections of this analysis that describe federal law, SAMHSA regulations, DEA regulations, and regulations covering disclosure of substance use disorder (SUD) treatment records (pages 21-37).

Accreditation body (SAMHSA) – "An organization that has been approved by the Secretary[4] in this part to accredit OTPs dispensing MOUD." 42 C.F.R. § 8.2 (2024).

Administer (CSA) – "The direct application of a controlled substance to the body of a patient or research subject by—(A) a practitioner (or, in his presence, by his authorized agent), or (B) the patient or research subject at the direction and in the presence of the practitioner whether such application be by injection, inhalation, ingestion, or any other means." 21 U.S.C. § 802(2) (2024).

Certification (SAMHSA) – "The process by which the secretary determines that an OTP is qualified to provide OUD treatment under the federal opioid use disorder treatment standards." 42 C.F.R. § 8.2 (2024).

Continuous medication treatment (SAMHSA) – "The uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days." In addition, "as used in this part, 'continuous medication treatment' is intended to be synonymous with the term 'maintenance treatment' as used in 21 U.S.C. 823(h)(1)." 42 C.F.R. § 8.2 (2024).

Controlled substance (CSA) – "A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986." 21 U.S.C. § 802(6) (2024).

Detoxification treatment (CSA) – "The dispensing, for a period not in excess of [180] days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period." 21 U.S.C. § 802(30) (2024).

[4] "Secretary" is a defined term and included in this glossary. It refers to the Secretary of HHS.

Detoxification treatment (DEA) – "The dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. There are two types of detoxification treatment: Short-term detoxification treatment [30 days or less] and long-term detoxification treatment [31-180 days]." 21 C.F.R. § 1300.01(b) (2024).

Dispense (CSA) – "To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. 21 U.S.C. § 802(10) (2024).

Dispenser (CSA) – "A practitioner who so delivers a controlled substance to an ultimate user or research subject." 21 U.S.C. § 802(10) (2024).

Dispenser (DEA) – "An individual practitioner, institutional practitioner, pharmacy, or pharmacist who dispenses a controlled substance." 21 C.F.R. § 1300.01(b) (2024).

Federal opioid use disorder treatment standards (SAMHSA) – These are the standards contained in 42 CFR § 8.12, which are used to determine whether an OTP is qualified to engage in OUD treatment. 42 C.F.R. § 8.2 (2024).

Individual practitioner (DEA) – "A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner." 21 C.F.R. § 1300.01(b) (2024).

Institutional practitioner (DEA) – "A hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy." 21 C.F.R. § 1300.01(b) (2024).

Lawful holder (HHS) – "A person who is bound by [42 C.F.R. Part 2] because they have received records as the result of one of the following: (1) written consent in accordance with [42 C.F.R.] § 2.31 with an accompanying notice of disclosure; [or] (2) one of the exceptions to the written consent requirements in 42 U.S.C. 290dd-2 or [42 C.F.R. Part 2]." 42 C.F.R. § 2.11 (2024).

Maintenance treatment (CSA) – "The dispensing, for a period in excess of [21] days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs." 21 U.S.C. § 802(29) (2024).

Medical director (SAMHSA) – "A physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP." 42 C.F.R. § 8.2 (2024).

Medication for opioid use disorder or MOUD (SAMHSA) – "Medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD." 42 C.F.R. § 8.2 (2024).

Medication unit (SAMHSA) – "An entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services" and "can be a brick-and-mortar location or mobile unit." 42 C.F.R. § 8.2 (2024).[5]

Mid-level practitioner (DEA) – "An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the State in which they practice." 21 C.F.R. § 1300.01(b) (2024).

Mobile narcotic treatment program (DEA) – "A narcotic treatment program (NTP) operating from a motor vehicle, as defined in this section, that serves as a mobile component (conveyance) and is operating under the registration of the NTP, and engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II-V, at a location or locations remote from, but within the same State as, its registered location. Operating a mobile NTP is a coincident activity of an existing NTP, as listed in § 1301.13(e) of this chapter." 21 C.F.R.
§ 1300.01(b) (2024).

Narcotic drug (CSA) – "Any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

[5] SAMHSA occasionally refers to a "brick-and-mortar" medication unit as a "fixed medication unit" or a "non-mobile medication unit."

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium;

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E)." 21 U.S.C. § 802(17) (2024).

Narcotic treatment program or NTP (DEA) – "A program engaged in maintenance and/or detoxification treatment with narcotic drugs." 21 C.F.R. § 1300.01(b) (2024).

Opioid treatment program or OTP (SAMHSA) – "A program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1)." 42 C.F.R. § 8.2 (2024).

Opioid use disorder or OUD (SAMHSA) – "A cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period." 42 C.F.R. § 8.2 (2024).

Opioid use disorder treatment (SAMHSA) – "The dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD." 42 C.F.R. § 8.2 (2024).

Part 2 program (HHS) – "A federally assisted program (federally assisted as defined in [42 C.F.R. § 2.12(b)] and program as defined in [42 C.F.R. § 2.11])." 42 C.F.R. § 2.11 (2024).

Person (DEA) – A person "includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity." 21 C.F.R.
§ 1300.01(b) (2024).

Pharmacist (DEA) – "Any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (*e.g.*, pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State." 21 C.F.R.
§ 1300.01(b) (2024).

Practitioner (CSA) – "A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 21 U.S.C. § 802(21) (2024).

Practitioner (SAMHSA) – "A health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP." 42 C.F.R. § 8.2 (2024)..

Program (HHS) – "(1) A person (other than a general medical facility) that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
(2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers." 42 C.F.R. § 2.11 (2024).

Program sponsor (SAMHSA) – "The person named in the application for certification described in § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP." 42 C.F.R. § 8.2 (2024).

Secretary (CSA and SAMHSA) – The secretary of the U.S. Department of Health and Human Services. 21 U.S.C. § 802(24) (2024). / 42 C.F.R. § 8.2 (2024).

State Opioid Treatment Authority or SOTA (SAMHSA) – "The agency designated by the Governor of a State, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the State or Territory for governing the treatment of OUD with MOUD in OTPs." 42 C.F.R. § 8.2 (2024).

Withdrawal management (SAMHSA) – "The dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period." In addition, "the term 'withdrawal management' is intended to be synonymous with the term 'detoxification' as used in 21 U.S.C. 823(h)(1)." 42 C.F.R. § 8.2 (2024).

Scope of Project

This project's funding documents direct the research team, led by staff from the Legislative Analysis and Public Policy Association (LAPPA), to conduct a rigorous review of federal laws, legislation, and regulations relevant to pharmacy-based[6] methadone access and delivery models for opioid use disorder (OUD) treatment. The review should identify the types of federal and state laws and regulations that need to be changed to support a pharmacy-based methadone treatment model, as well as any that explicitly facilitate pharmacy-based methadone medications for OUD (MOUD).

Pharmacy-based Methadone: Analysis of Current Laws and Regulations

Introduction

An entity that provides methadone for opioid use disorder (OUD) treatment in the United States is subject to multiple levels of laws and regulations,[7] including:

(1) Federal laws enacted by Congress;
(2) Regulations promulgated by federal agencies, as well as binding transmittals and other guidance issued by those agencies that do not take the form of formal regulation;
(3) Laws enacted by a state, District of Columbia (D.C.). or territorial governing body;[8,9]
(4) Regulations (called "rules" in many states) adopted by state governmental agencies; and
(5) Provisions adopted by municipal governments (often called ordinances).

Levels (1) and (2) apply to all entities in all states. The existence of level (3), (4), or (5) provisions and how (or if) those provisions differ from federal laws and regulations, depends on the location of the entity seeking to provide methadone for OUD treatment. Currently, only opioid treatment programs (OTPs) may generally provide methadone for OUD treatment.[10] In contrast, methadone prescribed for pain treatment is not subject to the OTP limitation.

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[6] Unless otherwise specified, references to "pharmacy" in this analysis mean a community pharmacy, which is also known as a retail pharmacy.
[7] Although it is somewhat common practice to describe all governmental directives applying to an entity as "laws," that usage is imprecise. A "law" is something enacted by a legislative body. It is often synonymous with the word "statute," although there are examples of enacted laws that do not end up in statutory codes (*e.g.*, a law providing for specific appropriations in a fiscal year). Meanwhile, a "regulation" is written by a governmental agency to implement laws passed by the legislative branch. Within this analysis, "law" and "regulation" take on their specific definitions. Where the authors wish to refer to all levels of governmental rules/directives, we use the broader phrase "laws and regulations" or the verb "governing."
[8] Even though D.C. and U.S. territories are not states, for simplicity's sake in this analysis, the word "state" includes states, D.C., and U.S. territories unless otherwise specified.
[9] Depending on the location, a governing body may be called the legislature, general assembly, legislative assembly, council, or general court.
[10] Federal regulations do allow non-OTP individuals or entities to provide methadone for OUD treatment in limited circumstances (*e.g.*, the "three-day rule," or certain hospitals, long-term care facilities, or correctional

Beyond written laws and regulations, human factors also apply. As described below in the sections covering federal laws, federal regulations, and state laws and regulations, individuals/organizations who wish to form OTPs (or expand services from already existing OTPs), must seek approval from federal, state, or local agencies/entities before moving forward. This means that in addition to the actual statutory or regulatory text, how individuals at those agencies/entities interpret applicable (or potentially applicable) laws/regulations is important. Moreover, where the laws/regulations do not expressly allow or disallow an activity, those agencies/entity individuals' level of comfort with the proposed activity may be the deciding factor for approval.[11]

At the outset of this project, the research team identified three specific pharmacy-based methadone delivery models for express consideration in this analysis. These three models are:

(1) A pharmacy partners with an OTP to operate a medication unit[12] in the pharmacy;
(2) A pharmacy allows an OTP to park a mobile medication unit at or near the pharmacy parking lot; and
(3) A pharmacy dispenses methadone for OUD like any other controlled substance after being prescribed by a physician or other authorized prescriber (called the prescriber-enhanced delivery model within this analysis).

Starting on page 40, this analysis considers the following questions for each of the three specified delivery models:

- Are any federal law or regulation changes required before this delivery model can commence?
- Are any state law or regulation changes required before this delivery model can commence?
- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

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facilities who treat a patient for a primary condition other that OUD). Those limited circumstances are not the focus of this analysis.

[11] Here is a generic example of human factors that will be relevant to the analysis of pharmacy-based methadone for OUD treatment delivery models. Assume that federal laws/regulations allow the opening of "Thing A," but only after certain federal, state, and local agencies/entities give approval. Also, assume that state laws/regulations do not expressly disallow the opening of Thing A. Neither federal nor state laws/regulations, however, require that the federal, state, or local agencies/entities approve a request to open Thing A. Although the general rule-of-thumb is that if the law is silent about an activity an individual can do it, as a practical matter, Thing A cannot operate until the decisionmakers at the federal, state, or local agencies/entities approve it. This setup gives those decisionmakers considerable power to hinder the opening of Thing A, even though it is allowable under state and federal laws/regulations.

[12] As described in more detail below, a "medication unit" is an entity that is part of an already-established OTP, but located geographically separate from it.

Answering these questions requires a comprehensive understanding of laws and regulations as existing today. To provide this underlying, this analysis begins with a short description of the federal and state agencies that approve and regulate OTPs. Next, there is an extensive overview of the federal laws and regulations that directly apply to providing methadone for OUD now or are potentially relevant to pharmacy-based methadone delivery models. Then, the analysis summarizes the types of state level laws and regulations that may apply. With the understanding gained from these earlier sections, the final portion of this analysis addresses the three questions for each of the identified pharmacy-based methadone delivery models.

Federal and State Agencies

On the federal side, Congress and three federal agencies play important roles in governing methadone for OUD treatment. Congress is important because the starting point for the entire analysis is the federal Controlled Substances Act (CSA), codified at 21 U.S.C. § 801, et seq.
The three federal agencies are the U.S. Food and Drug Administration (FDA), the U.S. Drug Enforcement Administration (DEA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Drugs considered controlled substances under the CSA are classified into five schedules (I, II, III, IV, V), with the scheduling dependent upon the drug's acceptable medical use and dependency potential.[13] Methadone is a schedule II controlled substance.[14] The DEA is the agency within the U.S. Department of Justice (DOJ) tasked with primary enforcement of controlled substances laws and regulations.[15] In addition to regulations covering schedule II drugs generally, DEA has created regulatory provisions that apply specifically to methadone treatment for OUD. DEA regulations governing the implementation of the CSA are in Title 21, Chapter II (*i.e.*, Parts 1300 to 1321) of the Code of Federal Regulations (CFR or C.F.R.)). The list of substances included in schedule II is in 21 C.F.R. § 1308.12.

SAMHSA is an agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders (SUDs), and their families.[16] Prior to 2001, FDA had administrative oversight of entities providing methadone treatment for OUD. In 2001, those oversight responsibilities shifted to SAMHSA. SAMHSA regulations governing "Medications for Opioid Use Disorder" are in 42 C.F.R. Part 8.

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[13] *What Is a Controlled Substance?*, UNIV. CAL. LOS ANGELES ENV., HEALTH & SAFETY (last accessed Sept. 10, 2024), https://ehs.ucla.edu/what-controlled-substance-0. A schedule I drug has the most potential for abuse or dependency and the lowest (or no) accepted medical use.
[14] 21 C.F.R § 1308.12(c) (2024).
[15] *Drug Enforcement Administration,* FED. REG. (last accessed Sept. 10, 2024), https://www.federalregister.gov/agencies/drug-enforcement-administration.
[16] *Who We Are*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Apr. 17, 2024), https://www.samhsa.gov/about-us/who-we-are.

FDA is an agency within the U.S. Department of Health & Human Services (HHS) that, among other things, is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs.[17] FDA is the agency that approves a drug for a particular condition (*e.g.*, "methadone for opioid dependency") and then approves specific drug products, in unique dosage form/route of administration/strength combinations, for consumer use. FDA also provides information to the DEA to help in the DEA's calculation of production quotas for controlled substances and chemicals. FDA's actions in approving (or not approving) methadone products for OUD treatment is most relevant to this analysis, rather than FDA regulations themselves, which largely detail the process by which manufacturers submit drugs for approval. FDA's work includes issuing "risk evaluation and mitigation strategies" (REMS) for drugs, such as a its blanket REMS for opioids including all methadone formulations.[18]

At the state level, there are two types of entities involved. First, state laws addressing methadone for OUD treatment, if any, may authorize or direct one or more state agencies to adopt regulations/rules. One such agency may be a state department of health, or sub-department/agency within it, as this is the state agency most likely to have a mission similar to SAMHSA. State agencies that oversee controlled substances may also develop regulations governing methadone for OUD treatment.[19] Depending on the state, many agencies including state boards of pharmacy, state departments of professional regulation, state departments of health, and in a few states, the attorney general or other law enforcement agency have the authority to regulate controlled substances.[20,21]

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[17] *Food and Drug Administration,* FED. REG. (last accessed Sept. 10, 2024), https://www.federalregister.gov/agencies/food-and-drug-administration.

