

**COLORADO**

Office of Behavioral Health

Department of Human Services

About Opioid Medication Assisted Treatment Programs

Due to the increase in prevalence of opioid addiction among the general public, Opioid Medication Assisted Treatment Programs have increased in visibility in recent years. This document outlines the ways in which Opioid Medication Assisted Treatment Programs are operated and regulated, as well as the zoning and Individuals with Disabilities Act implications that affect where the programs are located.

Opioid Addiction

Opioids are drugs based upon the chemical structure of opium. Opioid addiction occurs when a person develops a physical dependence on the drug (experiences withdrawal when use is ceased) and loses control over the desire to use the drug, experiencing overwhelming cravings and desires to use the drug. Opioid addiction is a chronic brain disease and, like other behaviorally based diseases such as heart disease or diabetes, opioid addiction can be effectively managed through the use of medication and lifestyle changes. The most common medications used in the treatment of opioid addiction approved by the Food and Drug Administration are methadone, naltrexone, and buprenorphine. The goal of medication-assisted treatment is to assist the individual to recover from addiction.

Methadone provides a safe, legal, and controlled level of medication to overcome the compulsive use of an opioid. It is prescribed and administered under the supervision of a physician for the express purpose of eliminating the physical, psychological and social problems that accompany addiction. By effectively eliminating the necessity to seek illicit opioids in order to avoid painful withdrawal, methadone provides the stability individuals who are addicted need in order to lead productive, pro-social lives.

An extensive body of research has demonstrated that treatment with methadone can effectively reduce the use of illicit opioids, decrease criminal behavior, decrease the spread of infectious diseases and reduce mortality from opioid addiction (An extensive review by the National Institute on Drug Abuse is available at <https://www.drugabuse.gov/sites/default/files/pdf/partb.pdf>). The effectiveness of methadone treatment is one of the best-documented bodies of treatment literature and dates back to the mid-1970's. These studies have demonstrated across countries and populations that methadone can be effective in improving treatment retention, criminal activity, and heroin use (Mattick, Breen, Kimber, et al., 2003; Marsch, 1998).

Federal Regulation of Opioid Addiction Treatment

Drug treatment programs that utilize Opioid Medication Assisted Treatment are regulated by the federal government, which entails adherence to treatment standards through accreditation and record keeping requirements for use of controlled pharmaceuticals. Multiple federal agencies support and regulate Opioid Medication Assisted Treatment: the Drug Enforcement Agency (DEA) through the Food and Drug Administration (FDA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Federal statutes governing opioid treatment include: the Controlled Substances Act (21 C.F.R. Chapter 13 Part C) requires practitioners who prescribe, dispense, or administer controlled substances to register with the Drug Enforcement Administration; the Narcotic Addict Treatment Act (NATA) (21 U.S.C 802 (1974)) recognizes the use of an opioid (narcotic) drug to



treat opioid (narcotic) dependence and defines long-term or maintenance treatment; and the Drug Enforcement Administration (21 U.S.C. 823(g) (1974)) requires separate registration of medical practitioners.

Regulations ensuring the implementation of Opioid Medication Assisted Treatment include Federal Opioid Treatment Standards (United States Code of Federal Regulations 42 C.F.R. 8.12). These regulations address the following aspects of all approved opioid treatment programs:

- Administrative and organizational structure of opioid treatment programs
- Quality assurance/improvement
- Diversion Control Plan
- Staff credentials
- Patient admission criteria
- Required services
- Record keeping and patient confidentiality
- Medication administration, dispensing
- Unsupervised use
- Interim maintenance
- Detoxification

National Accreditation

Opioid Medication Assisted Treatment programs are also required by SAMHSA to be accredited by private or state accreditation organizations (The Joint Commission, The Commission on the Accreditation of Rehabilitation Facilities, and the Council on Accreditation). Accreditation is the process by which SAMHSA-approved accreditation bodies conduct periodic site visits and review policies, procedures, practices and patient services of Opioid Medication Assisted Treatment programs.

State Regulation

Opioid Medication Assisted Treatment programs must also meet State regulatory guidelines, including another set of stringent treatment requirements, controlled substances accountability, payer requirements and other health and safety requirements. Additionally, programs must adhere to local ordinances, such as zoning laws, that strictly regulate where and whether an Opioid Medication Assisted Treatment program can operate.

Colorado Licensing Process

There are a total of 16 Licensed Opioid Medication Assisted Treatment programs in the state of Colorado; eight in the Denver Metropolitan region, two in the Colorado Springs area, one in Pueblo, one in Longmont, one in Grand Junction program, one in Durango, one in Alamosa and a medication unit in Fort Collins.

