



Members Brief

An informational brief prepared by the LSC staff for members and staff of the Ohio General Assembly

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Medication-Assisted Treatment for Opioid Use Disorders

Medication-assisted treatment, often referred to as MAT, is the use of medications in combination with counseling and behavioral therapies to treat substance use disorders, including opioid use disorders. The most commonly used MAT medications for opioid use disorders are methadone, buprenorphine, and naltrexone. Common locations for MAT are opioid treatment programs (OTPs) and office-based settings (referred to as office-based opioid treatment or OBOT).

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Treatment of opioid use disorders

In recent years, the misuse of and addiction to opioids – including prescription pain relievers, heroin, and synthetic opioids such as fentanyl – has become a serious national crisis that affects public health, as well as social and economic welfare.¹ Ohio has been particularly impacted. Beginning in 2007 and continuing through at least 2018, unintentional drug poisoning

¹ National Institute on Drug Abuse, *Opioid Overdose Crisis*.

has been the leading cause of injury death in Ohio, surpassing motor vehicle crashes.² In fact, Ohio is among the states with the highest rates of death due to drug overdose according to 2018 data from the U.S. Centers for Disease Control and Prevention (CDC).³

Although often subject to stigma and misunderstanding,⁴ one method that has proven effective for treating opioid use disorders is the combined use of medication with counseling and behavioral therapies. This treatment is known as medication-assisted treatment or MAT.

Drugs approved for medication-assisted treatment

Currently, there are three drugs approved by the federal Food and Drug Administration (FDA) for the treatment of opioid dependence: methadone, buprenorphine, and naltrexone. As indicated in the table below, one way to distinguish among them is whether they are agonists or antagonists. An agonist is a drug that activates certain receptors in the brain. Full agonist opioids activate the opioid receptors in the brain resulting in the full opioid effect. Examples of full agonists are heroin, oxycodone, hydrocodone, and morphine, as well as the MAT drug methadone. Partial agonist opioids activate the opioid receptors in the brain, but to a much lesser degree than a full agonist. Buprenorphine is an example of a partial agonist. An antagonist is a drug that blocks opioids by attaching to the opioid receptors without activating them. Antagonists cause no opioid effect and block full agonist opioids. Examples are naltrexone and naloxone.⁵

FDA-Approved MAT Drugs			
	Methadone ⁶	Buprenorphine ⁷	Naltrexone ⁸
Type of drug	Full opioid agonist	Opioid partial agonist (often known by the brand name Suboxone [®])	Antagonist (often known by the brand name, for its injectable extended-release form, Vivitrol [®])

² Ohio Department of Health, [Drug Overdose](#). For additional statistics, current and past versions of the Ohio Department of Health's drug overdose report can be found at the preceding link.

³ CDC, [Drug Overdose Deaths](#).

⁴ U.S. Department of Health and Human Services, [Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs, A Treatment Improvement Protocol](#).

⁵ U.S. Department of Health and Human Services, Indian Health Service, [Pharmacological Treatment](#).

⁶ Substance Abuse and Mental Health Services Administration (SAMHSA), [Methadone](#).

⁷ SAMHSA, [Buprenorphine](#).

⁸ SAMHSA, [Naltrexone](#).

FDA-Approved MAT Drugs			
	Methadone ⁶	Buprenorphine ⁷	Naltrexone ⁸
Controlled substance	Schedule II (classified as having a high potential for abuse which may lead to severe psychological or physical dependence) ⁹	Schedule III (classified as having 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)	No (very limited, if any, abuse and diversion potential)
Available forms	Liquid, powder, tablets, and diskettes	Tablets, films, injections, and implants ¹⁰	Pills and injections
Dosing frequency	Daily	Varies from daily up to every six months	Varies from daily to monthly
Availability	Dispensed only through certified opioid treatment programs (OTPs); after a period of progress and consistent program compliance, patients may be allowed to take methadone at home between OTP visits	In addition to dispensing at OTPs, may be prescribed by or dispensed in physician offices, as well as other health care settings; prescribers must acquire and maintain a federal waiver to legally dispense or prescribe outside of an OTP	May be prescribed by any health care professional who is licensed to prescribe drugs

Medication access and length of treatment

The FDA recommends that individuals seeking addiction treatment be offered access to all approved MAT medications in order to select the best treatment for an individual's needs.¹¹ Ohio law specifically requires prescribers, before initiating MAT, to give patients information about all FDA-approved treatment drugs, both orally and in writing.¹² Per the FDA, there is no

⁹ U.S. Department of Justice Drug Enforcement Administration, *Controlled Substance Schedules*.

