



Pharmacy-Based Dispensing of Methadone for Opioid Use Disorder

Permissibility & Feasibility

Methadone is a schedule II controlled substance approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder (OUD). Advocates for people with OUD have called for a change in federal law to “authorize” pharmacy-based dispensing of methadone for the treatment of OUD.¹ A change in federal law is not necessary because dispensing of methadone in pharmacies is already permissible (and happening) through OTP medication units co-located in pharmacies. To increase access to methadone, it is more efficient to reduce regulatory burdens and delays hindering the establishment of OTP medication units.

This fact sheet explains how federal law permits pharmacy-based dispensing of methadone for OUD. It also describes the results of a clinical trial that investigated the feasibility of pharmacy-based dispensing of methadone for OUD.

This fact sheet does not address state law and does not provide legal advice. Entities interested in dispensing methadone or any other controlled medication should obtain legal counsel from an attorney with experience in drug law.

Medical Treatment for Opioid Use Disorder

Three million people in the U.S. live with OUD.² Opioid-involved poisonings killed more than 78,000 Americans in the 12 months ending November 2022.³

Three FDA-approved medications for OUD (methadone, buprenorphine, and naltrexone) are effective and help save lives, especially when combined with counseling, peer supports, primary care, or wrap-around services. Evidence-based treatment guidelines recommend that all three FDA-approved medications for OUD be available to all patients who have OUD.⁴ Yet, many Americans who need treatment with medication for OUD cannot get it, especially in rural areas.⁵

Opioid Treatment Programs

Opioid Treatment Programs (OTPs) are medical clinics specializing in addiction treatment that deliver evidence-based treatment to people with OUD. OTPs are typically staffed by physicians, nurses, and counselors and must make substance use disorder counseling, medical, vocational, educational, and other assessment and treatment services available to all patients. OTPs offer all three FDA-approved medications for OUD. Other than hospitals, OTPs are the only medical settings that can provide methadone for OUD. At OTPs, methadone is most commonly dispensed in liquid form for oral ingestion.

Pharmacy-Based Dispensing

To expand access to treatment for OUD, advocates have called for a change in federal law to permit pharmacy-based dispensing of methadone for the treatment of OUD.⁶ If adopted, the change would allow treatment providers to circumvent OTPs to prescribe methadone themselves, thereby reducing emphasis on, and participation in, the multimodal therapies available to patients through OTPs. A change in federal law is not necessary because pharmacy-based dispensing of methadone for the treatment of OUD is already permissible through medication units.

Medication Units

OTPs may establish satellite clinics known as medication units to dispense methadone for OUD. Medication units facilitate access to treatment for patients who would otherwise have to travel greater distances to obtain treatment.⁷ Medication units may be freestanding entities or co-located (if permitted by state law) in pharmacies, hospitals, homeless shelters, jails, prisons, public health departments, and federally qualified health centers.⁸ They receive their medication supplies from the OTP and must follow other regulations enforced by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA).

To establish a medication unit, an OTP must obtain approval from its State Opioid Treatment Authority and notify the SAMHSA by submitting an online form.⁹ SAMHSA will process and forward the form to the DEA, which will arrange and conduct an inspection. Each medication unit must have a unique DEA registration.¹⁰

Initial Medical Examinations

Each OTP patient must undergo a physical evaluation by an OTP physician, primary care physician, or an authorized healthcare professional under the supervision of an OTP physician, before being admitted to the OTP and receiving medication for OUD.¹¹

A more thorough medical examination, including the results of laboratory and other tests, must be completed within 14 days following admission.¹²

Other Required Services

OTPs are required to establish and update treatment plans for all patients enrolled in their program.¹³

OTPs may offer in-house substance use disorder counseling, medical, vocational, educational, and other assessment and treatment services, or they may establish written agreements with third parties to provide furnish these services.¹⁴

OTPs must provide each patient at least eight random drug tests per year.¹⁵ Specimens may be collected at medication units.¹⁶

