METHADONE TREATMENT: RECENT REVISION TO REGULATION COVERING FACILITIES TREATING INDIVIDUALS FOR A PRIMARY DIAGNOSIS OTHER THAN OPIOID USE DISORDER

JUNE 2024

Methadone is one of the three medications approved by the U.S. Food and Drug Administration (FDA) used for the treatment of opioid use disorder (OUD). It is safe and effective when used as directed, and evidence shows that for patients who suffer a nonfatal overdose, subsequent methadone treatment reduces the likelihood of a future fatal opioid overdose by over 50 percent.

In 2024, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued the first substantive changes to its federal methadone regulations in over 20 years.[1] This final rule updated and modified several aspects of existing regulations with the goal of expanding the use of methadone for OUD treatment. As part of the revisions, SAMHSA clarified that a hospital, long-term care entity, or correctional facility, if appropriately registered with the Drug Enforcement Administration (DEA), can provide and initiate methadone as a treatment for OUD to those with a primary diagnosis other than substance withdrawal or OUD.

In this fact sheet, the Legislative Analysis and Public Policy Association (LAPPA) details the changes to the above-referenced "primary diagnosis" regulation and what the regulation does, and importantly, does not, do. LAPPA also briefly describes the federal regulatory scheme for methadone for OUD and explains what led to SAMHSA's decision to revise its regulations.

FEDERAL METHADONE REGULATION

In the late 1960s, researchers uncovered methadone's potential to treat heroin dependency. Subsequently, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. No. 91-513, codified throughout the U.S. Code) (CDAPCA), directed the U.S. Department of Health and Human Services (HHS) "after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, [to] determine the appropriate methods of professional practice in the medical treatment of narcotic addiction of various classes of narcotic addicts."[2] In 1972, the FDA, an agency within HHS, finalized regulations on the use of methadone for OUD, limiting who could administer and dispense the medication, the dose available to patients each day, and the method for dispensing it.[3] In 1974, the Narcotic Addict Treatment Act (Pub. L. No. 93-281, codified throughout 21 U.S.C.) amended the Controlled Substances Act (CSA; 21 U.S.C. § 801, *et seq.*)) to provide for increased control of "narcotic treatment programs" by both HHS and the Attorney General,[4] who delegated this authority to the DEA, an agency within the U.S. Department of Justice (DOJ). These actions resulted in the joint HHS/DOJ regulatory scheme covering methadone for OUD treatment that remains today.

The FDA restrictions remained largely unchanged until 2001, when HHS shifted oversight of methadone treatment

[1] Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7,528 (Feb. 2, 2024) (final rule), https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder.
[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 92-513, § 4, 84 Stat. 1236, 1241 (1970). The CDAPCA is commonly called the Controlled Substances Act (CSA). However, to be precise, the CSA only encompasses Title II of CDAPCA. The quoted information comes from Title I of CDACPA, codified at 42 U.S.C. § 290bb-2a (2024).
[3] *See* Methadone: Listing as New Drug with Special Requirements and Opportunity for Hearing, 37 Fed. Reg. 26,790 (Dec. 15, 1972).
[4] Narcotic Addict Treatment Act, Pub. L. 93-281, 88 Stat. 124 (1974). Most importantly, this Act added the subsection now found at 21 U.S.C. § 823(h) providing "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." 21 U.S.C. § 823(h) (2024). Even today, the CSA and DEA regulations still contain what many consider as "outdated" terminology for OUD and medications for OUD.

programs to SAMHSA, another HHS agency, as part of a rulemaking first proposed in 1999.[5] SAMHSA's 2001 regulation, codified at 42 C.F.R. Part 8, gave OUD treatment providers more discretion in dosage amounts and the decision to allow take-home doses.

Under the regulations of both SAMHSA and the DEA, a facility that wishes to offer methadone as a treatment for OUD must satisfy the certification and registration requirements of both agencies. A certified and registered facility that offers methadone treatment for a primary diagnosis of OUD under SAMHSA is designated as an opioid treatment program (OTP).[6] An OTP must adhere to strict oversight, drug security, and reporting requirements as well as obtain a yearly renewal. An OTP may dispense methadone in accordance with dosing guidelines but cannot prescribe the medication for patient pickup at a pharmacy. As a result, all patients must travel to the OTP to obtain methadone doses. Initially, patients are required to travel to the OTP daily to receive individual doses. Over time, patients may be granted the ability to receive a block of doses ("take-home doses") covering up to 28 days.

Continuous, therapeutic treatment of OUD with methadone takes place exclusively in OTPs within the United States. However, many suffering from OUD may go elsewhere to receive medical care, withdrawal support, or OUD treatment. With the increasing rates of overdoses, medical complications due to adulterants in the drug supply, and an uptick in rural opiate use, emergency departments, other divisions in hospitals, and skilled nursing facilities are often the first to encounter a patient with OUD. SAMHSA and DEA regulations, however, both significantly limit treatment for OUD with methadone by a facility not certified and registered as an OTP.

