



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

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Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

Fact Sheet: Opioid Maintenance Therapy

Opioid maintenance therapy is the use of narcotic drugs in the treatment of opioid use disorder. The term “methadone clinic” has been used in reference to the facilities that administer this therapy. Facilities with opioid treatment programs are regulated by State and Federal regulations.

Licensing Requirements

Licensing and oversight for opioid maintenance therapy (OMT) programs in Maryland is jointly administered by the Office of Health Care Quality (OHCQ) and the Behavioral Health Administration (BHA), agencies that fall under the Department of Health and Mental Hygiene (Department). In Baltimore City, oversight authority is also exercised by Behavioral Health System Baltimore. Requirements specific to programs that provide opioid maintenance therapy are specifically set forth in Code of Maryland Regulations (COMAR) 10.47.02.11.

An applicant for certification as an OMT program must comply with the requirements set forth in COMAR 10.47.04 by, among other requirements, submitting to OHCQ and BHA an application, a Policy and Procedure Manual describing the operation of the proposed program, and notice from the Fire Marshall's office that the facility is suited for its intended function as an OMT treatment facility. If an applicant has met all of the qualifications required of them in statute and regulation, a certification is issued.

A new applicant is issued an **Initial** certification after receipt and review of the application, a review of the submitted Policy and Procedure manual, and an on-site visit by the surveyor. The onsite visit is to determine the facility's suitability as an OMT site, i.e., signage, handicap access, habitability etc.

After issuance of the **Initial** certification approval by OHCQ (BHA prepares and issues the Certification) the OHCQ surveyor returns within six months to review charts, interview staff, check staff credentials, etc. If major deficiencies are not cited, the OHCQ approves a **General** Certification which authorizes the program to operate for two years.

It is important to note that these requirements are separate from any local zoning or use ordinances.

Notification of the Public

The Department is greatly restricted in its ability to notify the public or local elected officials when an application for a substance use disorder treatment clinic is received. According to the Americans with

Disabilities Act, the Department cannot issue special notification for a facility that serves a specific class of people, in this case, individuals in need of substance use disorder treatment. The Department has consulted with the Maryland Office of the Attorney General, and has been advised that treating notification of the public of these facilities differently than others may subject the Department to civil litigation.

General Questions

How often are OMT providers surveyed for regulatory compliance by OHCQ and BHA?

BHA reviews all OMT programs annually. OHCQ surveys programs for certification every two years. If violations of COMAR are found by OHCQ, the provider is given a Statement of Deficiencies and given 10 days to provide a Plan of Correction (POC) to OHCQ. OHCQ then review the POC to determine if it fully addresses the COMAR violations.

How is the clinic monitored to ensure compliance with its accepted Plan of Correction?

The follow up is done at the next scheduled review unless the problem is serious enough to merit some sort of administrative action such as resolution meetings, show cause hearings, or settlement agreements.

Are regulations dependent on the location of the facility and the type of care provided?

COMAR 10.47. is not based on the location of a program. There are different regulations based on the type of services being provided, i.e. residential, outpatient, etc.

Can a clinic's hours of operation be restricted based on its location and the type of care provided?

COMAR 10.47.02.11 (D) states that a program shall have hours that meet the needs of the patients. The regulations offer no restriction on hours of operation.

Are there requirements to be a patient at one of these facilities? If so, what are the minimum requirements?

COMAR 10.47.01.04 regulates the admission criteria for OMT programs. In part it says that programs shall have a detailed description of patient placement criteria using guidelines such as the American Society of Addiction Medicine Patient Criteria (ASAM). The minimum criteria would be to have been diagnosed as Opioid Use Disorder based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).

Is the provider responsible for the patients once they leave the premises?

There are no regulations that require an OMT to be responsible for the behavior of their patients once the patient is off of their premises. However, in order to help patients who are not on the

facility premises, BHA encourages providers to take the following steps when responding to complaints regarding patient activities that occur off-site: (1) restructure the reporting times to reduce large congregations of patients, (2) work with the patients to encourage them to respond to community concerns, (3) meet with the community organizations impacted by the problems to get their input, (4) meet with local police to understand whether any patients might be participating in criminal activities, (5) set up an immediate alert system if there are problems involving their patients, and (6) take other appropriate action that will reduce complaints.

Can a clinic administer multiple doses at one time? (i.e. giving doses for Friday and Saturday on Friday)

COMAR 10.47.02.11 (J) regulates the administration of take-home methadone medication. In part it says "Before the patient may take home any dose the patient shall meet the criteria set within 42 Code of Federal Regulations (CFR) Part 8."

42 CFR Part 8 says in part that "Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays."

Are patients required to take doses on site?

COMAR 10.47.02.11 (J) regulates the administration of methadone medication to be taken off site. In part it says, "Before the patient may take home any dose the patient shall meet the criteria set within 42 CFR Part 8."

42 CFR Part 8 says in part that:

"Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

- (i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
- (ii) Regularity of clinic attendance;
- (iii) Absence of serious behavioral problems at the clinic;
- (iv) Absence of known recent criminal activity, e.g., drug dealing;
- (v) Stability of the patient's home environment and social relationships;
- (vi) Length of time in comprehensive maintenance treatment;
- (vii) Assurance that take-home medication can be safely stored within the patient's home; and

- (viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

How do regulatory agencies determine if medication is being diverted?

The agencies investigate incoming complaints with a review of medical records and conduct interviews to determine if medication is being appropriately administered or diverted. If law enforcement confiscates medication during an arrest, the appropriate regulatory agency should be notified.