



Opioid Treatment Programs and Related Federal Regulations

Federally certified opioid treatment programs (OTPs)—often called methadone clinics—offer opioid medications, counseling, and other services for individuals addicted to heroin or other opioids. The use of opioid medications to treat opioid addiction is subject to federal regulations beyond those that apply to the same medications used for other purposes (e.g., treating pain). The medications methadone and buprenorphine are both opioids; their use to treat opioid addiction is often called *opioid substitution therapy* or *opioid replacement therapy*. With few exceptions, the use of methadone to treat opioid addiction is limited to OTPs; however, physicians who wish to treat opioid addiction using buprenorphine may obtain a waiver to do so outside an OTP. A non-opioid medication used in the treatment of opioid addiction, naltrexone, may be used by OTPs, physicians with waivers, or anyone with the authority to write prescriptions.

To understand how OTPs are regulated, it is helpful to have some background information about the medications used to treat opioid addiction and how each is regulated.

Medication-Assisted Treatment (MAT)

Medication-assisted treatment (MAT) is the combined use of medication and other services to treat addiction. Three medications are currently used in MAT for opioid addiction: methadone, buprenorphine, and naltrexone (naloxone, a medication used to reverse opioid overdose, is not used to treat opioid use disorders).

Methadone

Methadone is a full opioid agonist, meaning it binds to and activates opioid receptors in the brain. Methadone carries risk of abuse but is less addictive than some other full opioid agonists (e.g., heroin). Methadone suppresses withdrawal symptoms in detoxification therapy and controls the craving for opioids in maintenance therapy.

Buprenorphine

Buprenorphine is a partial opioid agonist, meaning it binds to opioid receptors in the brain and activates them, but not as much as full opioid agonists. Buprenorphine carries risk of abuse but is less addictive than methadone. Like methadone, buprenorphine is used for detoxification and maintenance therapy.

Naltrexone

Naltrexone is an opioid antagonist, meaning it binds to opioid receptors but does not activate them; it prevents opioid agonists from binding to and activating opioid receptors. Naltrexone carries no known risk of abuse. Naltrexone is used for relapse prevention because an individual on naltrexone who uses opioids will not experience the effects of that opioid.

Regulatory Framework

Two overlapping systems of federal law apply to MAT for opioid addiction: one regulating pharmaceuticals and the other regulating controlled substances.

Federal Food, Drug, and Cosmetic Act (FFDCA)

Under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.), the Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS) has primary responsibility for ensuring the safety and effectiveness of pharmaceuticals, regardless of whether they are controlled substances. See CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*. Methadone, buprenorphine, and naltrexone are subject to the FFDCA.

Controlled Substances Act (CSA)

Under the Controlled Substances Act (CSA, 21 U.S.C. §§801 et seq.), the Drug Enforcement Administration (DEA) in the Department of Justice (DOJ) has primary responsibility for regulating the use of controlled substances for legitimate medical, scientific, research, and industrial purposes, and for preventing these substances from being diverted for illegal purposes. See CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*, by Brian T. Yeh. Methadone and buprenorphine are subject to the CSA. Naltrexone, which carries no known risk of abuse, is not.

As shown in **Table 1**, methadone, buprenorphine, and naltrexone are classified differently under the CSA, which assigns various plants, drugs, and chemicals to one of five schedules based on accepted medical use, potential for abuse, and severity of potential psychological or physical dependence. Schedule I contains substances that have no currently accepted medical use and are not available by prescription (such as heroin). Schedules II, III, IV, and V include substances that have recognized medical uses and are progressively less dangerous and addictive.

Table 1. FDA-Approved Medications for Opioid MAT

Medication	Class	CSA Schedule
Methadone	Full Opioid Agonist	II
Buprenorphine	Partial Opioid Agonist	III
Naltrexone	Opioid Antagonist	none

Source: Prepared by the Congressional Research Service based on information publicly available from FDA and DEA.

Opioid Treatment Programs (OTPs)

Under the CSA, responsibility for regulating OTPs falls to both DEA in DOJ and the Substance Abuse and Mental Health Services Administration (SAMHSA) in HHS. OTPs must obtain

- accreditation from a SAMHSA-approved accreditor,
- certification from SAMHSA, and
- registration from DEA.