¹⁰ The National Alliance of Advocates for Buprenorphine Treatment, *What exactly is Buprenorphine?*; Pharmacy Times, *A Brief Review of Buprenorphine Products*.

¹¹ FDA, *Information About Medication-Assisted Treatment (MAT)*.

¹² R.C. 3719.064. If the prescriber is not a qualifying practitioner and the patient's choice is opioid treatment, the prescriber generally must refer the patient to an OTP.

maximum recommended duration of maintenance treatment; for some patients, treatment may continue indefinitely.¹³

Opioid treatment programs

OTPs are providers of MAT that are certified by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an independent, SAMHSA-approved accrediting body. Additionally, OTPs must be state-licensed and registered with the federal Drug Enforcement Administration.¹⁴

Under Ohio law, only community addiction services providers are eligible for state OTP licensure.¹⁵ A community addiction services provider is a provider of drug addiction services that are certified by the Director of the Ohio Department of Mental Health and Addiction Services (OhioMHAS). Community addiction services providers also may provide related recovery supports.¹⁶

License qualifications

An OTP applicant must meet the following requirements under Ohio law:¹⁷

1. During the three-year period preceding the date of the application, the provider (or any owner, sponsor, medical director, administrator, or principal of the provider) must have been in good standing to operate an OTP in all other locations where the provider or such other person has been operating a similar program.
2. It must affirmatively appear to OhioMHAS that the provider is adequately staffed and equipped to operate an OTP.
3. It must affirmatively appear to OhioMHAS that the provider will operate an OTP in strict compliance with all laws and rules relating to drug abuse.
4. The proposed OTP must not be located within 500 linear feet of a public or private school, child daycare center, or child-serving agency, unless a waiver is obtained.
5. The OTP must meet any additional requirements established by OhioMHAS in rules.

¹³ *Information About Medication-Assisted Treatment (MAT)*.

¹⁴ SAMHSA, *Certification of Opioid Treatment Programs (OTPs)*; 42 Code of Federal Regulations (C.F.R.) 8. Under prior Ohio law, OTPs were referred to as methadone programs.

¹⁵ R.C. 5119.37(A).

¹⁶ R.C. 5119.01(A)(7). Since 2019, Ohio law generally requires withdrawal management, residential addiction services, and outpatient addiction services to be provided by community addiction services providers, licensed health professionals, or accredited hospital outpatient clinics. R.C. 5119.35.

¹⁷ R.C. 5119.37(C).

Program operation

Ohio law specifies that methadone can be administered and dispensed only in a liquid form intended for ingestion. Additionally, MAT drugs cannot be administered or dispensed for pain or other medical reasons.¹⁸

Much of the regulation of day-to-day operations of OTPs is set forth in rules, including standards for the control, storage, furnishing, use, dispensing, and administering of medications used in MAT, as well as minimum standards for the operation of the OTP component of the provider's operations.¹⁹

Office-based opioid treatment

With few exceptions, the use of methadone to treat opioid use disorders is limited to OTPs, as described above; however, physicians who wish to treat opioid addiction using controlled substances other than methadone, such as buprenorphine, may do so under an office-based opioid treatment (OBOT) model. OBOT is generally outpatient treatment for opioid use disorder that is provided in a setting other than an OTP, such as a primary care or general health care practice. To provide OBOT, a physician must obtain a waiver under federal law and comply with state licensing requirements.