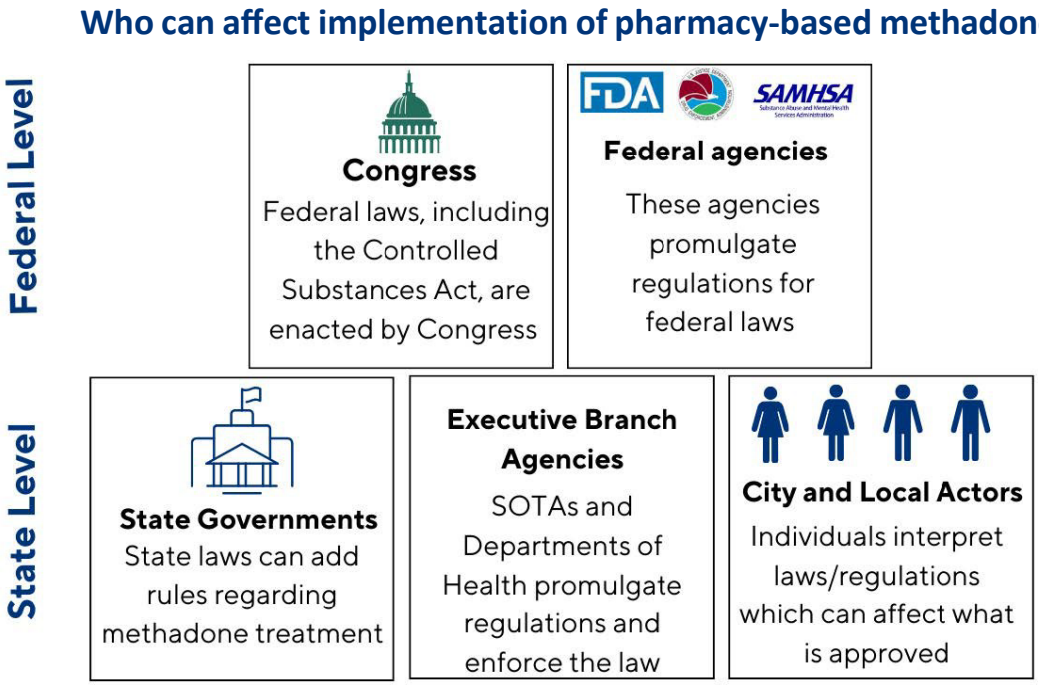
[18] *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, U.S. FOOD & DRUG ADMIN. (Nov. 14, 2023), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems; *Approved Risk Evaluation and Mitigation Strategies (REMS) – Opioid Analgesic REMS*, U.S. FOOD & DRUG ADMIN. (April 9, 2021), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17.

[19] Virtually all states have their own controlled substances act and controlled substances schedules. These provisions largely track the federal versions although not without exception. The most notable difference is where a state "legalizes" cannabis for certain uses or up to certain amounts, which involves, among other things, removing cannabis from the state's controlled substance schedule I. (Cannabis remains in federal controlled substance schedule I, at least as of October 2024.)

[20] *See Members 2023-24*, NAT'L ASSOC. OF STATE CONTROLLED SUBSTANCE AUTH. (Oct. 20, 2022), https://www.nascsa.org/members.

[21] Although not the focus of this analysis in any way, when identifying the various types of agencies charged with regulating controlled substances at the state level, it is worth mentioning the concept of "regulatory capture." Regulatory capture occurs when a regulatory agency becomes dominated by the industries or interests it regulates, with the result being that the agency prioritizes the interests of the regulated industry over the public interest. Will Kenton, *Regulatory Capture Definition with Examples*, INVESTOPEDIA (Aug. 1, 2024), https://www.investopedia.com/terms/r/regulatory-capture.asp. Should regulatory capture occur to any extent, a state's legislature may be less likely to be able to direct the extent of the agency's rulemaking.

Second, SAMHSA's regulations covering methadone for OUD treatment grant authority for monitoring OTP operations within a state, as well as making recommendations about new and renewal OTP applications, to the "state opioid treatment authority" or "SOTA."[22] SOTA is an agency designated within a state "to exercise the responsibility and authority within the State or Territory for governing the treatment of OUD with MOUD in [treatment facilities providing methadone.]"[23] Although the definition of SOTA refers to an "agency," SAMHSA publishes a list of SOTAs that identify a singular individual in each state as the SOTA.[24]



Terminology Note

As the glossary of terms at the beginning of this analysis shows, there is a bifurcated vocabulary system with respect to methadone for OUD treatment; in some places the CSA and DEA regulations use different words/phrases than SAMHSA regulations to refer to the same thing.[25] To avoid confusion, this analysis uses CSA/DEA terminology when describing CSA/DEA regulations and SAMHSA terminology when describing SAMHSA regulations.[26]

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[22] *State Opioid Treatment Authority (SOTA) Role Explained*, NAT'L ASSOC. OF STATE ALCOHOL & DRUG AGENCY DIRECTORS (May 3, 2023), https://nasadad.org/2023/05/state-opioid-treatment-authority-sota-role-explained/.
[23] 42 C.F.R. § 8.2 (2024) (definition of "state opioid treatment authority").
[24] *State Opioid Treatment Authorities*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Aug. 23, 2024), https://www.samhsa.gov/medications-substance-use-disorders/sota.
[25] Although many individuals consider some CSA/DEA words and phrases outdated, such terminology still exists in the statute and regulations.
[26] Do note that there are some instances where DEA or SAMHSA regulations intentionally use the other agency's terminology.

Further complicating matters is the varied, and to some extent confusing, definitions of the term "practitioner" found in the CSA, DEA regulations, and SAMHSA regulations. SAMHSA's definition of practitioner is the most straightforward, a "health care professional" who can "prescribe and/or dispense medications for opioid use disorders." This definition is narrow (*i.e.*, limited to medications for OUD) and refers to an individual, not an entity.[27] The CSA defines practitioner more broadly. It encompasses "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person"[28] with the legal authority to "distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis" a controlled substance. At first, the verb "prescribe" appears conspicuously absent from this definition. However, the CSA's definition of dispense includes prescribing.[29] The CSA definition expressly identifies two types of inanimate entities—pharmacy and hospital—but also uses the pronoun "he," which does not make complete sense if a practitioner can be an individual or an entity.

DEA regulations do not separately define practitioner, and thus the CSA definition applies within DEA regulations. However, DEA regulations define three related terms, "individual practitioner," "institutional practitioner," and "mid-level practitioner." Both a pharmacist and a pharmacy are expressly excluded from the definitions of individual practitioner and institutional practitioner. Moreover, neither a pharmacist nor a pharmacy fall under DEA's definition of mid-level practitioner, as a mid-level practitioner is defined as a certain subset of individual practitioners, and pharmacists are, by definition, not individual practitioners. Despite this, registered pharmacists are allowed to obtain a mid-level practitioner DEA registration so long as it is permitted by state law.[30]

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[27] For purposes of this analysis, the narrowness of the SAMHSA definition is not an issue. However, this narrowness opens the possibility that SAMHSA regulations outside of OUD treatment might use a different definition of practitioner.

[28] The CSA itself does not define "person." However, in statutory/regulatory language, drafters commonly use person to refer to individuals and other entities (such as corporations, partnerships, etc.). DEA regulations use the defined term "person" in this manner.

[29] This conclusion is also somewhat difficult to discern. Under the CSA, dispense means to "deliver" a controlled substance "including the prescribing and administering of a controlled substance." 21 U.S.C § 802(10) (2024). Phrased in this fashion, one could conclude that dispense covers only the contemporaneous prescribing and then administering of a controlled substance. However, the DEA's Practitioner's Manual states that dispensing "includes by definition administering and prescribing." *Practitioner's Manual: An Informational Outline of the Controlled Substances Act*, DRUG ENFORCEMENT ADMIN. 12 (2023), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf. When phrased in this order, it is clearer that prescribing and administering are two separate activities that do not need to occur contemporaneously to fall within dispense.

[30] *See Mid-level Practitioners Authorization by State*, DRUG ENF'T ADMIN (Dec. 2, 2022), https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (identifying the states in which a "registered pharmacist" can obtain a mid-level practitioner registration). In states where registered pharmacists cannot obtain a DEA mid-level practitioner registration, the prohibition is due to state restriction, not DEA restriction.

DEA Registration Note

According to DEA regulation, "every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26."[31,32] A "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."[33]

There are nearly 20 categories of DEA registration, which include the following registration categories appearing on DEA's registration webpage:[34]

- Practitioner;
- Mid-level practitioner;
- Pharmacy;
- Hospital/clinic;
- Teaching institution;
- Automated dispensing machines; and
- Narcotic treatment program.[35]

Once the DEA issues the registration, in the form of a "DEA number," the first letter of the DEA number corresponds to the registration category.[36] If DEA issues the registration to an individual, the second letter of the DEA number is the first letter of the individual's last name. If DEA issues the registration to a business address, the second digit of the DEA number is "9." [37]

A key component of federal law and regulations covering methadone for OUD treatment is the need for practitioners to obtain a separate DEA registration to do so. In practical terms, this separate registration is the registration labeled "narcotic treatment program" in the list above, which DEA issues to a business address. It is separate from the DEA registration a person would need to manufacture, distribute, dispense, import, or export any controlled substance.

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[31] 21 C.F.R. § 1301.11(a) (2024).
[32] The exemptions in 21 C.F.R. §§ 1301.22 to 1301.26 (2024) pertain to certain agents/employees of a registered individual or hospital, miliary personnel, law enforcement, ocean vessels and aircraft, and importing/exporting controlled substances for personal medical use.
[33] 21 C.F.R. § 1300.01(b) (2024).
[34] *Application for Registration under Controlled Substances Act of 1970 (New Applicants Only)*, DRUG ENF'T ADMIN. (last accessed Sept. 10, 2024), https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s1.
[35] On the DEA registration webpage, the link to this registration is labeled "Narcotic Treatment Clinics." However, DEA regulations themselves use the term narcotic treatment program or NTP.
[36] Walker, Elaine, *DEA Numbers and the Pharmacy Technician Exam*, PTCB TEST PREP (Jan. 24, 2020), https://ptcbtestprep.com/what-are-dea-numbers/.
[37] *Id.*

Federal Law

Controlled Substances Act

The fact that a joint DEA/SAMHSA regulatory scheme applies to methadone for OUD treatment is a product of a provision from the CSA. In 21 U.S.C. § 823(h), the CSA provides that:

> (h) Practitioners[38] dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications
>
> Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General[39,40] shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both):
>
> (1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;
>
> (2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and
>
> (3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.[41,42]

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[38] The CSA, SAMHSA regulations, and DEA regulations contain many defined terms and phrases. The glossary at the beginning of this document contains definitions for some of them. When *quoting* statutory or regulatory text in the portions of this analysis covering federal laws/regulations and state laws/regulations (pages 21-37), the authors place terms defined in the glossary in bold typeface to highlight that the quoted language relies on defined terms.

[39] This statute, and many regulations discussed below, capitalize general titles such as "Attorney General" and "Secretary." This contrasts with style guides that suggest writers should not capitalize a job title unless the title precedes an expressly identified individual (*e.g.*, DEA Administrator Anne Milgram).

[40] The CSA grants the authority to administer its provisions to the attorney general, as the DEA is an agency within the DOJ. As a result, 21 U.S.C. § 823(h) references the attorney general. The attorney general, however, grants this authority to the administrator of the DEA via regulation. 28 C.F.R. § 0.100 (2024).

[41] 21 U.S.C. § 823(h) (2024).

[42] Note that 21 U.S.C. § 823(g) contained the block-quoted provision until December 2022, when Congress added a new subsection before it in § 823. Accordingly, some secondary sources (and places within active DEA and SAMHSA regulations, too) still contain the now outdated reference to § 823(g) instead of § 823(h).

The definition of narcotic drugs includes methadone. In practice, the entire phrase "narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment" means methadone for OUD treatment, as there is no other narcotic drug in schedule I or II that is FDA-approved for such purpose. The separate registration is the narcotic treatment program or NTP registration provided by the DEA (referenced above). The joint scheme language is found in items (h)(1) and (h)(3), which requires HHS (because secretary refers to the secretary of HHS) to determine that an applicant is qualified to provide methadone for OUD prior to DEA issuing the NTP registration. SAMHSA is the HHS agency that makes this determination.

The CSA grants the attorney general (and thus the DEA) the ability to waive DEA registration requirements in some situations. 21 U.S.C. § 822(d) provides that "the Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety."[43] This provision applies to all DEA registration categories (listed above) including the NTP registration. In fact, DEA cited § 822(d) when it revised its existing regulations for NTPs in 2021 to allow NTP registrants to operate a "mobile component" (*i.e.*, a mobile medication unit) as a "coincident activity" under the same NTP registration,[44] rather than obtaining another NTP registration, as is required to open a fixed medication unit.[45] This is not a case-by-case individualized process. Rather, it is a formal DEA rulemaking, as the CSA directs that it be done "by regulation." In the case of the mobile component change, DEA issued a notice of proposed rulemaking on February 26, 2020, and the final rule took effect on July 28, 2021, 17 months later.[46] Absent such a formal rulemaking by DEA, the separate registration requirement for "practitioners [to] dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment" is unavoidable unless the CSA's language changes, which would require Congress to pass a bill and the president signing it into law.

Federal fraud and abuse laws

Although not specific to methadone for OUD treatment, any individual or other entity providing healthcare of any sort for which payment from one or more federal healthcare programs (*e.g.*, Medicaid, Medicare, TRICARE) is anticipated should be aware of several federal fraud and abuse laws. These laws are:

- False Claims Act;[47]
- Anti-Kickback Statute (AKS);[48]

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[43] 21 U.S.C. § 822(d) (2024). As with § 823(h), the attorney general delegates this authority to the DEA administrator.
[44] *Registration Requirements for Narcotic Treatment Programs with Mobile Components*, 86 Fed. Reg. 33,861, https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components.
[45] See further discussion *infra*.
[46] *Registration Requirements for Narcotic Treatment Programs with Mobile* Components, *supra* note 44, at 33,862.
[47] 31 U.S.C. §§ 3729-3733 (2024).
[48] 42 U.S.C. § 1320a-7b(b) (2024).

- Physician Self-Referral Law (Stark law);[49]
- Exclusion Statute;[50] and
- Civil Monetary Penalties Law.[51,52]

It is self-evident that fraudulent conduct by an entity providing healthcare can run afoul of the law. For example, the False Claims Act makes it a crime for a healthcare provider to submit claims for payment to a federal healthcare program that the provider knows or should know are false or fraudulent.[53] The Exclusion Statute prevents healthcare providers convicted of certain criminal offenses from being approved for payment by federal healthcare programs.[54] The Civil Monetary Penalties Law allows HHS (through the Office of Inspector General, or OIG) to seek civil monetary penalties or an exclusion from providing healthcare at all for a variety of illegal conduct.[55]

The Stark law and AKS, however, apply to conduct that may not appear overtly fraudulent but, nonetheless, is not allowable. An individual or entity providing methadone for OUD treatment must be aware of the circumstances in which these laws could apply. Importantly, however, neither law serves as a general bar that would prevent methadone delivery in a pharmacy or by a pharmacist.

The Stark law is quite specific. It prohibits physicians from referring patients to entities with which the physician or an immediate family member has a financial relationship to receive "designated health services" payable by Medicare, unless an exception applies. There is a discrete list of such designated health services.[56] Moreover, in the absence of the physician or the physician's family member having a financial relationship with the referred service, the Stark law is inapplicable. There is nothing about methadone delivery in a pharmacy or by a pharmacist that makes the Stark law more likely to be implicated there than in any other type of healthcare practice.