IMPETUS FOR CHANGES TO SAMHSA REGULATIONS

Many of the restrictions on methadone treatment for OUD, for both OTP and non-OTP facilities, result from ambiguous wording within the laws and regulations. Regulators put other restrictions in place, however, with the intent to avoid diversion of methadone away from authorized users as well as other potential abuses. Regulators also worried that unsupervised methadone doses could harm individuals due to its sedative effects.

With the COVID-19 pandemic and resulting emergency lockdowns, OTPs and patients faced new challenges complying with methadone administration regulations. Most patients at that time were required to visit the OTP every day to receive a daily dose. Additionally, to maintain compliance with the OTP programming rules, patients were required to submit drug screening samples and show proof of attendance at counseling sessions. The COVID lockdown led both SAMHSA and the DEA to create emergency procedures expanding the use of telehealth for patient counseling and check-in as well as increasing the number of take-home doses authorized for patients, even at early stages of treatment.

The emergency changes provided an opportunity for regulators and treatment providers to study the tangible effects of relaxing some aspects of supervision for people on methadone. The results proved positive in that the number of overdose fatalities involving methadone remained stable during the effective period of the emergency procedures, while overdose deaths not involving methadone increased. Additionally, the number of diverted doses was low, and people receiving treatment reported increased functionality and engagement in life activities such as employment, treatment, and family.

In December of 2022, HHS, via SAMHSA, filed a Notice of Proposed Rule Making ("NPRM") requesting feedback from the treatment and medical communities on planned changes to SAMHSA regulations.[7] SAMHSA

[5] Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4,076 (Jan. 17, 2001) (final rule), https://www.federalregister.gov/documents/2001/01/17/01-723/opioid-drugs-in-maintenance-and-detoxification-treatment-of-opiate-addiction.

[6] Under DEA regulations, an OTP must obtain a narcotic treatment program (NTP) registration from the DEA.

[7] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77,330 (Dec. 12, 2022) (proposed rule), https://www.federalregister.gov/documents/2022/12/16/2022-27193/medications-for-the-treatment-of-opioid-use-disorder.

indicated that it based the proposed changes on the results of the COVID-era emergency orders, such as the expanded access to telehealth initiation of services. The NPRM also sought to eliminate language that might stigmatize those with OUD and restrictions to access to methadone. The feedback from the NPRM, published as part of the final rule described below, demonstrated that the benefit of easing the regulation to expand access to methadone outweighed the potential harm or risk to patients and the public in limiting its reach.

SAMHSA published its revisions to 42 C.F.R. Part 8 in February 2024, with an effective date of April 2, 2024.[8] The changes to the regulations included:

- Making COVID-19 era flexibilities permanent, allowing patients to receive up to 28 days of take-home methadone after one month in treatment;
- Allowing patients to start methadone treatment without first demonstrating a one-year history of OUD;
- Expanding the workforce in OTPs, allowing nurse practitioners, physician assistants, and others to dispense methadone (to the extent allowed by individual state law); and
- Allowing OTPs to provide some services through telehealth.

Additionally, the changes clarified several rules that had caused confusion over the past 20 years, including the provision on providing methadone as a treatment for OUD to patients with a primary diagnosis other than substance use withdrawal or OUD treatment.

2024 CHANGES TO THE PRIMARY DIAGNOSIS REGULATION

The SAMHSA and DEA regulations allow healthcare facilities other than OTPs to provide methadone treatment for OUD in limited cases. As originally adopted in 2001, SAMHSA's regulations provided that a hospital or long-term care facility did not have to become an OTP in order to dispense methadone to a person who presented for a separate, primary medical concern. The 2001 version of 42 C.F.R. Part 8 provided:

Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility.[9]

The April 2024 rule changes clarified the following about the existing regulation.

1. The regulation now expressly authorizes correctional facilities to provide methadone as a treatment for OUD to certain individuals in their care, in addition to hospitals and long-term care facilities.
2. To qualify for the exemption, the facility must register with the DEA as a "hospital/clinic."
3. The facility may initiate methadone on its own, without the person being an established OTP patient prior to arrival. In the past, facilities interpreted the provision's original form as allowing methadone only when needed to maintain an individual previously established on medication for OUD or to help in withdrawing from opioid use, but not to establish a new patient on methadone.

With the April 2024 changes in place, 42 C.F.R. Part 8 now provides:

> Certification as an OTP under this part is not required for 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 Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD,

[8] Medications for the Treatment of Opioid Use Disorder (final rule), *supra* note 1.
[9] 42 C.F.R. § 8.11(i)(2) (2001). The original regulations, quoted here, used the same "outdated" terminology as is found in the Controlled Substances Act and DEA regulations. The April 2024 changes updated the language.