Pharmacy-Based Dispensing of Methadone

An OTP may authorize methadone dispensing within a medication unit co-located in a pharmacy by entering into a written agreement with the pharmacy.¹⁷ Under the agreement, pharmacy personnel who take possession of and dispense the OTP's methadone, are agents of the OTP.¹⁸ The agreement must specify the pharmacy personnel's authority and duties.¹⁹ The pharmacy personnel who dispense the methadone within the medication unit must be either:

1. An OTP-employed, state-licensed practitioner authorized to dispense controlled medications;²⁰
2. A registered nurse under the direction of the licensed practitioner;
3. A licensed practical nurse under the direction of the licensed practitioner; or
4. A pharmacist under the direction of the licensed practitioner.²¹

Clinical Trial of Pharmacy-Based Dispensing of Methadone

A feasibility clinical trial conducted in 2020 by Duke University School of Medicine Professor Li-Tzy Wu, RN, ScD, MA, and other researchers investigated the feasibility of an OTP physician directing the dispensing of methadone for OUD through collaboration with a pharmacy. This feasibility trial found OTP physician-directed, pharmacy-based dispensing of methadone for OUD to be feasible and acceptable. The treatment retention rate at month three was 80 percent (16 of 20 participants). Medication adherence among the 16 patients who were retained was 100 percent.

Eliminating Regulatory Burdens

Rather than passing legislation, a more direct and efficient way to increase access to methadone is to reduce regulatory barriers and delays hindering the establishment of OTP medication units. The DEA should decrease its documentation requirements to a single, simple form that the OTP and pharmacy can easily complete, sign, and submit. The DEA should also speed up the approvals of OTP medication units.

Making regulatory approvals for medication units easier and faster under current law would expand access to high-quality, multimodal OUD treatment directed by OUD specialists and supported by nurses and counselors at OTPs.

For more detailed information on the dispensing of methadone for OUD, see [Federal Guidelines for Opioid Treatment Programs](#) and [Narcotic Treatment Program Manual](#).

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1. Modernizing Opioid Treatment Access Act, H.R.1359, 118th Cong. (2023); David Ovalle, As Drug Deaths Soar, Experts Urge Expanded Access to Methadone, WASH. POST (March 5, 2023).
2. MOHAMMADREZA AZADFARD ET AL., OPIOID ADDICTION (James M. Leaming, ed., 2022).
3. Ctr. Disease Control, Provisional Drug Overdose Death Counts, (Feb 15, 2023).
4. NAT'L ACAD. SCI, ENG'G, AND MED., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES (Alan I. Leshner and Michelle Mancher eds., 2019).
5. Robert A Kleinman, Comparison of Driving Times to Opioid Treatment Programs and Pharmacies in the US, 77 JAMA PSYCHIATRY, 1163-71 (2020) <https://pubmed.ncbi.nlm.nih.gov/32667648/>.
6. Ovalle, supra note 1.
7. Substance Abuse & Mental Health Servs. Admin., PEP15-FEDGUIDEOTP, Federal Guidelines for Opioid Treatment Programs (2015) [hereinafter SAMHSA Guidelines for Opioid Treatment Programs].
8. Id.; Pew, Opioid Treatment Programs: A Key Treatment System Component, (July 16, 2021).
9. Letter from Kimberly Nelson, Acting Dir., Ctr. Substance Abuse Treatment, to Dirs., Opioid Treatment Programs, (Sept. 19, 2021) (on file with author).
10. SAMHSA guidelines for Opioid Treatment Programs, supra note 10.
11. 42 C.F.R. § 8.12 (2016).
12. Id.
13. Id.
14. Id.
15. Id.
16. SAMHSA guidelines for Opioid Treatment Programs, supra note 10.
17. 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).
18. Id.
19. Id.
20. 21 C.F.R. § 1301.74(i) (2023)
21. Id.



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