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[49] 42 U.S.C. § 1395nn (2024).
[50] 42 U.S.C. § 1320a-7 (2024).
[51] 42 U.S.C. § 1320a-7a (2024).
[52] *Fraud and Abuse Laws*, U.S. DEPT OF HEALTH & HUMAN SERV., OFF. OF INSPECTOR GEN. (last accessed Sept. 10, 2024), https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/.
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] The designated health services are: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. *Physician Self-referral*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 29, 2023), (https://www.cms.gov/medicare/regulations-guidance/physician-self-referral.

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the federal healthcare programs.[57] It applies to any entity, not just physicians, who might request, receive, offer, or pay kickbacks intended to generate healthcare business.[58] Outright payments ("we'll pay you $X to prescribe drug X or refer to provider Y") are clearly problematic. However, the definition of renumeration is broad and can cover anything of value, including discounts.

One situation where the AKS could be implicated is an arrangement where an entity rents space to a healthcare provider who could potentially provide referrals or business (paid for by federal healthcare programs) to the landlord provider. If the landlord entity charges little or no rent to the tenant, then this "deal" on rent could be illegal "renumeration" in exchange for providing business to the landlord. In the context of methadone provided by or in a pharmacy, the situation could occur if the entity providing OUD treatment rents space from the pharmacy. Importantly, the AKS contains eleven exceptions (or "safe harbors") covering conduct that is not considered illegal even though it technically falls under the general prohibition. Space rental is one of the safe harbors. So long as the lease between landlord and tenant meet the requirements of the safe harbor,[59] the arrangement does not run afoul of the AKS.[60] The linked regulatory provision in footnote 59 provides the full details of the safe harbor for rental space. In summary, the lease must be a written, arms-length transaction that lasts at least one year, sets rent at a fair market value, and does not condition rent on any business being referred from the tenant to the landlord.

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[57] *Fraud and Abuse Laws*, *supra* note 52.
[58] Lieberman, David W.S., *AKS – Anti Kickback Statute Explained*, WHISTLEBLOWER LAW (Jan. 9, 2024), https://www.whistleblowerllc.com/anti-kickback-statute/.
[59] The safe harbor for space rental is found at 42 C.F.R. § 1001.952(b) (2024).
[60] The fact that the landlord (the pharmacy in this scenario) potentially receives additional business due to increased foot traffic or recommendations by the entity providing methadone for patients to purchase items at the store is not problematic by itself, so long as the pharmacy does not induce or reward the medical provider to make these recommendations. In the absence of such inducement or reward, only the pharmacy obtains the benefits, which is allowable.

SAMHSA Regulations

42 C.F.R. Part 8 contains SAMHSA's regulations covering "Medications for the Treatment of Opioid Use Disorder." Despite the broadly worded title, Part 8 does not apply to all medications for OUD in all contexts. Rather, per 42 C.F.R. § 8.1, the official scope of Part 8 is to:

> [E]stablish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)).[61]

The defined term "OTP" is connected to the CSA via its definition. An OTP is a "program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1)."[62] What complicates matters from a terminology perspective is that DEA regulations do not use the term "OTP." Instead, as described in the DEA regulations section below (and mentioned in the DEA Registration Note above) as part of the process of becoming a certified OTP, the OTP must obtain a narcotics treatment program (or NTP) registration from DEA.[63]

Part 8 is subdivided into four general subject areas: (1) scope and definitions (§§ 8.1 to 8.2); (2) provisions related to determining the organizations that accredit OTPs (§§ 8.3 to 8.6); (3) the certification of, and treatment standards for, OTPs (§§ 8.11 to 8.15); and (4) procedures for suspending or revoking OTP certification or withdrawal of accreditation body approval (§§ 8.21 to 8.34). For purposes of this analysis, neither 42 C.F.R §§ 8.3 to 8.6 nor 42 C.F.R §§ 8.21 to 8.34 are of particular importance. Out of the Part 8 sections that remain, the most important provisions are 42 C.F.R. § 8.11 and 42 C.F.R. § 8.12. SAMHSA's regulations largely cover the services provided by an OTP while the DEA regulations described in the section below largely cover the inventory, recordkeeping, storage, and security of the methadone itself.

42 C.F.R. § 8.11 covers the certification of OTPs. Within § 8.11, some of the provisions address the actual mechanics of certification, such as information that must be included in an application for certification or the actions the secretary may take in response to an application. Other more substantive elements of § 8.11, however, are identified below, in the order in which they appear in the regulation;

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[61] 42 C.F.R. § 8.1(a) (2024).
[62] 42 C.F.R. § 8.2 (2024).
[63] To date, the authors of this analysis have not uncovered a description for why there is this terminology split. One possible explanation may be that the DEA continues to use NTP because it tracks with the language of the CSA regarding dispensing narcotic drugs for maintenance or detoxification treatment.

- Subsection (a) provides that an OTP must: (1) have a current, valid certification from the secretary to be considered qualified under the CSA to dispense MOUD in the treatment of OUD; and (2) be found qualified by the attorney general by being registered by the attorney general to dispense MOUD to individuals for treatment of OUD. Stated differently, item (2) means that the OTP needs an NTP registration from DEA;

- Subsection (a) also provides that an OTP must meet the federal opioid use disorder treatment standards in 42 C.F.R. § 8.12 and be the subject of a current, valid accreditation by an accreditation body;[64]

- Among other things, subsection (e) expressly subjects OTPs to state and local laws and regulations, except for OTPs operated by a federal department or agency, such as the Department of Veterans Affairs or the Indian Health Service. The subsection also requires OTPs to allow inspections of OTP premises by HHS, SAMHSA, DEA, accreditation bodies, or "any other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises;"[65]

- Subsection (g) provides for a case-by-case exemption from certain aspects of § 8.11 and
  § 8.12, upon application, with a stated example being "a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards." [66] This subsection further provides that "the OTP shall support the rationale for the exemption with thorough documentation . . . [and] [t]he Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate State authority prior to taking action on an exemption request;"[67] and

- Subsection (h), described more fully below, covers medication units, long-term care facilities, and hospitals.

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[64] Pursuant to SAMHSA regulations, nonprofit groups or state governmental entities can apply for approval to accredit OTPs. These accreditation bodies evaluate OTPs and perform an accreditation survey to ensure treatment standards are met. *Become a SAMHSA-approved Opioid Treatment Program (OTP) Accrediting Body,* SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (May 9, 2024), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/become-accrediting-body. As of August 2024, there are six accreditation bodies in the U.S. *Approved Accreditation Bodies*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Aug. 29, 2024), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/approved-accreditation-bodies.

[65] 42 C.F.R. § 8.11(e) (2024).

[66] 42 C.F.R. § 8.11(g) (2024).

[67] SAMHSA has a webpage devoted to instructions for submitting such exemption requests. *Submit an Opioid Treatment Exception Request*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Feb. 2, 2024), https://www.samhsa.gov/medications-substance-use-disorders/otp-resources/submit-exception-request. According to SAMHSA, the two most common reasons for submitting such a request are: (1) a temporary increase in the number of take-home doses permitted for unsupervised use; and (2) an exception to the detoxification standards in the regulation. *Id.*

Section 8.11(h)(1) provides that certified OTPs may establish medication units that are authorized to dispense MOUD. A medication unit is an "entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services."[68] A medication unit can be a fixed structure (also called "brick-and-mortar") or a mobile unit. Under § 8.11(h)(2), all services provided by an OTP can be provided in a medication unit (but do not have to be), so long as there is sufficient space for that to occur.

Before establishing a medication unit, an OTP must notify the secretary (via a form) and comply with DEA regulations. Interestingly, DEA regulations do not define (or use) the term "medication unit." DEA treats fixed medication units as a wholly separate NTP operation from the OTP's main location. As a result, an OTP wishing to establish a fixed medication unit must obtain another NTP registration, covering the fixed medication unit's location, beyond the NTP registration the OTP already obtained for its original location. In contrast, a mobile medication unit, which the DEA calls a "mobile narcotic treatment program," does not need another NTP registration from DEA, as the DEA considers the mobile medication unit to be a "coincident activity" of an already existing OTP.[69]

Finally, although not directly relevant to this analysis, § 8.11(h)(3) provides that OTP certification is not required:

> [F]or the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the [DEA] as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.[70]

This corresponds with the "incidental adjunct" exception in DEA regulations described below.

42 C.F.R. § 8.12 covers the numerous and detailed treatment standards that OTPs and medication units must follow. The topics covered by § 8.12 include:

- Administrative and organizational structure;
- Continuous quality improvement;
- Staff credentials;
- Patient admission criteria;

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[68] 42 C.F.R. § 8.2 (2024).

[69] 21 C.F.R. § 1300.01(b) (2024) (see definition of "mobile narcotic treatment program"). This resulted from DEA's 2020 to 2021 rulemaking described on page 22 above.

[70] 42 C.F.R. § 8.11(h) (2024).

- Required services, including initial medical examinations, special services for pregnant patients, initial and periodic physical and behavioral health assessments, counseling and psychoeducational services, and drug testing;
- Recordkeeping and patient confidentiality requirements;
- Instructions on medication administration, dispensing, and use;
- Unsupervised or "take-home" medication doses; and
- Interim treatment (as defined in 42 C.F.R. § 8.2).

At a minimum, each OTP must formally designate a program sponsor and medical director. The program sponsor agrees on behalf of the OTP to adhere to all requirements set forth in Part 8. The medical director assumes responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director is responsible for ensuring that the OTP complies with all applicable federal, state, and local laws and regulations. Besides the express requirement that an OTP designate both a program sponsor and medical director, SAMHSA regulations are otherwise silent on who may own or operate OTPs.

Under the federal opioid use disorder treatment standards, MOUD may be "administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law."[71] Further, methadone "shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse."[72]

SAMHSA publishes a guidance document on OTPs, *Federal Guidelines for Opioid Treatment Programs* (hereafter "*SAMHSA Guidelines*"), which provides a description of the statutory and regulatory requirements as well as recommended practices. As of April 2024, the most recent version of this document was published in March 2015.[73] Interestingly, and something to keep in mind in developing pharmacy-based methadone delivery models, there is an entire section of the *SAMHSA Guidelines* on "community relations and education" noting that "there is a strong need to educate all entities affected by the [OTP] program's presence, including the medical community, neighbors, and those who provide support services" and that "OTPs must have policies and procedures to measure and minimize the negative impact an existing or new program may have on a community, promote peaceful coexistence, and plan for change and program growth."[74]

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[71] 42 C.F.R. § 8.12(h)(1) (2024).
[72] 42 C.F.R. § 8.12(h)(3)(i) (2024).
[73] *Federal Guidelines for Opioid Treatment Programs*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (January 2015), https://store.samhsa.gov/product/federal-guidelines-opioid-treatment-programs/pep15-fedguideotp (the cover date is January 2015 but the publication date, per SAMHSA webpage, is March 2015).
[74] *Id.*, at 16.

In September 2021, shortly after the DEA revised its regulations to include mobile NTPs, SAMHSA issued a letter that "revises and supersedes" portions of the *SAMHSA Guidelines* "by clarifying the range of services that can be provided in both mobile and non-mobile [*i.e.*, fixed or "brick-and-mortar"] medication units."[75] Specifically, the letter lists several types of services that may occur in mobile medication units "assuming compliance with all applicable federal, state, and local law," and in other medication units "where space allows for quality patient care and are consistent with state and local laws and regulations."[76] Additionally, the letter expressly states that "any required services not provided in mobile and non-mobile medication units must be conducted at the OTP, including medical, counseling, vocational, educational, and other assessment and treatment services."[77,78]

DEA Regulations

Title 21, Chapter II (*i.e.*, Parts 1300 to 1321) of the CFR contains all regulations promulgated by the DEA. These regulations contain the federal controlled substance schedules. Pursuant to 21 C.F.R § 1308.12(c), methadone is a schedule II opiate.

21 C.F.R. § 1300.01 contains the definitions of terms used by DEA besides those already defined in the CSA. The glossary at the front of this analysis sets forth several of those terms. In addition to the definitions, about a dozen other DEA regulations expressly reference NTPs. In numerical order, these regulations are:

- 21 C.F.R. § 1301.13, which covers the basic registration requirement for different types of entities, including NTPs;
- 21 C.F.R. § 1301.44, which places the burden of proving the satisfaction of registration requirements on certain applicants, including NTP applicants;
- 21 C.F.R. § 1301.51, which addresses registration modifications;
- 21 C.F.R. §§ 1301.72 to 1301.74, which cover drug security controls for non-practitioners, NTPs, and mobile NTPs;
- 21 C.F.R. § 1304.04, which covers records and inventories generally;
- 21 C.F.R. §§ 1304.24 to 1304.25, which cover specific recordkeeping requirements for NTPs and mobile NTPs;
- 21 C.F.R. § 1305.06, which covers individuals entitled to fill orders for schedule I and II controlled substances;
- 21 C.F.R. § 1306.07, which covers the administration and dispensing of narcotic drugs; and
- 21 C.F.R. § 1317.05, § 1317.40, and § 1317.75, each of which pertain to drug disposal or collection of drugs for disposal.

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[75] *Letter to OTP Directors, SOTA, and State Directions*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (September 29, 2021), https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf.
[76] *Id.*
[77] *Id.*
[78] The differing treatment of medication units under the two sets of regulations is confusing. SAMHSA regulations (including the referenced letter) refer to "mobile medication units" and "non-mobile medication units" of OTPs. Under DEA regulations, however, a mobile medication unit is an extension of an already existing NTP, while a non-mobile medication unit is an entirely separate NTP requiring a separate DEA registration, even though an already existing NTP operates it, or at the very least, is fully responsible for its activities.

21 C.F.R. § 1306.07, titled "administering or dispensing of narcotic drugs," is the starting point for understanding DEA regulation of methadone for OUD treatment. It contains the primary rule that methadone for OUD treatment must occur at special facilities except in limited other circumstances. The primary rule, subsection (a), allows a practitioner to "administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment" so long as the practitioner is: (1) "separately registered with DEA as a narcotic treatment program"; and (2) in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs.[79]

Although § 1306.07(a)'s language encompasses narcotic drugs in all controlled substance schedules, subsection (d) exempts from the separate registration requirement practitioners wishing to "administer or dispense (including prescribe)" schedule III, IV, or V narcotic drugs for maintenance or detoxification treatment if certain conditions are met.[80] This removes buprenorphine, a schedule III narcotic drug also used to treat OUD, from subsection (a)'s requirement.[81]

The remainder of § 1306.07 contains several exceptions to the methadone-only-via-NTP-registered entity rule. Section 1306.07(b), for example, is the emergency treatment provision, or so-called "three-day rule." This provision clarifies that § 1306.07 does not prohibit a practitioner "not specifically registered to conduct a narcotic treatment program, from dispensing (but not prescribing) narcotic drugs . . . for the purpose of initiating maintenance treatment or detoxification treatment (or both) . . .while arrangements are being made for referral for treatment."[82] The allowance covers no more than a three-day supply to one person at one time and cannot be extended or renewed.