> and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.[10]

The new language clarifies that these designated facilities may utilize methadone as a treatment while a person is in their care. However, as explained below, it has its limitations.

PRIMARY VS. SECONDARY DIAGNOSES

Under 42 C.F.R. § 8.11(h)(3), a hospital, long-term care or correctional facility may only dispense methadone as a secondary treatment, where the individual in, or going to, the facility seeks "treatment of medical conditions other than OUD."[11] In the DEA regulation that complements this provision, providing methadone is described as "an incidental adjunct to medical or surgical treatment of conditions other than addiction."[12]

For example, if someone presents to a hospital emergency department for treatment of a severe flesh wound related to injection drug use, the hospital treatment team may dispense and administer methadone to keep him or her comfortable and avoid withdrawal symptoms during the person's stay. This would be in conjunction with any other medically necessary treatments for the wound care. The hospital is permitted to administer the methadone because the primary treatment is for the person's flesh wound. However, if someone presents to a hospital solely due to substance withdrawal, under 42 C.F.R. § 8.11(h)(3), the hospital is not authorized to dispense methadone since the primary diagnosis is OUD.[13]

Neither SAMHSA nor DEA regulations specify the primary treatments or diagnoses that enable a facility to offer methadone as a secondary treatment. This gives discretion to a treatment team to determine when to initiate or continue methadone when a person needs care at a facility. In theory, any primary diagnosis other than OUD would likely suffice.

REGISTERING AS A "HOSPITAL/CLINIC"

SAMHSA's regulations do not provide clear guidance on what qualifies for registration with the DEA as a "hospital/clinic" for purposes of 42 CFR § 8.11(h)(3). However, a hospital/clinic is one of the roughly 20 controlled substance registrations available from the DEA. DEA Form 224 defines a hospital/clinic as:

> A physical location at which any combination of inpatient, outpatient, or emergency medical services are provided, based upon authority granted by the State in which it is located. This includes any school which provides medical services to human patients in the process of teaching medicine. This definition does not include individual practitioners, incorporated or otherwise, licensed to practice medicine in a State.[14]

Any hospital, long-term care entity, or correctional facility that meets these conditions and obtains the DEA hospital/clinic registration can use the 42 CFR § 8.11(h)(3) exemption to provide methadone to a person treated for a separate, primary diagnosis.

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[10] 42 C.F.R. § 8.11(h)(3) (2024).
[11] *Id.*
[12] 21 C.F.R. § 1306.07(c) (2024) ("This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction . . . .").
[13] Although not within the scope of this factsheet, should the patient be receptive to treatment, DEA's "three-day" rule could potentially apply. This rule allows the emergency provision of methadone for OUD treatment for up to three days, without renewal or extension, "while arrangements are being made for referral for treatment." 21 C.F.R. § 1306.07(b) (2024).
[14] "Application for Registration Under Controlled Substances Act of 1970," *Department of Justice, Drug Enforcement Agency,* https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s1.

BECOMING AN OTP

A hospital, long-term care entity, or correctional facility that wishes to offer methadone treatment for a primary diagnosis of OUD must go through the complete OTP accreditation and certification process outlined in both the SAMHSA and DEA regulations. This includes:

- Obtaining accreditation by an OTP accreditation body;
- Complying with the federal OUD treatment standards outlined in 42 C.F.R. § 8.12;
- Obtaining certification as on OTP by SAMHSA;
- Obtaining an NTP registration with the DEA; and
- Obtaining a license from the state of operation as well as complying with any applicable state laws.

More information about the application and accreditation process can be found online on SAMHSA's website.

CONCLUSION

Hundreds of thousands of individuals in the United States have suffered fatal overdoses in recent years, with 75 percent of those overdoses involving opioids. Moreover, an estimated 2.7 million individuals currently suffer from active OUD. Government agencies have long understood that one of the key treatments for OUD lies in maintaining an individual on, or relieving the symptoms of withdrawal with, methadone. Hospitals, long-term care entities, and correctional facilities are often at the front lines of the epidemic due to the increased medical interventions required with the introduction of fentanyl and other adulterants into the drug supply.

In its updated regulation, SAMHSA clarified that these facilities may administer methadone in conjunction with other medical interventions when a patient suffering from substance withdrawal or OUD presents in their facility. However, the regulations continue to restrict those facilities from offering methadone as a primary treatment for OUD without registering with both SAMHSA and the DEA to become an OTP.

RESOURCES

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ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to model laws and policies that can be used by national, state, and local criminal justice and substance use disorder practitioners who want the latest comprehensive information on law and policy. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, treatment in emergency settings, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and syringe services programs.

For more information about LAPPA, please visit: https://legislativeanalysis.org/.