Federal waiver for OBOT prescribers

The Drug Addiction Treatment Act of 2000 (DATA) permits qualified physicians to treat narcotic dependence with FDA-approved controlled substances in schedules III through V. The authorization was later extended to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.²⁰

To qualify for a waiver, a practitioner must (1) certify to the U.S. Department of Health and Human Services that he or she is a "qualifying practitioner," meaning licensed under state law with expertise as evidenced by a national certification related to addiction medicine, completion of an eight-hour training by designated organizations, or other approved training or experience, (2) have the capacity to refer patients for counseling and other services, and (3) comply with patient limits. The patient limits are 30 during the first year, but may increase to 100 after one year or immediately if the practitioner holds additional credentialing or operates in a qualified practice setting. The limits may increase to 275 under conditions specified in federal regulations.²¹

Ohio licensure

In addition to the federal waiver requirement, in 2017, Ohio began directly regulating OBOT by requiring licensure through the State Board of Pharmacy. For purposes of licensure, OBOT is broadly defined as the treatment of opioid dependence or addiction using a controlled

¹⁸ R.C. 5119.37(H).

¹⁹ R.C. 5119.37(F).

²⁰ 21 United States Code (U.S.C.) 823(g).

²¹ 21 U.S.C. 823(g); 42 C.F.R. 8.610.

substance.²² To provide OBOT to more than 30 patients, a provider generally must be licensed by the Pharmacy Board as a category III terminal distributor of dangerous drugs with an OBOT classification.

There are several limitations, however, that narrow who must be licensed. First, in determining whether more than 30 patients are being provided OBOT at a particular facility, patients receiving onsite treatment through the direct administration of addiction treatment drugs by health care professionals at the facility are excluded.²³ Second, numerous exceptions to licensure apply. For example, while an OTP would fall within Ohio's broad definition of OBOT, it is expressly exempt from the license requirement. The following are also exempt:

- Hospitals and facilities operated, owned, or controlled by hospitals;
- Clinical research facilities;
- Facilities licensed by OhioMHAS, if the license is approved by the Pharmacy Board;
- Federally qualified health centers and federally qualified health center look-alikes;
- State and local correctional facilities;
- Facilities that only treat patients onsite exclusively through direct administration of addiction treatment drugs by a health care provider at the facility;
- Other facilities specified in rules.²⁴

License requirements

Licensed OBOT providers must:²⁵

1. Be in control of a facility that is owned and operated solely by one or more physicians, unless the Pharmacy Board waives this requirement;
2. Comply with the requirements for conducting OBOT established in rules adopted by the State Medical Board (see below);
3. Require criminal records checks for any person with ownership of the facility and employees and applicants for employment;
4. Ensure that a person is not employed by the facility if the person, within the ten years preceding the date the person applied for employment, was convicted of or pleaded guilty to certain theft and felony drug offenses, unless the Pharmacy Board permits the person to be employed by waiving this requirement; and
5. Maintain a list of each person with ownership of the facility and notify the Pharmacy Board of any changes.

²² R.C. 4729.553(A)(4).

²³ R.C. 4729.553(B)(1) and (3).

²⁴ R.C. 4729.553(B)(2).

²⁵ R.C. 4729.553(D).

Rules governing treatment

Rules adopted by the Medical Board require physicians to conduct assessments prior to providing OBOT. The assessments must include a comprehensive medical and psychiatric history, brief mental status examination, substance abuse history, family history, physical examination, drug testing, pregnancy tests for women of childbearing age and ability, review of prescription information in Ohio's drug database, and testing for HIV and hepatitis B and C, as well as consideration of tuberculosis and STD screening for patients with known risk factors.²⁶

Other key provisions require a physician to:

- Provide OBOT in accordance with acceptable treatment protocols specified in the rules for assessment, induction, stabilization, maintenance, and tapering;
- Develop an individualized treatment plan for each patient;
- Not prescribe, personally furnish, or administer greater than 24 milligrams of buprenorphine per day to a patient; and
- Complete at least eight hours of certain continuing medical education relating to substance abuse and addiction every two years.