Another provision, § 1306.07(c) (referred to in this document as the "incidental adjunct" provision), notes that § 1306.07 does not limit "a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital," without an NTP registration, either: (1) to maintain or detoxify a person as an "incidental adjunct to medical or surgical treatment of conditions other than addiction" (*i.e.*, treating the person for something else); or (2) to persons with intractable pain for which no other relief or cure is possible.[83] In addition to hospitals, SAMSHA's regulations (and the DEA manual mentioned a few paragraphs below) provide that a long-term care facility or correctional facility can avail itself of the § 1306.07(c) exception if the entity registers with the DEA as a "hospital/clinic."[84]

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[79] 21 C.F.R. § 1306.07(a) (2024).
[80] 21 C.F.R. § 1306.07(d) (2024).
[81] *See* 21 C.F.R. § 1308.13(e) (2024). Naltrexone, the third FDA-approved medication for OUD in addition to methadone and buprenorphine, is not a controlled substance, nor a narcotic drug, and, thus, is not subject to this DEA regulation.
[82] 21 C.F.R. § 1306.07(b) (2024).
[83] 21 C.F.R. § 1306.07(c) (2024).
[84] 42 C.F.R. § 8.11(h) (2024).

DEA regulations further narrow who can dispense or administer methadone at an NTP (*i.e.*, an OTP or medication unit) beyond the practitioner or practitioner's agent language in 42 C.F.R. § 8.12 (see page 28 above). 21 C.F.R. § 1301.74 provides that "narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either: (1) the licensed practitioner, (2) a registered nurse (RN) under the direction of the licensed practitioner, (3) a licensed practical nurse (LPN) under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner."[85]

The DEA regulations include more stringent storage requirements for NTPs and mobile NTPs as compared to other locations that store controlled substances. 21 C.F.R. § 1301.71 contains security information for controlled substances that applies to all locations. "Physical security controls for practitioners" are found in 21 C.F.R. § 1301.75. This section does not cover either NTPs or mobile NTPs, which DEA considers to be "non-practitioners." Section 1301.75 is concise and uncomplicated, directing that "controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet."[86] In contrast, § 1301.72, entitled "[p]hysical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs; storage areas," is much more prescriptive about storage requirements. For schedule II substances like methadone, finished products must be kept in either a safe, steel cabinet, or vault, with the regulation providing additional detailed specifications (such as width of walls and ability to withstand an express number of "man-minutes against forced entry") for each.[87] There is also a separate subsection governing specifications for the vehicle(s) used for mobile NTPs and the vault contained within the vehicle.[88] Moreover, this subsection requires that at the end of operations on each day, the mobile NTP vehicle "must be immediately returned to the registered location, and all controlled substances must be removed from the conveyance and secured within the registered location."[89] An NTP can apply for an exception to this requirement, which will be evaluated and decided upon by DEA on "a case-by-case basis."[90] Absent an exception, this means a mobile NTP cannot park at a location overnight, but rather must start each day at the registered NTP location (*i.e.*, the OTP), travel to one or more locations, and then return back to the OTP.

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[85] 21 C.F.R. § 1301.74(i) (2024).
[86] 21 C.F.R. § 1301.75(b) (2024). The same requirement applies to the storage of schedule I substances, too. 21 C.F.R. § 1301.75(a) (2024).
[87] 21 C.F.R. § 1301.72(a) (2024).
[88] 21 C.F.R. § 1301.72(e) (2024).
[89] *Id.*
[90] *Id.*

21 C.F.R. § 1301.74 covers other security controls besides storage, again for "non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs." This includes information on distributing controlled substances, suspicious orders, reporting theft or loss of controlled substances, shipping controlled substances, accepting delivery of controlled substances, administering drugs at NTPs, NTP waiting areas, and the procedures for deploying controlled substances to the mobile NTP's vehicle(s).[91]

Augmenting its regulations, DEA has published a guidance document on NTPs, entitled *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations* (hereafter "*DEA Guidelines*") which provides a description of the statutory and regulatory requirements as well as recommended practices.[92] The latest version is from June 2022. As compared to the regulations themselves, the *DEA Guidelines* lays out specific DEA requirements in a more understandable and straightforward way, covering the following topics in this order:

- Registration requirements for NTPs;
- Recordkeeping requirements for NTPs;
- Inventory requirements for NTPs;
- Ordering schedule II controlled substances;
- Receiving narcotic controlled substances;
- Dispensing narcotic controlled substances;
- Compounding records;
- Security requirements for NTPs;
- Delivery of medication to enrolled NTP patients (off-site); and
- Theft, loss, disposal, or transfer of controlled substances.

Similar to the SAMHSA regulations, DEA regulations and the *DEA Guidelines* are silent on who may own or operate an NTP-registered facility.

Given the general requirement for a separate NTP registration and the list of individuals authorized to dispense or administer methadone, a natural question arises about which staff members at an NTP need which DEA registrations. Neither DEA regulations, SAMHSA regulations, the *SAMHSA Guidelines* nor the *DEA Guidelines* clearly answer this question. In practice, DEA and/or SAMHSA may have clear positions on the type of DEA registrations required for NTP staff (if any) that is made known to NTP operators during the approval process. When looking at the regulations by themselves, however, it is not completely clear. The next two paragraphs address two questions separately: (1) which staff members (if any) need an NTP registration; and (2) which staff members (if any) need an individual (non-NTP) DEA registration?

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[91] 21 C.F.R. § 1301.74 (2024).

[92] *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations*, DRUG ENFORCEMENT ADMIN. (June 2022), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-056)(EO-DEA169)_NTP_manual_Final.pdf ("DEA Guidelines").

The CSA directs practitioners to obtain the separate (*i.e.*, NTP) registration. Using the CSA's definition, a practitioner is an individual or entity allowed by federal and state law to prescribe, dispense, administer, etc., controlled substances. One can infer, therefore, that this requires the individual or entity submitting the NTP registration application or renewal to already have a non-NTP registration with DEA, or else the individual or entity would not qualify as a practitioner under the CSA. Although not expressly stated in DEA regulations, the *DEA Guidelines* refer to an NTP as a thing, rather than an individual.[93] Thus, it appears that one NTP registration covers the entire operation at one location. Stated differently, the individuals who dispense and administer methadone at a particular NTP location do not need their own individual NTP registrations beyond the one NTP registration obtained by the practitioner individual or entity.

The four types of individuals who can dispense or administer methadone at an NTP are a "licensed practitioner" and an RN, LPN, or pharmacist acting "under direction" from the licensed practitioner.[94] The term "licensed practitioner" is somewhat confusing because DEA regulations do not define it (or define "practitioner" by itself) and the CSA's definition of "practitioner" includes inanimate entities such as a hospital or pharmacy. It is possible that DEA considers "licensed practitioner" to mean the same thing as its defined term "individual practitioner." Alternatively, DEA could view a "licensed practitioner" as including both individual practitioners and "mid-level practitioners," another defined term. Either way, whomever is "the licensed practitioner" for the NTP under § 1301.74(i) appears to need an individual DEA registration. As for an RN, LPN, or pharmacist at the NTP, the answer must be that none of these staff members need an individual DEA registration. This must be the answer because § 1301.74(i) clearly allows such individuals to dispense and administer methadone, but DEA's "mid-level practitioner" registration is not available to most pharmacists, most RNs, or any LPNs.[95]

Other DEA regulations are also potentially relevant. One of the DEA's responsibilities is to set the following three types of manufacturing quotas for schedule I and II controlled substances each calendar year:

- Aggregate production quotas (APQs), which establish the total quantity of each basic class of schedules I and II controlled substances that may be produced by all manufacturers registered by the DEA to manufacture those substances in a calendar year;
- Individual manufacturing quotas (MQs), which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may manufacture during a calendar year; and

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[93] *See, e.g., id.*, at 5 ("When an NTP moves or changes *its* address . . .) (emphasis added); *id.* at 33, 37 (calling an NTP a "registered non-practitioner" and a "non-practitioner registrant").
[94] 21 C.F.R. § 1301.74(i) (2024).
[95] *See Mid-level Practitioners Authorization by State*, *supra* note 30. According to this DEA source, the mid-level practitioner registration is available to pharmacists in a few states, as well as to "nurse practitioners" in a greater number of states. DEA does not define "nurse practitioner," but it includes an advance practice registered nurse (APRN), who is an RN that obtains additional credentials and authority as the result of advanced training. *What is a Nurse Practitioner*, ANA NURSING RESOURCES HUB (Feb. 9, 2024), https://www.nursingworld.org/content-hub/resources/becoming-a-nurse/what-is-nurse-practitioner/. As a result, some RNs (those who are APRNs) may obtain an individual DEA registration if allowed by state law.

- Procurement quotas (PQs), which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances.[96]

Registered drug manufacturers apply to the DEA to receive MQs and PQs, which DEA further subdivides into different sub-quotas. Methadone, as a schedule II substance, is subject to these quotas. For example, in an April 2020 press release about COVID-19, DEA noted that it would "increase the APQ for methadone to ensure that opioid treatment programs have sufficient supplies to treat patients suffering from opioid use disorder."[97] Therefore, one or more of the quotas affecting methadone could potentially limit how much methadone is available for OTPs. However, quotas are worked out between the DEA and drug manufacturers. OTPs themselves are not subject to an individual DEA quota. Unfortunately, DEA's quota setting process is complex and obtuse. APQs are public information documented in the Federal Register.[98] It appears that MQs and PQs are confidential information not disclosed publicly. A U.S. Government Accountability Office report in 2015 about quotas noted that "the activities conducted by [DEA] Quota Unit staff are very complex, requiring staff to weigh data from at least five different sources and to make recommendations about how to authorize the APQ among various manufacturers."[99]

Finally, there is a miscellaneous DEA regulation that allows for a person to request an exemption from one or more DEA regulations which can be granted, or not granted, at the DEA's discretion. Specifically, the regulation provides that:

> Any person may apply for an exception to the application of any provision of this chapter [*i.e.*, all DEA regulations] by filing a written request with the Office of Diversion Control, Drug Enforcement Administration, stating the reasons for such exception .....The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.[100]

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[96] 21 C.F.R. § 1303.03 (2024).
[97] *DEA Takes Additional Steps to Allow Increased Production of Controlled Substances Used in COVID-19 Care*, DRUG ENF'T ADMIN. (Apr. 7, 2020), https://www.dea.gov/press-releases/2020/04/07/dea-takes-additional-steps-allow-increased-production-controlled.
[98] *See, e.g., Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024*, 89 Fed. Reg. 407 (Jan. 3, 2024), https://www.federalregister.gov/documents/2024/01/03/2023-28962/established-aggregate-production-quotas-for-schedule-i-and-ii-controlled-substances-and-assessment. For the 2024 APQs, DEA published the proposed APQs in November 2023 and gave stakeholders 30 days to comment.
[99] *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved*, U.S. GOV'T ACCOUNTABILITY OFF. 41 (Feb. 2015), https://www.gao.gov/assets/gao-15-202.pdf.
[100] 21 C.F.R. § 1307.03 (2024).

There is a recent example of this exception process with respect to methadone for OUD treatment. According to a March 16, 2020 letter from DEA to the then-head of SAMHSA, one day earlier SAMHSA leadership emailed DEA requesting that DEA provide an exception from the regulation identifying the individuals at an NTP allowed to directly dispense or administer methadone (then 21 C.F.R. § 1301.74(h), now § 1301.74(i)) so that the NTP could deliver methadone to patients at home quarantined due to COVID-19.[101] DEA granted the exception request "only to the extent that such activities will take place during the HHS-declared public health emergency," so long as an authorized NTP staff member, law enforcement, or a national guard member delivered the methadone.[102] The letter also noted that the administrator's delegated the authority to accept or reject the request "to the Assistant Administrator of the [DEA] Diversion Control Division."[103]

Disclosure of Treatment Records to Prescription Drug Monitoring Programs

Federal law authorizes HHS to issue regulations designed to protect the confidentiality of SUD patient records. The regulations are found at 42 C.F.R. Part 2 ("Part 2").[104] The regulations impose restrictions on the disclosure of records which "identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person" and "contain substance use disorder information obtained by a federally assisted substance use disorder program after March 20, 1972 (a part 2 program)."[105] Part 2 contains a complicated description of what constitutes "federal assistance,"[106] but generally it "encompasses a broad set of activities, including management by a federal office or agency, receipt of any federal funding, or registration to dispense controlled substances related to the treatment of SUDs."[107] A "program" is "an individual, entity (other than a general medical facility), or an identified unit in a general medical facility, that 'holds itself out' as providing and provides diagnosis, treatment, or referral for treatment for a SUD."[108] OTPs are Part 2 programs.

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[101] Letter from William T. McDermott to Elinore McCance-Katz, M.D., Ph.D. (Mar. 16, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-015)%20SAMHSA%20Exemption%20NTP%20Deliveries%20(CoronaVirus).pdf.

[102] *Id.*

[103] *Id.*

[104] Two agencies within HHS, SAMHSA and the Office for Civil Rights, jointly issue Part 2 regulations. Despite SAMHSA's involvement in promulgating Part 2 regulations, the term "SAMHSA regulations" in this document refers only to regulations covering OTPs in 42 C.F.R. Part 8. The authors will not refer to 42 C.F.R. Part 2 using that term.

[105] 42 C.F.R. § 2.12(a)(1) (2024).

[106] *See* 42 C.F.R. § 2.12(b) (2024)

[107] *Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. n.2 (last accessed July 15, 2024), https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf.

[108] *Id.*, at n.3.

One question that arises under Part 2 is whether a Part 2 program can report methadone dispensation to the state's prescription drug monitoring programs (PDMP). PDMPs are state-operated databases that collect information on certain dispensed medications.[109] State-specific laws and regulations govern which healthcare providers must report information to the PDMP and as to which drugs.[110] Pharmacies must submit required data to their state's PDMP for each prescription they dispense for specified controlled substances.[111] Retail pharmacies, in general, are not Part 2 programs, as they do not hold themselves out as providing SUD treatment.[112] As a result, as a matter of practice, pharmacies report to the PDMP their dispensation of buprenorphine for SUD treatment.[113]

Prior to 2020, Part 2 prohibited Part 2 programs, including OTPs, from reporting patient-identifying information to PDMPs, including information regarding dispensation of methadone for OUD treatment.[114] As of August 2020, however, new 42 C.F.R. § 2.36 provides:

> A part 2 program or other lawful holder is permitted to report any SUD medication prescribed or dispensed by the part 2 program to the applicable state prescription drug monitoring program if required by applicable state law. A part 2 program or other lawful holder must obtain patient consent to a disclosure of records to a prescription drug monitoring program under § 2.31 prior to reporting of such information.[115]

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[109] *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. 1 (Winter 2017), https://store.samhsa.gov/sites/default/files/sma16-4997.pdf.

[110] All states require the reporting of schedule II and schedule III controlled substances. Most states require the reporting of all schedule II-V drugs, while a few expand what must be reported beyond controlled substances.

[111] *Prescription Drug Monitoring Programs*, *supra* note 109, at 3.

[112] The question of whether a pharmacy becomes a Part 2 program (either in whole or in part) if it serves as a medication unit for an OTP will be addressed later.

[113] *See Protecting Patients with SUDs: The Relationship of PDMPs and 42 CFR Part 2*, PA. DEPT. OF HEALTH 3 (Aug. 2019), https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/programs/pdmp/08a_PHMC_Patient%20Privacy.pdf; Apostolos A. Alexandridis, et al., *Association Between Opioid Analgesic Therapy and Initiation of Buprenorphine Management: An Analysis of Prescription Drug Monitoring Program Data*, PLoS ONE (Jan. 10, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6953786/pdf/pone.0227350.pdf ("Buprenorphine is the only form of MAT prescribed by outpatient community physicians and dispensed by community pharmacies. As the only form of addiction treatment that is routinely captured in Prescription Drug Monitoring Program (PDMP) data, buprenorphine dispensing outcomes have been examined by others who have used these data."). Pharmacies also report their dispensation of methadone for pain. Unlike methadone for OUD treatment, methadone prescribed for pain is not subject to the SAMHSA regulations or DEA regulations covering NTPs. (It is subject to DEA regulations covering controlled substances generally.)

