

## Pharmacy-Based Dispensing of Methadone for Opioid Use Disorder

## How It Happens

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.

This fact sheet explains how methadone for OUD is dispensed in pharmacies where permitted by state law.

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.



An opioid treatment program (OTP) and pharmacy enter into a written agreement to:

- Establish a medication unit within the pharmacy, and
- Make pharmacy personnel agents of the OTP supervised by the OTP physician.



The OTP obtains a federal registration for the medication unit within the pharmacy.



The pharmacy obtains a methadone supply from the OTP and must follow applicable regulations enforced by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Administration.





A primary care physician, or an authorized health care provider under supervision of the OTP physician, physically evaluates the patient and communicates findings to the OTP physician.



If medically necessary, the OTP physician admits the patient into treatment and provides a medication order to the pharmacist with instructions to dispense the ordered amount of methadone directly to the patient.



The pharmacist dispenses methadone directly to the patient and observes ingestion.



The OTP physician ensures the patient receives other clinical assessments and services in accordance with state and federal OTP rules and timelines.



The OTP ensures compliance with all state and federal licensure, security, and methadone inventory, disposal, and recordkeeping requirements.

For more detailed information on the dispensing of methadone for OUD, see **Federal Guidelines for Opioid Treatment Programs** and **Narcotic Treatment Program Manual**.

Last updated May 11, 2023.

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).

