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EXPLAINER

How Red Tape Limits Access to Medications for Opioid Use Disorder

November 2023

Background

Opioids were involved in more than 80,000 deaths in the United States in 2021, and between 3 million and 7.6 million Americans are living with or have had an opioid use disorder (OUD). Although medication for opioid use disorder (MOUD) is currently considered the gold-standard treatment, access remains limited. Research indicates that only about one in four people living with an OUD receive targeted, medication-based treatment. While many barriers to such treatment exist, ranging from the social stigma of drug use to limited geographic availability, overly strict regulation plays a key role in limiting access and presents an area for intervention.

The Medications

The U.S. Food and Drug Administration (FDA) has approved three MOUDs: naltrexone, methadone and buprenorphine.

How Each Medication Works	Reduces Withdrawal?	Reduces Illicit Opioid Use?	Reduces Overdose?	Schedule
Naltrexone				
Opioid antagonist that binds to and blocks opioid receptors, stopping intoxication and sedation	No	Mixed; depends on route of administraion*	No	Not Controlled
Methadone				
Long-acting opioid agonist that binds to, occupies and slowly activates opioid receptors in the brain	Yes	Yes	Yes	II†
Buprenorphine				
Partial opioid agonist that binds to and weakly activates opioid receptors in the brain	Yes	Yes	Yes	III‡

* Because naltrexone initiation first requires full detoxification and withdrawal from opioids, induction rates are very low. Furthermore, oral naltrexone has poor adherence compared to other MOUDs. Extended-release injectable naltrexone has more promising outcomes among individuals who complete induction, but initial induction remains difficult.

† Drugs listed as Schedule II under the Controlled Substances Act have an accepted medical use but are deemed to have a "high potential for abuse which may lead to severe psychological or physical dependence."

‡ Schedule III substances have an accepted medical use and are deemed to have "a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence."

Restricted Access

Drug scheduling and additional federal and state regulations affect how and where MOUDs may be prescribed, dispensed and administered.

Office-Based Prescribing	Pharmacy Access	Other Access
Naltrexone		
Yes. Any licensed health care provider (HCP) who can prescribe medications can offer naltrexone.	Yes. No special monitoring is required.	The injectable formulation may be administered by any HCP who can give intramuscular injections.
Methadone		
No. Although HCPs registered with the Drug Enforcement Administration (DEA) to prescribe Schedule II-V substances may prescribe methadone for certain conditions—for example, chronic pain—they may not prescribe it for OUD.	No. Pharmacies may not dispense methadone for OUD, although they may carry and dispense the medication when prescribed for other approved conditions.	Methadone for OUD is available only through opioid treatment programs (OTPs), which are regulated by state and federal governments. Research shows that the majority of U.S. counties lack an OTP. Thus, one-way drive times average 37 minutes (49 minutes in rural areas)—more than twice the time it takes to reach general providers. Methadone patients must visit OTPs in person, up to six days per week, and take their medication under direct supervision. Limited take-home doses are available, but only after an individual is deemed "stable." The criteria for this vary from state to state.
Buprenorphine		
Any HCP with a DEA license to prescribe Schedule II-V substances, which requires completion of at least eight hours of training on substance use disorders, can prescribe buprenorphine. In addition, a temporary rule permits providers to prescribe buprenorphine through telehealth. This permission is set to expire in December 2024.	Yes, but it is monitored as a controlled substance. High-volume dispensing can trigger investigation, which dissuades some pharmacies from stocking the medication.	Approved buprenorphine prescribers may administer injectable extended-release buprenorphine in the office but must either acquire the medication through a SUBLOCADE risk evaluation and mitigation strategy (REMS)-certified pharmacy immediately before each specified appointment or register themselves with the SUBLOCADE REMS to stock the product for more general use. Pharmacies that stock injectable buprenorphine must register with the SUBLOCADE REMS program and may only dispense the product directly to HCPs.

Diversion

Proponents of the disproportionate restrictions on and monitoring of buprenorphine and methadone frequently cite concerns about diversion, which is typically defined as the medications being sold, purchased or used without the required prescription. However, research indicates that diversion fears are largely overstated. In fact, diversion rates for methadone and commonly prescribed buprenorphine formulations are lower than those for prescription antibiotics. Furthermore, studies have found that many people who access MOUDs through informal channels are using the medications to alleviate withdrawal symptoms in the short term or to independently initiate longer-term treatment, thereby filling an access gap created by excessive regulation. This conclusion is supported by the fact that MOUDs' involvement in overdoses did not increase when restrictions were temporarily relaxed during the COVID-19 pandemic.

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