[114] *Protecting Patients with SUDs, supra* note 113.

[115] 42 C.F.R. § 2.36 (2024).

This provision allows OTPs to report methadone dispensation to PDMPs, but only if state law requires it and the OTP obtains patient consent to the disclosure prior to reporting the information. A state law that allows OTPs to report information to PDMPs, but does not require it to do so, does not meet the requirement. Upon receipt of the information from a part 2 program, PDMPs become "lawful holders" of the dispensing information, which limits the PDMPs ability to use and redisclose the information.

State Laws and Regulations

The current federal regulatory scheme covering methadone for OUD treatment requires that it take place in an OTP or associated medication unit, except where the "three-day rule" or the provision allowing methadone treatment as an "incidental adjunct" to treatment for another medical condition applies. Not surprisingly, the legislators and regulators that crafted state laws/regulations in force today that expressly address methadone for OUD treatment started from that premise (*i.e.*, such laws/regulations assume such treatment takes (or will take) place in an OTP/medication unit.) However, if one changes that fundamental premise and assumes that at some future point, methadone for OUD treatment may occur outside of the OTP/medication unit system, then other state laws and regulations not expressly tied to OTPs may become relevant. This section first describes state laws/regulations that expressly address OTPs. Then, it looks at other types of laws that could become relevant if federal policymakers remove the OTP limitation.

Laws and regulations expressly addressing OTPs

The federal laws and regulations described so far represent the baseline, or "floor," level of governmental controls for providing methadone for OUD. Although states cannot loosen these federal controls, they can enact laws or regulations that provide stricter control or govern areas not addressed by DEA or SAMHSA. States also may, and sometimes do, enact laws or regulations that either expressly match federal policy by direct reference or have the practical effect of matching. As a result, for any individual aspect of providing methadone for OUD, one of the following will be true:

- Federal law/regulation and state law/regulation both exist and match;
- Federal law/regulation exists but no state law/regulation does, so federal controls;
- No federal law/regulation exists, but there is state law/regulation, so state controls; or
- Federal law/regulation and state law/regulation both exist, but state law/regulation is more restrictive, so state controls.[116]

[116] A further layer to this is the fact that localities may (and do) impose additional restrictions to OTPs within their boundaries.

Fully identifying and summarizing all state laws and regulations addressing methadone for OUD is beyond the scope of this analysis. However, starting from a June 2021 data set of OTP-related state laws and regulations, The Pew Charitable Trusts published a research brief in September 2022 that described and analyzed state OTP laws and regulations that extend beyond what SAMHSA regulations require.[117] This report gives a sense of the type of governmental controls already in place (or could be put in place in the future) at the state level.

According to this report, as of 2021, almost every state and D.C. have laws/regulations addressing at least one aspect of OTPs. In reviewing these laws/regulations, Pew looked for provisions that either increase or remove barriers to care and the "patient experience" and then grouped the provisions into topical areas. The bullet points below contain Pew's findings. Rather than list the conclusions in the same order as the Pew report, however, the authors of this analysis arrange the findings based their view of the extent the type of state law/regulation could act as a potential barrier to pharmacy-based methadone for OUD treatment.

Group A

- Twelve (12) states have laws or regulations that expressly refer to medication units with 11 states expressly authorizing them (although not necessarily in all locations) and one state (Pennsylvania) expressly disallowing them.
- Nineteen (19) states and D.C. place restrictions on new OTPs, with such restrictions including requiring a "certificate of need" (all 20), a limit on the number of OTPs (Indiana), and a moratorium on new OTPs (West Virginia).
- Seven (7) states and D.C. restrict where an OTP can operate beyond the restrictions that apply to other medical facilities.
- Nine (9) states require OTPs to operate outside of regular business hours.
- Ten (10) states require OTPs to observe patients during urine sample collection.

Group B

- Sixteen (16) states require OTPs to obtain a pharmacy license or registration to operate.
- Five (5) states (of the 16 that require the OTP to obtain a pharmacy license or registration) additionally apply pharmacy regulations to OTPs.
- Fifteen (15) states require OTPs to hire a pharmacist or a consultant pharmacist.

Group C

- Eight (8) states require a government ID to access OTP services.

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[117] *Overview of Opioid Treatment Program Regulations by State*, THE PEW CHARITABLE TRUSTS (Sept. 19, 2022), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state.

- Ten (10) states limit the number of take-home doses available to a patient in the first 30-90 days of treatment more strictly than federal regulation (as it existed at the time of the study).
- Ten (10) states impose additional patient stability criteria beyond federal regulation (as it existed at the time of the study) for a patient to be eligible for take-home doses.
- Twenty-three (23) states impose a set counseling schedule.
- All states and D.C. (with laws or regulations) allow OTPs to terminate patients for violating program rules ("administrative discharge"), although two states (Massachusetts and South Dakota) prohibit an administrative discharge for the patient's failure to abstain from opioids or certain other drugs.
- Three (3) states restrict or discourage high maintenance doses.
- Twenty-six (26) states require more urine drug tests than federal regulation.
- Eight (8) states set discontinuation of methadone as the ultimate treatment goal.[118]

The state provisions described in Group A have the highest potential to limit or prevent pharmacy-based methadone for OUD treatment. The first three bullet points all relate to state laws/regulations that limit where an OTP/medication unit can be located. The final two bullet points in Group A are state-level restrictions that could affect pharmacy-based methadone for OUD treatment more so than stand-alone OTPs or medication units in other locations. A state law requiring OTPs to be open beyond normal business hours, if applied by the state to medication units, could conflict with some pharmacies' operating schedules. Several states also require observation of patients during urine sample collection. While this restriction worsens a patient's experience across all OTP/medication unit locations, this requirement could be particularly challenging at medication units inside of pharmacies given potential space limitations and/or the public nature of a pharmacy.

In contrast to Group A, the provisions identified in Group B could encourage pharmacy-based methadone for OUD treatment. This is because these laws/regulations require an OTP to act like (or be, essentially) a pharmacy in many ways, by obtaining a license through the state board of pharmacy, subjecting it to pharmacy regulations, and/or requiring a pharmacist on staff.

While the provisions described in Group C are barriers to methadone for OUD treatment generally, they are barriers faced by all OTPs or medication units regardless of location and would not appear to affect pharmacy-based care more than any other location.

Pharmacist scope of practice

Under current federal restrictions regarding where methadone for OUD treatment can take place, state limitations on a pharmacist's scope of practice are not implicated. If a pharmacist is involved, the involvement is as a staff member at an OTP or medication unit dispensing or administering methadone directly to the patient under direction of the OTP's licensed practitioner, as authorized by DEA and SAMHSA regulations.

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[118] *Id.*

However, one of the three pharmacy-based methadone delivery models expressly considered in this analysis assumes that pharmacists can provide methadone for OUD treatment at a pharmacy without involvement of an OTP. In such case, the role of a pharmacist in this delivery model and the scope of pharmacy practice authorized by state law/regulation becomes important. Assuming federal restrictions, as well as state restrictions (if any), on where methadone for OUD treatment can occur are removed, a pharmacist should be able to dispense methadone for OUD treatment to a patient for take-home use in the same manner the pharmacist currently dispenses methadone for pain or any other schedule II controlled substance (*e.g.*, stimulants for attention-deficit/hyperactivity disorder (ADHD)).

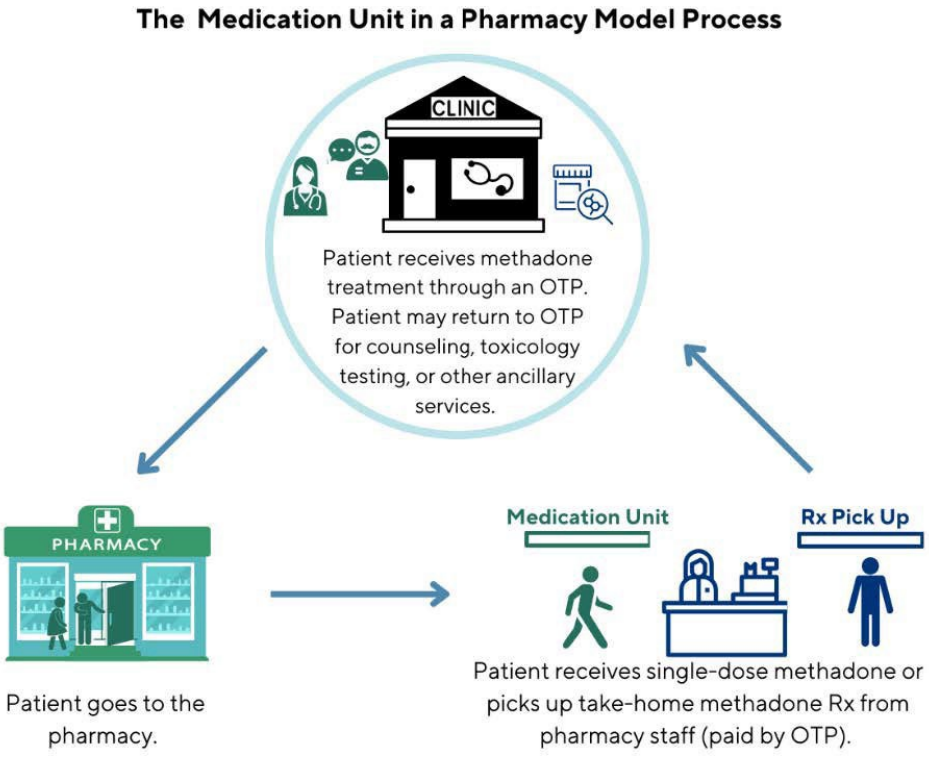
In contrast, state practice of pharmacy laws/regulations may limit a pharmacist's ability to administer drugs and medications. If a pharmacist's role in a proposed pharmacy-based methadone delivery model includes administering methadone to a patient at the pharmacy (*e.g.*, give methadone to a patient and observe the patient ingesting it), state practice of pharmacy laws/regulations might prevent this activity unless amended to include express permission to administer any FDA-approved form of methadone.

Changes to Federal and State Laws and Regulations Needed to Support Pharmacy-based Methadone Treatment Delivery Models

As described in the introduction, at the outset of this project, the research team identified three specific pharmacy-based methadone delivery models for express consideration in this analysis. These three delivery models are: (1) a pharmacy partnering with an OTP to allow the OTP to operate a medication unit in the pharmacy; (2) an OTP providing a mobile medication unit that is parked at or near the pharmacy; or (3) a pharmacy dispensing methadone like any other controlled substance after a physician or other medical provider with prescribing privileges prescribes it to a patient. Below, for each of these three delivery models, this analysis seeks to answer the following questions:

- Are any federal law or regulation changes required before this delivery model can commence?
- Are any state law or regulation changes required before this delivery model can commence?
- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

Model 1 - Pharmacy partners with an OTP to allow the OTP to operate a medication unit in the pharmacy



- Are any federal law or regulation changes *required* before this delivery model can commence?

No. Medication units are allowed under federal laws and regulations and the definition of a medication unit is broad enough to include a pharmacy. Indeed, the *SAMHSA Guidelines* first mentioned on page 28 provide that "medication units are not required to be free-standing entities. For example, a medication unit can be located at a hospital or community pharmacy."[119]

Piecing the instructions together, *SAMHSA's Guidelines, DEA's Guidelines*, and SAMHSA's September 2021 letter about medication units describe the following procedure for establishing a fixed medication unit generally:

- According to the letter, OTPs must secure state approval from the respective SOTA before submitting the form to notify SAMHSA of the proposed medication unit.
- The OTP submits all required materials to the SOTA to seek state approval, as appropriate.
- The OTP submits a form (SMA-162) to SAMHSA seeking a new medication unit with all requested attachments and signed documents.

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[119] *SAMHSA Guidelines*, *supra* note 73, at 13.

- SAMHSA processes the form and forwards it for approval to DEA, which will arrange an inspection of the proposed location.
- DEA will verify the medication unit's SOTA and SAMHSA authorization prior to approval.
- DEA issues a new registration number (*i.e.*, the NTP registration for the fixed medication unit location) to the medication unit.
- Medication units will be reviewed by the respective SAMHSA-approved accreditation body as part of the OTP's accreditation process, and the scope of reviews will be based on the accreditation standards for the services provided.
- The medication unit must maintain separate inventories, records, reports, and security in accordance with DEA regulations.[120]

Although not in DEA or SAMHSA regulations themselves, there is some evidence of the arrangement necessary for a medication unit placed in a pharmacy. According to a 2022 letter sent by the DEA to the New York Office of Addiction Services and Support:

> An OTP may authorize methadone dispensing within a medication unit co-located in a pharmacy by entering into a written agreement with the pharmacy. Under the agreement, pharmacy personnel who take possession of and dispense the OTP's methadone, are agents of the OTP. The agreement must specify the pharmacy personnel's authority and duties.[121]

Finally, as described on pages 35-37 above, no federal law or regulation changes are necessary to allow OTPs/medication units to report the methadone they dispense for OUD treatment to the state PDMP, assuming some requirements are met. Pursuant to 42 C.F.R. § 2.36, federal regulation allows the reporting so long as state law requires it, and the OTP obtains patient consent to report the information to the PDMP before doing so. The fact that the medication unit is in a pharmacy should not change this.

➢ Are any state law or regulation changes *required* before this type of delivery model can commence?

This answer varies by the individual state. If a state has one or more of the laws or regulations included within the five categories identified in Group A on page 38 in place, those laws/regulations may need revision before a medication unit can operate out of a pharmacy.

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[120] *See SAMHSA Guidelines, supra* note 73*; Letter to OTP Directors, SOTAs, and State Directors, supra* note 75; *DEA Guidelines*, *supra* note 92.

[121] *Pharmacy-based Dispensing of Methadone for OUD: Permissibility & Feasibility*, CTR. FOR U.S. POLICY (May 16, 2023), https://centerforuspolicy.org/pharmacy-based-dispensing-of-methadone-for-oud-permissibility-feasibility/ (citing to Letter from Thomas W. Prevoznik, Deputy Assistant Admin., DEA Div. Control Division, to Steve Hanson, Assoc. Comm'r, N.Y. Off. Addiction Serv. & Support (Feb, 2, 2022) (on file with author)).

In Pennsylvania, for example, a medication unit cannot be placed in a pharmacy because medication units are not allowed anywhere.[122] In Ohio, a pharmacy is not an authorized location for a medication unit unless the county where the medication unit is fits under one of two exceptions.[123] One exception is for "Appalachian counties" (the regulation references an online list of the counties that qualify as such) so long as the medication unit is between 45 and 90 miles from the OTP. The other exception is a county with under 60,000 residents, so long as the medication unit is no further than 90 miles from the OTP.