Programs meeting all requirements may “administer or dispense directly (but not prescribe)” any drug approved by FDA for treatment of opioid addiction. They may also administer a drug being studied for treatment of opioid addiction, as authorized by FDA under an investigational new drug application.

With few exceptions, the use of methadone to treat opioid addiction is limited to OTPs, which may also offer other forms of MAT, including buprenorphine for detoxification or maintenance and naltrexone for relapse prevention.

OTPs generally administer methadone on a daily basis with staff observing as a patient takes an oral dose of liquid methadone; however, a stable patient may receive a few take-home doses (e.g., for a weekend).

According to SAMHSA’s National Survey of Substance Abuse Treatment Services, most U.S. substance abuse treatment facilities (91%) do not have OTPs. As of March 31, 2016, the 1,308 facilities with OTPs had 345,443 clients in treatment with methadone.

OTP Accreditation

Accreditation is based on a peer review process in which SAMHSA-approved accrediting organizations evaluate OTPs by making site visits and reviewing policies, procedures, and practices. Examples of accrediting organizations include the Joint Commission and the Commission on Accreditation of Rehabilitation Facilities.

OTP Certification

Certification is based on SAMHSA’s determination that an accredited program is qualified to carry out treatment conforming to standards in federal regulation. SAMHSA uses the results of the accreditation process as well as other information to determine whether a program is qualified. SAMHSA promulgates guidelines to help accrediting organizations and OTPs conform to treatment standards.

OTP Registration

Registration with DEA as an OTP is separate from—and in addition to—the DEA registration required of any “person” (including a hospital, pharmacy, or doctor, among others) who handles controlled substances. OTPs must also comply with relevant DEA regulations addressing records maintenance, security controls, and other matters.

DATA-Waived Providers (DWP)

Under the Drug Addiction Treatment Act of 2000 (DATA 2000, P.L. 106-310), a physician may obtain a waiver to treat opioid addiction with buprenorphine (but not methadone) outside an OTP. DATA 2000 waives the requirement for separate DEA registration as an OTP if both the practitioner and the medication meet specified conditions. As of May 1, 2018, the number of DATA-waived providers exceeded 36,000; the number is updated daily on SAMHSA’s website.

Practitioner Requirements

To qualify for a waiver, a practitioner must notify the HHS Secretary of the intent to use opioid replacement therapy and must certify that he or she is a qualifying physician (licensed under state law with expertise as evidenced by certification, training, or experience); has the capacity to refer patients for appropriate counseling and other services; and will comply with a limit on the number of patients. The patient limit is 30 during the first year, may increase to 100 after one year (per the Office of National Drug Control Policy Reauthorization Act of 2006, P.L. 109-469), and may increase to 275 under conditions specified in regulation (per 81 *Federal Register* 44711, July 8, 2016).

The Comprehensive Addiction and Recovery Act (P.L. 114-198) temporarily (through October 1, 2021) allows nurse practitioners or physician assistants meeting specified criteria to obtain DATA waivers.

Medication Requirements

DATA-waived providers (DWPs) may administer, dispense, or prescribe opioid replacement therapy using a medication that is a narcotic drug in schedule III–V, that is FDA-approved for use in detoxification or maintenance treatment, and that has not been the subject of an adverse determination (as defined in statute). Buprenorphine is currently the only medication to meet the conditions for a DATA waiver. DEA assigns each DATA-waived provider a special identification number, which must be included (along with the provider’s regular DEA registration number) on all buprenorphine prescriptions for MAT.

Table 2 summarizes who can administer, dispense, or (in some cases) prescribe different types of MAT.

Table 2. MAT Used by OTPs, DWPs, and Others

Medication	Used to Treat Opioid Addiction by		
	OTPs	DWPs	Other Prescribers
Methadone	Yes	No	No
Buprenorphine	Yes	Yes	No
Naltrexone	Yes	Yes	Yes

Source: Prepared by the Congressional Research Service from 21 U.S.C. §§801 et seq. and information publicly available from SAMHSA.

Johnathan H. Duff, jduff@crs.loc.gov, 7-0970