In order to open an Opioid Medication Assisted Treatment programs in Colorado, several conditions must be met, and the Program receives oversight by three different agencies:



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- A program must apply for and receive a Controlled Substance License (Title 27 Article 80 Part 2), from the Office of Behavioral Health within the Colorado Department of Human Services (referenced in 2 CCR 502-1 Volume 21.300-21.300.9)
- A program must apply for and receive a federal Opioid Medication Assisted Treatment programs registration number from the federal Substance Abuse and Mental Health Services Administration.
- Once that number is issued, then the Drug Enforcement Agency authorizes the facility to order medications using a federal form, called the Drug Enforcement Agency 222 form. Once the facility receives the medications, they stock them, store them and dispense them according to all of all of the Drug Enforcement Agency guidelines.
- All Opioid Medication Assisted Treatment programs are also licensed by the CDHS, Office of Behavioral Health. All agencies or individuals seeking a license for an Opioid Medication Assisted Treatment program must follow all General provisions outlined in Colorado Regulations: 2 CCR 502-1 Volume 21 (21.000-21.190.62, as well as 21.320-21.320.9 found here: <http://www.sos.state.co.us/CCR/2%20CCR%20502-1.pdf?ruleVersionId=5432&fileName=2>)

Once a full application is submitted, the CDHS, Office of Behavioral Health conducts a formal site visit to assess for adherence of state and federal standards. If all of the required elements are in place, the CDHS, Office of Behavioral Health will issue a provisional license for 90 days, at which point the program can get a Drug Enforcement Agency registration number. After they receive their Drug Enforcement Agency number, the CDHS, Office of Behavioral Health will issue another 90-day provisional license to begin treating patients. At the time of the expiration of the second provisional license, another formal site visit occurs to review charts and determine if the program is in compliance with rules. If the program is in full compliance, the CDHS, Office of Behavioral Health will issue a full license.

Lastly, all Opioid Medication Assisted Treatment Programs must be accredited by one of the nationally recognized healthcare quality accreditation agencies.

License Enforcement

A license issued under the Controlled Substance Act does not permit a licensee to distribute or professionally use controlled substances beyond the scope of the licensee's federal registration. The CDHS, Office of Behavioral Health may deny, suspend, or revoke a license upon a finding of the following violations:

- Furnishing false or fraudulent information in an application.
- Entering a plea of guilty or nolo contendere to, or being convicted of a felony under any state or federal law relating to a controlled substance.
- Having a federal registration to manufacture, conduct research with, distribute, or dispense a controlled substance suspended or revoked.
- Violating any provision of the Act or the State Board of Human Services' rules.

The CDHS, Office of Behavioral Health must:

- Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances.



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- Cooperate with the Drug Enforcement Agency, local, state, and other federal agencies by maintaining a centralized unit to accept, catalogue, file, and collect statistics.
- Gather records of dependent and other controlled substance law offenders within the state, and make the information available for enforcement or regulatory purposes.
- Cooperate with state licensing boards regarding violations of the Act and make information available to those boards.
- Engage in educational and research activities designed to determine and prevent the misuse and abuse of controlled substances.

Determining Program Locations:

Opioid Medication Assisted Treatment Programs must have approval by the federal Substance Abuse and Mental Health Services Administration through their Center for Substance Abuse Treatment.

1. Program location decisions and state roles:

- Businesses have full discretion to request the location of their choice. Businesses typically run their own needs assessment as a part of their business plan.
- The CDHS, Office of Behavioral Health does not have a role in determining locations.
- The CDHS, Office of Behavioral Health provides potential applicants with publicly available data about statewide alcohol and drug use patterns and trends.

2. Businesses with past regulatory violations:

- If the violations occurred in the State of Colorado, the state considers the severity of the violation and the success of any corrective actions taken when reviewing for licensure.
- There are no current CDHS, Office of Behavioral Health rules that prevent a business from applying/reapplying with past violations, unless the violations were severe enough for the Attorney General to intervene.
- Attorney General intervention can provide support to deny an application from a particular entity.

3. Opportunities for public input on licensing decisions:

- There is an opportunity for public input through the local zoning process. At this time, the State rule regarding licensing procedures do not include a public input on licensing a specific location.
- All Opioid Medication Assisted Treatment Programs must have been approved for local zoning for the anticipated location.

Zoning decisions are also subject to the Americans with Disabilities Act law, which reads:

No qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.

Zoning qualifies as a public program and service and the enforcement of a zoning ordinance constitutes an activity of a locality within the meaning of 32-200. The ADA protects qualified people with a disability. A person is qualified if she has (1) mental or physical impairment. The term includes conditions such as drug addiction. The anti-discrimination provision of the



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ADA prohibits zoning decisions by a locality that discriminate against drug and alcohol rehabilitation programs.

Opioid Medication Assisted Treatment Programs are not marijuana dispensaries:

An Opioid Medication Assisted Treatment Program is different from a marijuana dispensary, as the latter sells medical or recreational marijuana. A marijuana dispensary is not an addiction treatment program but rather a business selling a product to consumers. Marijuana dispensaries are not regulated by the CDHS, Office of Behavioral Health. Since the use of marijuana remains illegal at the federal level, the Drug Enforcement Agency oversight or involvement is not present.