Few states (12, according to the 2022 Pew report) have laws/regulations that even mention medication units. Even though state restrictions on opening OTPs generally do not expressly refer to medication units, they are also problematic because a medication unit is an entity "established as part of" an OTP.[124] As a result, when interpreting state law/regulatory restrictions, state decisionmakers could view a proposed medication unit as a proposed OTP location, particularly if the state's laws/regulations do not contain provisions expressly addressing medication units. Besides numerical limits on new OTPs or moratoriums preventing them altogether, several states prevent OTPs from operating within a certain distance of schools or child-care centers. Such restrictions could hamper placing a medication unit in a pharmacy. For example, Oregon law provides:

> (1) It is unlawful for any person to commence operating a methadone clinic:
> (a) Within 1,000 feet of the real property comprising an existing public or private elementary, secondary or career school attended primarily by minors; or
> (b) Within 1,000 feet of the real property comprising an existing licensed child care facility. As used in this section, "licensed child care facility" means a child care center certified under [OR. REV. STAT.] 329A.280 that is operating under authority of a valid business license.
>
> (2) Commencing operation of a methadone clinic within 1,000 feet of a school or licensed child care facility is a nuisance and operation of the clinic shall be enjoined and abated as provided in [OR. REV. STAT.] 105.550 to 105.600.[125]

[122] 28 PA. CODE § 715.25 (2024) ("Narcotic treatment medication units are prohibited.").
[123] OHIO ADMIN. CODE § 5122-40-15 (2024) (a fixed medication unit can be placed only in homeless shelters, jails, prisons, county or local boards of public health, federally qualified health centers, "providers certified to provide ASAM level three residential substance use disorder services," "Appalachian counties," or a county with under 60,000 residents).
[124] 42 C.F.R. § 8.2 (2024) (definition of "medication unit").
[125] OR. REV. STAT. § 430.590 (West 2024). The law does allow a county or a local public health authority to waive the restriction.

In addition, the Pew report notes that approximately 40 percent of all states require an entity seeking to establish an OTP to obtain a "certificate of need." Moreover, some of the medication unit-specific provisions in the states that have them also reference certificates of need as part of the approval process. Certificate of need laws are mechanisms for approving major capital expenditures and projects for certain healthcare facilities which generally require that a health planning agency or other entity approve the creation of new healthcare facilities or the expansion of an existing facility's services in a specified area.[126] As a practical matter, certificate of need requirements act as barriers to healthcare because the petitioning process takes a lot of time, costs a lot of money, and opens up the request to challenge from competitors and those opposed to the proposal.[127]

The categories of state laws/regulations identified in Group A above also contain restrictions that could affect pharmacy-based methadone for OUD treatment more than stand-alone OTPs or medication units in other locations. A state law requiring OTPs to be open beyond normal business hours, if applied by the state to medication units, could conflict with some pharmacies' operating schedules. For example, Missouri regulation provides that, "Services shall be offered at least six (6) days per week. Medical and psychosocial services shall be available during the early morning and/or evening to ensure individuals have access to services."[128] Several states also require observation of patients during urine sample collection. While this restriction worsens a patient's experience across all OTP/medication unit locations, it could be particularly challenging at medication units inside of pharmacies given potential space limitations and/or the public nature of a pharmacy.

In contrast to Group A, the provisions identified in Group B on page 38 could encourage pharmacy-based methadone for OUD treatment. This is because these laws/regulations require an OTP to act like (or be, essentially) a pharmacy in many ways, by obtaining a license through the state board of pharmacy, subjecting it to pharmacy regulations, and/or requiring a pharmacist on staff. One example of such a provision is Mississippi, which requires that:

> The operation of each Opioid Treatment Program must be in compliance with the MS Pharmacy Practice Act (Section 73-21-69 et. seq. of the Mississippi Code of 1972, Annotated) as well as current rules and regulations promulgated by the MS Board of Pharmacy; and, must at a minimum obtain and maintain a "Pharmacy Permit," as defined and authorized by the MS Board of Pharmacy.[129]

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[126] *Certificate of Need State Laws*, NAT'L CONFERENCE OF STATE LEGISLATURES (updated Feb. 26, 2024), https://www.ncsl.org/health/certificate-of-need-state-laws.
[127] Matthew Mitchell and Dr. William Mitchell, *How more states can free up emergency health care*, THE HILL (Apr. 10, 2020), https://thehill.com/opinion/healthcare/492070-how-more-states-can-free-up-emergency-health-care/.
[128] MO. CODE REGS. ANN. tit.9, § 30-3.132(4)(B) (2024).
[129] 24-2 MISS. CODE R. § 53.1(D) (2024).

Worth noting as part of the discussion in this section about required and desired changes is the fact that changes to laws and regulations often are difficult and time-consuming. As introduced, a bill may propose significant changes to current law. However, to become enacted, a bill needs to obtain support from a majority of the legislators in: (1) one or more committees in the originating chamber; (2) the originating chamber as a whole; (3) one or more committees in the second chamber; and (4) the second chamber as a whole. Then, either the governor must approve it or one of the mechanisms for enacting a law without the governor's signature (such as a legislative override) must occur. To achieve that level of consensus among legislators from different areas and different viewpoints, legislators often revise a bill's original text and aim. The result may be a law that makes a less significant change than originally hoped. Proposed changes to agency regulations face similar challenges. The typical agency rulemaking process gives stakeholders (including the regulated industry, regulated individuals, and the general public) notice of the proposed change and an opportunity to comment. Agencies are generally reluctant to push forward changes to regulations that receive considerable negative reaction from stakeholders during the notice and comment process.

To the extent policymakers desire it, state law would need to change to allow OTPs to report methadone dispensed at a pharmacy-based medication unit to state PDMPs in any states not already requiring this. Although pharmacies in general are not part 2 programs and thus can report information about the buprenorphine they dispense to PDMPs, state PDMP laws must change to require this to occur in the context of a medication unit.[130] In the case of a pharmacy-based medication unit, the pharmacy has hybrid functions. Most of a retail pharmacy's activities (such as general prescription drug dispensing and over-the-counter sales) are not in connection to part 2 program activities. However, a medication unit is, by definition, "part of" an OTP, and thus, part of a part 2 program. Given that Part 2 is designed to prevent disclosure of information except where expressly permitted, the logical conclusion is that a pharmacy-based medication unit is considered a part 2 program under Part 2 with respect to its medication unit functions.[131] Moreover, the medication unit may fall under the definition of a part 2 program directly, as it would seem to be "an identified unit within a general medical facility that holds itself out as providing, and provides, [SUD] diagnosis, treatment, or referral for treatment."[132]

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[130] Of course, pharmacies report information about the drugs they dispense to state PDMPs because of those already-existing state laws and regulations governing the healthcare providers that must report information to PDMPs and the types of controlled substances and other drugs that must be reported.

[131] The Health Insurance Portability and Accountability Act (HIPAA) allows for "hybrid" covered entities, which are entities that can segment their functions into those of HIPAA-covered entities (subject to HIPAA regulations) and those functions that are not. Part 2 does not provide for hybrid part 2 programs. This begs the question of whether a pharmacy that acts as a medication unit becomes a part 2 program with respect to all of its activities. Any answer but "no" may prove untenable from the business perspective of the pharmacy. The DEA letter described on page 42 makes clear that in a pharmacy-based medication unit, the pharmacy personnel are "agents" of the OTP. On the one hand, this distinction may mean that methadone-related activities at the pharmacy will be considered the OTP's activities, rather than the pharmacy's. On the other hand, this suggests the strong need to keep methadone-related patient records separate from all other patient records in the pharmacy.

[132] 42 C.F.R. § 2.11 (2024) (definition of "program").

- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

Yes. According to SAMHSA, as of June 2023, there are over 2,000 OTPs operating in the United States.[133] Fewer than 100 medication units of any type exist, however, as of October 2021.[134] Few medication units currently exist in pharmacies, even though federal and most state laws and regulations allow for it. This indicates that the logistical, administrative, and financial difficulty of setting up such units exceeds the willingness and resources to do it, at least to date. Lessening these burdens likely would assist in making this delivery model easier to implement.

The fact that there are few medication units across the country (and not just smaller geographic regions, or states, without them) suggests a couple things. First, policymakers may not fully realize what medication units are and where they could be located. Second, federal laws and regulations must play a role in the logistical, administrative, and financial difficulties in setting them up. Although many types of changes to federal laws or regulations might encourage medication units at pharmacies, the authors highlight three significant types of changes. First, regulators could streamline and simplify the DEA and SAMHSA approval processes for a medication unit (described on pages 41-42 above), either for all medication units or just medication units at pharmacies.

A second change would be to allow operators of medication units at pharmacies to obtain and store methadone in the same manner that the pharmacy already uses for all other controlled substances dispensed at the pharmacy. As described on pages 31-32, the DEA's controlled substance storage/security requirements for "practitioners" (which include a pharmacy operating traditionally), are much less restrictive than those for "non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs."[135] Per DEA's current storage/security requirements, an NTP/medication unit must store methadone in a costly, specialized safe or vault. In contrast, a retail pharmacy is required only to store controlled substances—which could include methadone prescribed for pain—in a locked, substantially constructed cabinet. Where a medication unit is within a facility that already operates as a DEA-registered institutional practitioner (*i.e.*, a pharmacy), it seems unnecessary to require the facility to store methadone for one particular use (OUD treatment) in a wholly different manner than all other controlled substances.[136]

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[133] *Medications for the Treatment of Opioid Use Disorder*, 89 Fed. Reg. 7528, 7529 (Feb. 2, 2024), https://www.federalregister.gov/d/2024-01693.

[134] Li-Tzy Wu, et al., *Patient Perspectives on Community Pharmacy Administered and Dispensing of Methadone Treatment for Opioid Use Disorder: A Qualitative Study in the U.S.*, ADDICTION SCIENCE & CLINICAL PRAC. 18, 45 (2023), https://ascpjournal.biomedcentral.com/articles/10.1186/s13722-023-00399-6

[135] 21 C.F.R. § 1301.72 (2024).

[136] Although not the focus of this analysis, OTPs/medication units may dispense other controlled substances besides methadone to patients for OUD treatment (*i.e.*, buprenorphine, a schedule III controlled substance). Retail pharmacies also regularly dispense buprenorphine for OUD treatment. In current form, DEA's regulations would seem to require a pharmacy operating as a medication unit to store/secure buprenorphine for the same ultimate use (OUD treatment) in two different ways—one for prescriptions ordered by physicians and one for patients receiving it via OTP services.

A related issue is how a medication unit within a pharmacy obtains controlled substances. SAMHSA regulations do not address how, or from whom, a medication unit obtains its supply of methadone. The *SAMHSA Guidelines* indicate that a medication unit will receive methadone from its parent OTP, but do not provide a supporting citation for this conclusion.[137] DEA regulations, as well as the *DEA Guidelines*, only provide information about the process by which an NTP obtains controlled substances.[138] As a fixed medication unit has a separate NTP registration from the parent OTP, it is possible that DEA concludes a fixed medication unit must only use the stated process for schedule II-controlled substances to obtain methadone. It is also possible that DEA allows a fixed medication unit to obtain its methadone supply from the parent OTP, as the *SAMHSA Guidelines* suggest. Regardless of which process occurs in practice, there is nothing that expressly exempts a pharmacy acting as fixed medication unit from having to utilize the same process as any other fixed medication unit, even though the pharmacy already has a method by which it orders and tracks controlled substances for retail sale. This could require a pharmacy to set up a second process to handle and track methadone orders and deliveries for its medication unit services.

Finally, changes could be made to allow operators of medication units at pharmacies to use the inventory, recordkeeping, and reporting systems already in place for all other controlled substances dispensed at the pharmacy. Within the *DEA Guidelines*, DEA notes that: (1) "[r]ecords and inventories of schedule II controlled substances must be maintained separately from all other records of the NTP";[139] (2) "[s]eparate records must be maintained by a [DEA] registrant for each independent activity for which he or she is registered or authorized";[140] and (3) "[m]edication units also are required to maintain separate inventories, records, reports, and security in accordance with DEA regulations."[141] All of these point to the need, under current regulations, for an NTP-activity-specific record and inventory system. In the case of a pharmacy operating as a medication unit, this appears to duplicate the pharmacy's already existing records and inventory system.

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[137] *See SAMHSA Guidelines, supra note 73,* at 66-67.

[138] *DEA Guidelines, supra* note 92, at 12-22.

[139] *Id.*, at 9. In contrast, the separate requirement does not apply to schedule III-V substances, as an NTP's records and inventories about those controlled substances "must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records." *Id.*

[140] *Id.* (citing to 21 C.F.R. § 1304.21(c) (2024)). As applied to a retail pharmacy operating as a medication unit, this could mean that the retail pharmacy's activities as a DEA pharmacy registrant (one type of DEA registration) must be kept separate from the records associated with its activity as an NTP (a different type of DEA registration).

[141] *Id.*, at 8 (citing to 21 C.F.R. §§ 1304.03(a), 1301.71 to 1301.74 (2024)).

Congress could require each of these three types of changes by enacting legislation. In the alternative, such changes could be made by DEA and/or SAMHSA. The first suggestion on page 46 would require changes to both DEA and SAMHSA regulations. The second and third changes described on pages 46-47 only involve DEA regulations. (Although SAMSHA regulations do address OTP recordkeeping, the regulations may not *require* a separate system).[142] Similar to the DEA's revised regulations regarding mobile medication units described on page 22 above, DEA and/or SAMHSA could go through the standard rulemaking process to revise medication unit regulations generally, or at least for medication units at pharmacies. The benefit of this route is that there would be new regulations applicable to all medication units in pharmacies. Alternatively, both DEA and SAMHSA could grant exceptions to the regulations (like DEA's COVID-era change re methadone dose deliveries described on page 35), although those exceptions are more likely to be temporary and perhaps subject to case-by-case determination.

It would also be helpful for HHS to issue formal regulations or other guidance to pharmacy-based medication units explaining which parts of their operations must adhere to 42 C.F.R. Part 2's restrictions on disclosures of SUD treatment records and which parts do not.[143] Until HHS provides such formal guidance, individual OTPs and pharmacies may be unsure about how best to do this.

State action to encourage pharmacy-based medication units should create a clear, express process for the approval and siting of such units. On the one hand, laws and regulations often place severe administrative burdens on OTP operators who wish to establish new services at OTPs (including by establishing medication units), such as documenting, proving, and convincing state and local decisionmakers of the need for new services greatly reduces the attractiveness of the delivery model. Current federal laws/regulations already provide for layers of approval by DEA, SAMHSA, and SOTA, making state requirements unnecessary and overly burdensome. On the other hand, the lack of laws and regulations expressly addressing medication units at all is also problematic. In the absence of an express provision that a medication unit in a pharmacy is both *allowable and will be allowed* if certain conditions are met, state and local decisionmakers may place roadblocks (intentional or unintentional) that delay or prevent implementation. Ideally, states should have a clear, express provision about medication units and medication unit locations that provides for a simple and streamlined process for approval.

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[142] *See* 42 C.F.R. § 8.12(g)(1) (2024) (providing that OTPs must establish a recordkeeping system that is "adequate to document and monitor patient care," "compl[ies] with all Federal and State reporting requirements relevant to MOUD approved for use in treatment of OUD," and keeps the records "confidential in accordance with all applicable Federal and State requirements").

[143] Stated differently, how do pharmacies separate the prescription records of the individuals receiving methadone for OUD treatment from the prescription records of customers obtaining all other prescription drugs.