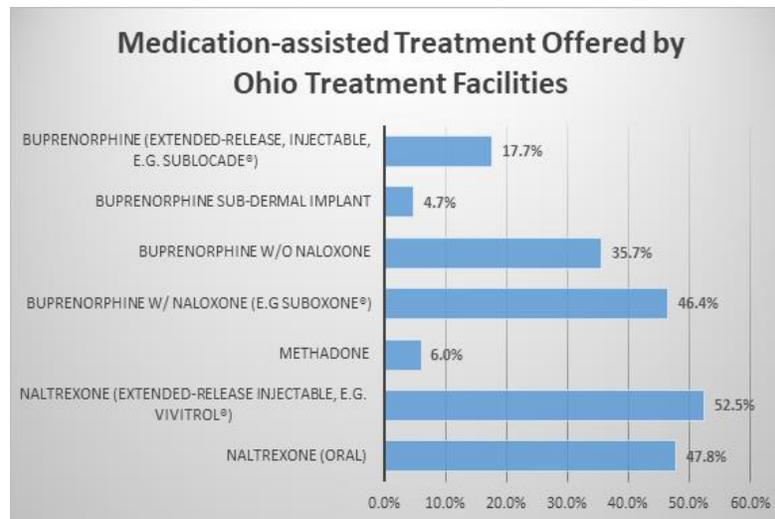
Utilization

According to SAMHSA, while MAT's ultimate goal is full recovery, it has been shown to improve patient survival, increase retention in treatment, decrease illicit opiate use and other criminal activity among people with substance use disorders, increase patients' ability to gain and maintain employment, and improve birth outcomes among women who have substance use disorders and are pregnant. Despite these positive outcomes, according to SAMHSA's most recent National Survey of Substance Abuse Treatment Services, as indicated in the following chart, availability of various types of MAT varies in Ohio's 554 treatment facilities.²⁷ On the date referenced in that survey, those facilities served 66,296 clients overall.²⁸

²⁶ Ohio Administrative Code 4731-33-03.

²⁷ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *National Survey of Substance Abuse Treatment Services (N-SSATS): 2019 Data on Substance Abuse Treatment Facilities* (August 20, 2020).

²⁸ *National Survey of Substance Abuse Treatment Services (N-SSATS): 2019 Data on Substance Abuse Treatment Facilities* at 229.



Ohio's Section 1115 Substance Use Disorder Demonstration

Through September 2024, the federal Centers for Medicare and Medicaid Services has approved a waiver to allow Ohio to support a comprehensive continuum of care for Medicaid recipients with substance use disorders, including opioid use disorders. The waiver expands Ohio's efforts to increase support for individuals in the community and home – outside of institutions – and improve access to a continuum of high-quality, evidence-based services, including MAT, based on clinical guidelines set by the American Society of Addiction Medicine. A central part of the waiver focuses on enhancing residential treatment services by permitting Ohio to receive federal funding for Medicaid services for individuals who temporarily reside in inpatient or residential treatment facilities.²⁹ Under the waiver, Medicaid provider standards will include a requirement that residential treatment facilities offer MAT onsite or facilitate access off-site.

Funding sources

Besides Medicaid, various other funding sources help to provide Ohioans increased access to MAT. Two federal sources include the State Targeted Response Grant, which was created in the 21st Century Cures Act,³⁰ and the State Opioid Response Grant (created in the 2018 omnibus appropriations bill).³¹ OhioMHAS is using the grants in part to increase access to MAT.³² Ohio's total share of State Opioid Response funding is \$235.1 million since the inception of the program.³³

²⁹ Ohio Department of Medicaid, [Substance Use Disorder Section 1115 Demonstration Waiver](#); see also Department of Health and Human Services, [September 24, 2019 approval letter](#).

³⁰ Public Law 114-255 (2016).

³¹ Pub. L. 115-141 (2018).

³² Greenbook, LBO Analysis of Enacted Budget, [Department of Mental Health and Addiction Services](#).

³³ Ohio Mental Health and Addiction Services, [Ohio Receives \\$96M in State Opioid Response Grants to Fight Addiction](#).