Washington provides an example of state stakeholders seeking these types of changes to state laws/regulations and then seeing those changes adopted. In February 2021, the Washington State Supreme Court issued a ruling that found the Washington controlled substance statute unconstitutional. This decision led to the passing of Senate Bill 5476 that, among other things, created the Substance Use Recovery Services Advisory (SURSA) Committee.[144] The SURSA Committee, in conjunction with the Washington State Health Care Authority, developed a "substance use and recovery services plan" that included 17 recommendations, including a recommendation to "increase access to opioid treatment program (OTP) services in rural areas."[145] As part of this recommendation, the plan's authors recommended for the state to:

> Create state rules/regulatory process[es] for OTP[s] that want to establish offsite medication units (1) located as a free-standing facility; (2) co-located within in a variety of community settings such as but not limited to hospitals/medical primary care systems/pharmacies/FQHCs, as well as correctional health settings, etc. [146]

The plan's authors noted that the state department of health "already has set up a regulatory process for OTP[s] to apply for mobile medication units specifically, but not other types of medication units" and that the department "should set up a process for regulating and establishing all types of OTP medication units allowable under federal law."[147]

Further, the plan recommended changing state laws and regulations:

> To ensure that OTP branch sites of all kinds (including mobile, and fixed, site medication units) are clearly seen as 'essential public facilities' and that they cannot be zoned out or stalled by moratoriums by City and/or County legislative authorities.[148]
>
> ***
>
> These changes are necessary in Washington because the Washington SOTA must interact with local legislative authorities and planning commissions and "often local municipalities want to create zoning requirements for OTP[s] that are different and more burdensome than other behavioral health and/or physical health setting types."[149]

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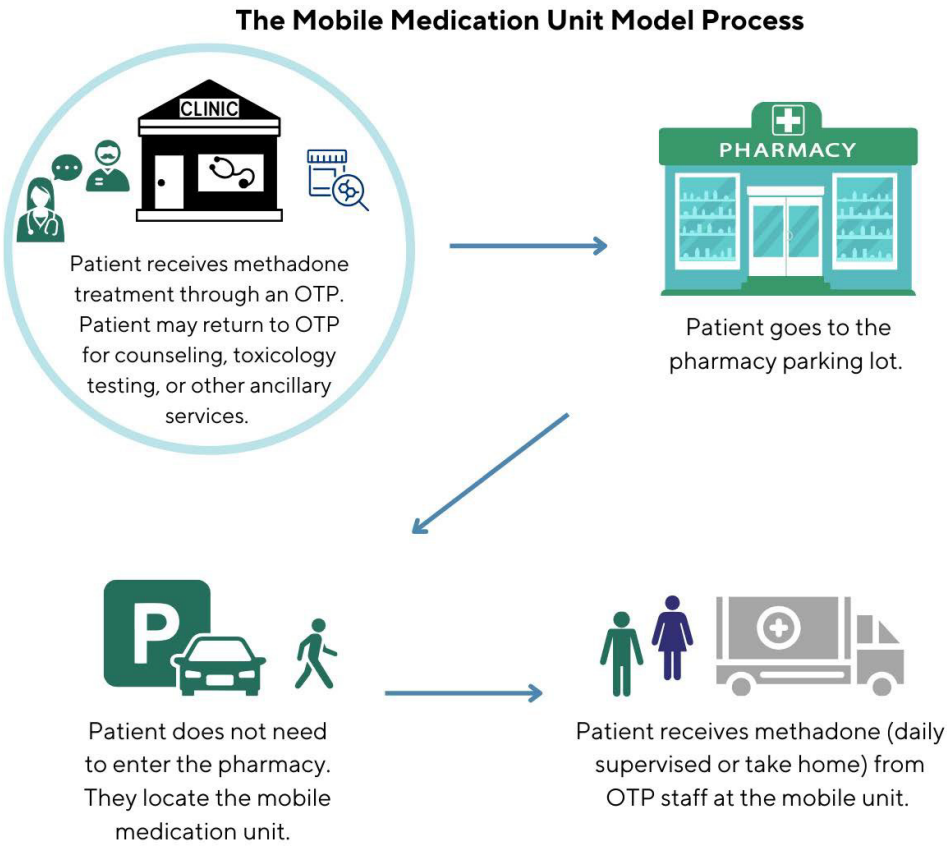
[144] 2021 WASH. LEGIS. SERV. CH. 311 § 1 (West).
[145] *Substance Use and Recovery Services Plan*, WASH. STATE HEALTH CARE AUTH. (Dec. 2022-2023), https://www.hca.wa.gov/assets/program/substance-use-and-recovery-servics-plan-leg-report-2023.pdf
[146] *Id,*, at 114.
[147] *Id.*
[148] *Id.*, at 115.
[149] *Id.*

In 2023, Washington lawmakers amended the state's "siting of essential public health facilities" law. The law now expressly includes "opioid treatment programs including both mobile and fixed-site medication units" in the list of essential public facilities.[150]

Finally, a delivery model that cannot generate sufficient funds to remain in business is unattractive. In terms of providing methadone for OUD treatment, this means that the OTP/medication unit must receive public and private health insurance reimbursement for services at a level that can sustain ongoing operations. Insurance reimbursement rates, particularly under Medicaid and Medicare, are a product of a complex set of federal and state regulations and policies. Put simply for this analysis, however, federal or state action that increases the insurance reimbursement rate(s) for providers of methadone for OUD treatment should help the attractiveness of a pharmacy-based methadone for OUD treatment model.

Model 2 - Pharmacy allows an OTP to place a mobile medication unit in the parking lot of the pharmacy



[150] WASH. REV. CODE. ANN. § 36.70A.200(1)(a) (West 2024) (change effective Aug. 15, 2023).

- Are any federal law or regulation changes *required* before this delivery model can commence?

No. Mobile medication units are allowed under federal laws and regulations and there is no provision that serves as an outright bar to a mobile medication unit operating at or near a pharmacy.

The procedure for establishing a mobile medication unit resembles, to some extent, the procedure for establishing a fixed medication unit. Piecing the instructions together, *SAMHSA's Guidelines, DEA's Guidelines*, and SAMHSA's September 2021 letter about medication units describe the following procedure for establishing a mobile medication unit generally:

- The OTP submits all required materials to the SOTA to seek state approval, as appropriate.
- The OTP submits a form (SMA-162) to SAMHSA seeking a new medication unit with all requested attachments and signed documents.
- According to the letter, OTPs must secure state approval from the respective SOTA before submitting the form to notify SAMHSA of the proposed medication unit.
- The NTP registrant must notify the local DEA office, in writing, of its intent to operate a mobile unit.
- The NTP must receive explicit written approval from the local DEA office prior to operating the mobile unit.
- The mobile unit may only operate in the same state in which the NTP is registered.
- An NTP's motor vehicle(s) must possess valid county/city and state information (*e.g.*, a vehicle information number (license plate number) on file at the registered location of the NTP and provide proper city/county and state licensing and registration to DEA at the time of inspection, and prior to transporting controlled substances away from the NTP's registered location.

- Are any state law or regulation changes *required* before this type of delivery model can commence?

As with the Option 1 delivery model, this answer varies by individual state. The discussion on pages 42-45 applies equally to this delivery model.

- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

Yes. The analysis of this question under Option 1 (pages 46-50) largely applies here, as well.

With respect to federal regulations, just like with fixed medication units, streamlining and simplifying the DEA and SAMHSA approval processes for a mobile medication unit would assist in making this delivery model more attractive. However, because the mobile medication unit would exist wholly outside of the pharmacy's walls, the fact that DEA and SAMHSA require methadone storage, security, recordkeeping, and reporting requirements different from typical pharmacy operations should create fewer administrative and logistical issues to the pharmacy itself. An added complication for mobile medication units is the requirement in DEA regulations described on page 31 that unless DEA grants an exception, the mobile medication unit cannot park at the pharmacy overnight and must begin and conclude each day's operations from the OTP. To the extent no exception is granted, this places a practical limit on how far the pharmacy can be from the OTP.

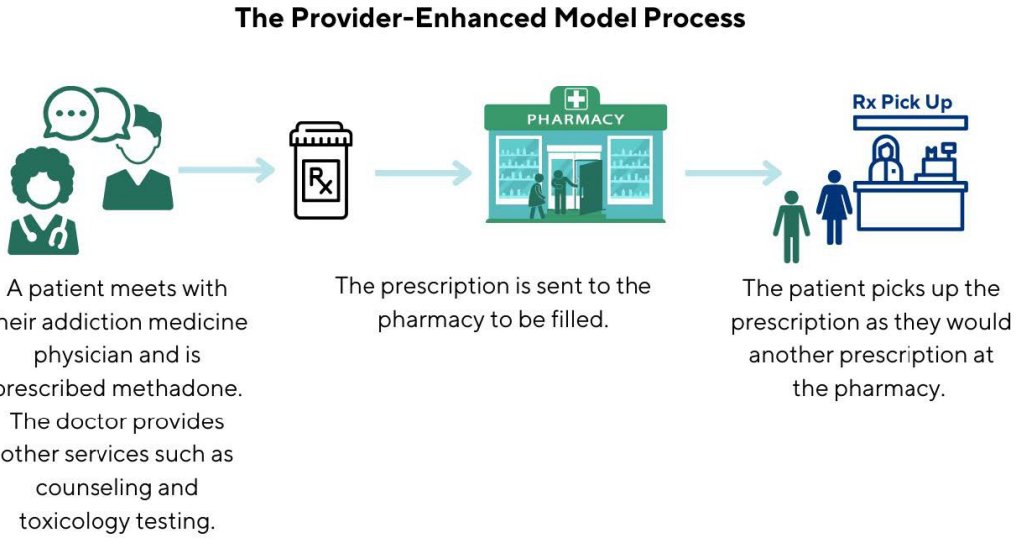
As with Option 1, states should craft clear, express provisions about mobile medication units that provide a simple and streamlined process for approval and indicate such approval will be granted if conditions are met. The SURSA Committee plan recommendations in Washington first described on page 49 also provide an example of locality-based complications specific to mobile medication units. The plan recommendations note that the lack of express state laws/regulations on mobile medication units created the following issue:

> Recently 4 King County Cities would not allow a prospective OTP mobile medication unit to bring services to their cities, and several of the cities talked with the OTP about the need to set up moratoriums while they wait to decide if the OTP mobile medication unit should be zoned as a "food truck" and/or threatened to not allow them a permit to operate in a mobile capacity within city limits saying they needed to be zone[d] as a "permanent" structure.[151]

Washington legislators addressed this issue with the 2023 law change described on page 50, as mobile medication units are now within the list of essential public facilities.

[151] *Id.*

Model 3 - Pharmacy dispenses methadone like any other controlled substance from a pharmacy after being prescribed by a physician or other authorized prescriber (the prescriber-enhanced delivery model)



- Are any federal law or regulation changes *required* before this delivery model could commence?

Yes. This delivery model is not allowed under current federal laws and regulations, which provide that practitioners cannot prescribe methadone for OUD treatment at all, require a separate DEA registration for methadone dispensing for OUD, and require any methadone dispensing for OUD treatment to occur via OTPs/medication units, except in limited circumstances.[152]

As both the CSA and DEA/SAMHSA regulations block implementation of the prescriber-enhanced delivery model now, action by Congress, DEA, and SAMHSA will be needed to put the necessary changes in place. While the final product of those changes is clear—allowing practitioners to prescribe methadone for OUD and allowing retail pharmacies to dispense it—there are many paths that Congress, DEA, and SAMHSA could take to achieve the desired result. Congress could revise 21 U.S.C. § 823(h), repeal it, or create exceptions to its application. Moreover, assuming Congress acts, subsequent revisions to DEA and SAMHSA regulations greatly depend on how Congress changes § 823(h).

[152] Such limited circumstances being the "three-day rule" or to in treating a patient at a hospital, long-term care facility, or correctional facility with methadone as an incidental adjunct to a condition other than OUD.

There is information about one way Congress could act, appearing in the form of a Congressional bill, "Modernizing Opioid Treatment Access Act" (MOTAA), introduced in both the Senate (S.644) and House (H.R.1359) in March 2023.[153] According to the official bill summary, the bill (as introduced):

- Waives provisions of the [CSA] that require qualified practitioners to obtain a separate registration from the [DEA] to prescribe and dispense methadone to treat OUD;
- Directs the DEA to register certain practitioners to prescribe methadone that is dispensed through a pharmacy for an individual's unsupervised use;
- Requires those qualified practitioners to be licensed or authorized to prescribe controlled substances, and to either work for an OTP or be a physician or psychiatrist with a specialty certification in addiction medicine;
- Allows a state to ask the DEA to stop registering such practitioners in its jurisdiction;
- Requires individuals who receive methadone for unsupervised use to continue to have access to other care through an OTP;
- Requires exclusive use of electronic prescribing, establishes prescription limits, and sets out requirements for informed consent;
- Permits the use of telehealth to provide methadone treatment and related services if the state and HHS jointly determine the use is feasible and appropriate; and
- Requires DEA and SAMSHA to jointly issue reports to Congress on the waiver. [154]

The new statutory language the amended version of the bill proposes is hard to follow. The bill proposes to revise the language of 21 U.S.C. § 823(h). The current form of § 823(h), after changes made effective December 29, 2022, is set out in its entirety on page 21 above. The bill's first direction to the reader is "in paragraph (1)—(A) in the matter preceding subparagraph (A), in the first sentence, by inserting "(other than narcotic drugs in schedule III, IV, or V)" after "drugs"; and . . ." However, in the current form of § 823(h), the only thing that could be considered paragraph (1) is the clause "(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought." As between the three numerical items in the current form of § 823(h), the only one that contains an "A" or "B" is (2), not (1). Moreover, the word "drugs" does not appear in the clause labeled (1). There are other elements to the bill that also do not fit in well with the current form of § 823(h).

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[153] As introduced in 2023, the House and Senate bills matched. A Senate committee reported amendments to S.644 in February 2024, while the House has taken no reported action on H.R.1359. Accordingly, the analysis in this section sets forth the language from S.644, as amended, which for now is the most up-to-date version of the proposal.

[154] S.644, 118th Cong., 2nd Sess. (2024) (summary located at https://www.congress.gov/bill/118th-congress/senate-bill/644?s=1&r=1&q=%7B%22search%22%3A%22s644%22%7D).

However, the bill's directions for amendments to § 823(h) make much more sense if applied to the version of § 823(h) that existed prior to December 29, 2022, when Congress eliminated from § 823(h) the requirement for practitioners to apply for a special waiver (the "DATA waiver" or "X waiver") in order to prescribe buprenorphine for the treatment of opioid use disorder.[155, 156]

Using the pre-December 29, 2022 version of § 823(h) as the way to determine where the amendments go, here is what § 823(h) would look like if S.644 is enacted, using red color text to show additions and ~~strikethrough~~ to show deletions (as compared to the 2024 version of
§ 823(h)):

> (h) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications
> (1) Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment (or both)
>
> (A) ~~(1)~~ if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;
>
> (B) ~~(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and~~ if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting-
>
> (i) security of stocks of narcotic drugs for such treatment; and
>
> (ii) the maintenance of records (in accordance with section 307) on s such drugs; and
>
> (C) ~~(3)~~ if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

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[155] *Removal of the "X-Waiver" Requirement,* THE NETWORK FOR PUBLIC HEALTH LAW (Feb. 2023), https://www.networkforphl.org/wp-content/uploads/2023/02/Removal-of-the-X-Waiver-Requirement-Fact-Sheet.pdf.

[156] This link (subscription required) shows 21 U.S.C. § 823(h) as it existed between December 2, 2022 and December 29, 2022. (Prior to December 2, 2022, what is now § 823(h) was § 823(g).) To summarize, in the pre-December 29, 2022 version of § 823(h), the portion of § 823(h) that remains in 2024 was labeled as paragraph (1), with the three set out clauses identified as (A), (B), and (C). The remainder of § 823(h), identified as paragraph (2) (and no longer in existence in 2024), extensively described the process for obtaining a buprenorphine waiver.

(2) (A) The requirements of paragraph (1) applicable to methadone medication for opioid use disorder are waived, and the Attorney General, in consultation with the Secretary, shall separately register persons described in subparagraph (B) to prescribe methadone for opioid use disorder to be dispensed through a pharmacy for individuals for unsupervised use.

(B) Persons described in this subparagraph are persons who-

(i) are licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which they practice, to prescribe controlled substances in the course of professional practice; and

(ii) are addiction medicine physicians or addiction psychiatrists who hold a subspecialty board certification in addiction medicine from the American Board of Preventive Medicine, a board certification in addiction medicine from the American Board of Addiction Medicine, a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology, or a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(C) The prescribing of methadone pursuant to subparagraph (A) shall be-

(i) exclusively by electronic prescribing and dispensed to the patient treated pursuant to subparagraph (A);

(ii) for a supply of not more than 30 days pursuant to each prescription; and

(iii) subject to the restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations, or successor regulation or guidance.

(D) The dispensing of methadone to an individual pursuant to subparagraph (A) shall be in addition to the other care that the individual continues to have access to through an opioid treatment program.

(E) Persons registered pursuant to subparagraph (A) shall-

(i) ensure and document, with respect to each patient treated pursuant to subparagraph (A), informed consent to treatment; and

(ii) include in such informed consent, specific informed consent regarding differences in confidentiality protections applicable when dispensing through an opioid treatment program versus dispensing through a pharmacy pursuant to subparagraph (A).

(F) At the request of a State, the Attorney General shall-

(i) cease registering persons in the State pursuant to subparagraph (A); and

(ii) withdraw any such registration in effect for a person in the State.

(G) Maintenance treatment or detoxification treatment provided pursuant to subparagraph (A) and other care provided in conjunction with such treatment, such as counseling and other ancillary services, may be provided by means of telehealth.

(3) Not later than 180 days after the date of enactment of this paragraph, and annually thereafter, the Assistant Secretary for Mental Health and Substance Use and the Administrator of the Drug Enforcement Administration shall jointly submit to Congress a report that includes-

(A) the number of persons registered pursuant to paragraph (2);

(B) a list of States in which persons are registered pursuant to paragraph (2).

Under § 823(h), as revised by S.644, new § 823(h)(1) appears to continue the current OTP/medication unit process under present-day DEA and SAMHSA regulations. From here, tracking how the system would look is a bit murky.

A reasonable reading of new § 823(h)(2) post-MOTAA is that the new practitioner prescribing/pharmacy dispensing mechanism would be completely pulled out from all current DEA and SAMHSA regulations governing OTP and NTPs (*i.e.*, all the restrictions on security, inventory, federal opioid treatment standards, etc.) save for the express reference to the "restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations" which covers take-home doses of methadone. However, MOTAA does provide, in new § 823(h)(2)(A), that "the Attorney General, in consultation with the Secretary, shall separately register persons described in subparagraph (B) to prescribe methadone for opioid use disorder to be dispensed through a pharmacy for individuals for unsupervised use."[157] This seems to suggest (or even require) a new DEA registration category for the individuals identified in § 823(h)(2)(B)[158] as well as new DEA and SAMHSA regulations covering this methadone dispensing mechanism. New regulations could very well reintroduce some of the logistical and administrative challenges that OTPs/medication units face currently. Such challenges could include:

- Methadone storage requirements similar to those in 21 C.F.R. §§ 1301.72 to 1301.74;
- Restrictions on patient eligibility for a full 30-day supply of methadone (*e.g.*, requiring patients starting on methadone to travel to the pharmacy multiple times per week to obtain a few days' supply at a time); and/or

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[157] *Id.*

[158] "[P]ersons who: (i) are licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which they practice, to prescribe controlled substances in the course of professional practice; and (ii) are addiction medicine physicians or addiction psychiatrists who hold a subspecialty board certification in addiction medicine from the American Board of Preventive Medicine, a board certification in addiction medicine from the American Board of Addiction Medicine, a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology, or a subspecialty board certification in addiction medicine from the American Osteopathic Association." *Id.*

- Requiring patients to still go to an OTP for mandated services (*i.e.*, MOTAA provides that pharmacy dispensing of methadone would be "in addition to the other care that the individual continues to have access to through an opioid treatment program" without explaining if such services are mandatory).

➢ Are any state law or regulation changes *required* before this type of delivery model may commence?

Until this delivery model becomes allowable at the federal level and the way(s) Congress, DEA, and SAMHSA make it allowable are known, determining specific required changes to current state laws and regulations is highly speculative. However, unless Congress adds a provision in a new law that expressly preempts more stringent state requirements (which is not included in the current form of MOTAA), any state laws and regulations that require methadone for OUD treatment to occur only via OTPs/medication units, either directly or by practical effect, would need to be revised for the delivery model to work.[159]

Assuming there are no such state laws/regulations or policymakers change them, then the pharmacist's role under the new methadone dispensing scheme is the key question. Pharmacists routinely dispense schedule II controlled substances (e.g. ADHD drugs, opioid pain relievers) for a patient's use at home. Accordingly, if this is a pharmacist's role under the new pharmacy-based methadone delivery model, it should be immediately allowable.

[159] As compared to a law or regulation that governs how healthcare providers at OTPs/medication units must provide treatment, this would be a law or regulation that expressly states that methadone for OUD treatment can only be provided at OTPs/medication units or expressly precludes prescribing practitioners in the state from prescribing methadone for OUD treatment.

In contrast, however, pharmacists' ability to administer drugs and medications may be limited by states' practice of pharmacy laws/regulations. For example, although pharmacists in Rhode Island can administer medications in the 25 drug classes (including buprenorphine) listed in regulation to any age group, methadone is not one of the classes.[160] Another example is the District of Columbia, where the scope of the practice of pharmacy expressly refers to administering only: (1) immunizations and vaccinations; (2) anticoagulation therapy; and (3) "a prescribed drug, device, and biological in accordance with regulations issued by the Mayor."[161] This limitation does not exist in all states, however. Legislators in several states have expanded pharmacist scope of practice in recent years to the point that pharmacists could administer methadone for OUD treatment if allowed by federal laws/regulations. For example, as of August 2024, the practice of pharmacy in Colorado includes "dispensing or administering any FDA-approved product for opioid use disorder in accordance with federal law and regulations, including medications for opioid use disorder."[162] If federal laws/regulations change to allow pharmacists to administer methadone in a retail pharmacy, parts of Colorado's new practice of pharmacy law would appear to allow it without needing to change while other parts would need to change.[163]

Finally, pursuant to § 823(h)(2)(F) under MOTAA, states can opt out of the new mechanism by asking DEA to stop registering individuals. Should a state do this, such action creates a roadblock to methadone treatment for OUD via pharmacy at the state level which would need to be subsequently revised for the delivery model to work there.

- Besides required changes, would any other changes to federal or state laws/regulations assist the desirability of this delivery model?

As noted above, until this delivery model becomes allowable at the federal level and the way(s) Congress, DEA, and SAMHSA make it allowable are known, determining desirable changes to federal or state laws/regulations is somewhat speculative. However, if enacted federal changes give states the ability to restrict, avoid, or opt-out of this delivery model, as MOTAA does (at least per its current language), the preference would be for states *not* to act in that respect.

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[160] 216-40 R.I. CODE REGS. § 15-1.11.3 (2024).
[161] D.C. CODE ANN. § 3-1201.02(11)(A) (West 2024).
[162] COLO. REV. STAT. ANN. § 12-280-103(39)(I) (West 2024) as amended by 2024 COLO. LEGIS. CH. 470, § 10 (West).
[163] As of August 2024, Colorado's statutory definition of the "practice of pharmacy" now includes "[d]ispensing or administering any FDA-approved product for opioid use disorder in accordance with federal law and regulations, including medications for opioid use disorder." COLO. REV. STAT. ANN. § 12-280-103(39)(I) (West 2024) as amended by 2024 COLO. LEGIS. CH. 470, § 10 (West). This covers buprenorphine and naltrexone and seems to cover methadone (if allowed by federal law). However, Colorado's new law also gives pharmacists the ability to independently prescribe "any FDA-approved product indicated for opioid use disorder" as part of a collaborative practice agreement (CPA), but only if it is "authorized pursuant to part 6 of this article 280." COLO. REV. STAT. ANN. § 12-280-103(39)(g)(V) (West 2024) as amended by 2024 COLO. LEGIS. CH. 470, § 10 (West). New Colorado CPA law limits that prescribing authority to schedule III-V medications, which prevents a pharmacist from prescribing methadone under a CPA. COLO. REV. STAT. ANN. § 12-280-604(2) (West 2024) as amended by 2024 COLO. LEGIS. CH. 470, § 11.

In closing, an acknowledgement of the role of pharmacy benefit managers (PBMs) in methadone for SUD treatment is worthwhile, although a comprehensive explanation and discussion of PBMs is outside the scope of this analysis. PBMs are "third party companies that function as intermediaries between insurance providers and pharmaceutical manufacturers. PBMs create formularies, negotiate rebates (discounts paid by a drug manufacturer to a PBM) with manufacturers, process claims, create pharmacy networks, review drug utilization, and occasionally manage mail-order specialty pharmacies."[164] In recent years, policymakers and stakeholders investigating the reasons for ever-increasing prescription drug costs place at least some of the blame on PBMs. In fact, in July 2024, a U.S. House of Representatives committee published a detailed report critical of PBMs that concludes "the three largest PBMs have used their position as middlemen and integration with health insurers, pharmacies, providers, and recently manufacturers, to enact anticompetitive policies and protect their bottom line."[165] The U.S. Federal Trade Commission also issued a report criticizing PBMs the same month.[166]

The current extent of PBM involvement in OTP-provided methadone is unclear to this document's authors, as neither the reports noted above nor other recent articles mention it.[167] Depending upon the individual patient, OTP services often are covered by a state Medicaid program, Medicare, or private health insurance. It is certainly possible that the reimbursement rate the OTP receives from the patient's insurance provider is affected by PBMs. But OTPs are not retail pharmacies and retail pharmacies, at least to date, are not involved in providing methadone for OUD treatment. Therefore, the pharmacy network aspect of PBMs may not be involved (or as involved) in OTPs/medication units at present as compared to traditional retail pharmacy practice. Moreover, such aspect of PBMs still may not come into play if retail pharmacies become medication units for pharmacies, as the OTP retains operational control over such a unit.[168] Should MOTAA or something similar take effect, however, methadone for SUD treatment may move out from the dominion of OTPs, in whole or in part, and more in line with the traditional scope of retail pharmacy practice. In such a situation, PBM influence on methadone for OUD treatment may increase.

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[164] *Pharmacy Benefit Managers: Background*, NAT'L ASSOC. OF INSURANCE COMM'RS (June 1, 2023), https://content.naic.org/insurance-topics/pharmacy-benefit-managers.

[165] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, U.S. HOUSE COMM. ON OVERSIGHT & ACCOUNTABILITY 4 (July 23, 2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

[166] *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, U.S. FEDERAL TRADE COMM'N, OFFICE OF POL'Y PLANNING (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[167] Although this does not prove the nonexistence of such materials, an August 2024 search for federal, state, and news materials on the Westlaw database uncovers nothing substantive that contains the phrase "pharmacy benefit manager" (or PBM) within 30 words of either "methadone" or the phrase "opioid treatment program" (or OTP).

[168] As mentioned in the sections on federal regulations, SAMHSA regulations require each OTP to have a "medical director" and "program sponsor" who are responsible for the activities of the OTP, which includes responsibility for the activities of any medication unit the OTP chooses to establish.

PBMs are subject to both federal and state laws and thus efforts to revise PBM practice could be enacted by Congress and/or state legislators. The House report identifies eight bills pending in the 118th Congress[169] that would reform PBM practice in numerous ways including "stopping retroactive [direct and indirect renumeration] fees, setting reimbursement and rate floors, delinking PBM compensation from the price of a medication, standardizing performance measures for pharmacies, eliminating narrow definitions of specialty drugs that turn patients away from preferred pharmacy towards that of the PBM, stopping compulsory mail-order for patients, and expanding in-network pharmacy coverage."[170] In addition, since 2017, all states have enacted PBM legislation of some kind.[171] The most five common types of state provisions are:

- Prohibiting PBMs from preventing a pharmacy or pharmacist from disclosing specific cost-related information to patients, or explicitly authorizing such disclosures (58 laws in 44 states);
- Limitations on patient cost-sharing for drugs (35 laws in 30 states);
- PBM licensure/registration requirements (35 laws in 29 states);
- Prohibitions on discrimination against non-PBM affiliated pharmacies (27 laws in 23 states); and
- Requirements for PBMs to report rebate and other information to states (24 laws in 23 states).[172]

In April 2024, the U.S. Government Accountability Office (GAO) released a report highlighting PBM laws in five states – Arkansas, California, Louisiana, Maine, and New York.[173] The GAO identified notable state reforms in those states in the following four areas: (1) fiduciary or other "duty of care" requirements; (2) drug pricing and pharmacy reimbursement requirements; (3) transparency, including licensure and reporting requirements; and (4) pharmacy network and access requirements.[174]

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[169] The 118th Congress runs from January 3, 2023 to January 3, 2025. Any bill that is not passed by both the House and Senate by the end of the session "dies," and must be reintroduced during a future Congressional session.

[170] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, *supra* note 165, at 46 (followed by a summary of each of the eight bills).

[171] *State Pharmacy Benefit Manager Legislation*, NAT'L ACADEMY FOR STATE HEALTH POL'Y (Nov. 7, 2023), https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/.

[172] *Id.*

[173] *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers, GAO-24-106898*, U.S. GOV'T ACCOUNTABILITY OFF. (Mar. 18, 2024), https://www.gao.gov/products/gao-24-106898.

[174] *Id.* at ii-iii.

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The Heller School at Brandeis University seeks to drive positive social change through research, education, and public engagement that inform policies and programs designed to address disparities in well-being and social inclusion in a sustainable way. Within The Heller School, the Schneider Institutes for Health Policy and Research includes the Institute on Healthcare Systems and the Institute for Behavioral Health which are dedicated to bringing greater knowledge to policymakers through state and national forums, policy studies and research. Our broad expertise in payment options, delivery systems, patient care practices and quality allow us to develop real-world solutions, particularly for vulnerable populations. For more information about the Heller School, please visit: https://heller.brandeis.edu/.

The Opioid Policy Research Collaborative (OPRC) in the Institute for Behavioral Health serves as a primary resource for state and federal health officials, policymakers, and private organizations. OPRC offers rigorous scientific evaluation of interventions to reduce the incidence and harm of opioid use disorder and expand access to treatment for people suffering from this life-threatening condition. For more information about the OPRC, please visit: https://heller.brandeis.edu/opioid-policy/.

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