

Methadone Clinic Regulation

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October 20, 2022 | 2022-R-0232

Issue

This report provides a broad overview of the certification and licensure of methadone clinics in Connecticut.

Summary

Opioid treatment programs (such as methadone clinics) must meet (1) federal certification and accreditation requirements and (2) state licensing requirements. Under federal regulations, opioid treatment programs must be [certified](#) by the federal Substance Abuse and Mental Health Services Administration (SAMHSA), which is part of the U.S. Department of Health and Human Services. The regulations also require these programs to be accredited by an independent, SAMHSA-approved accrediting body to dispense opioid treatment medications (e.g., the [Commission on Accreditation of Rehabilitation Facilities](#) (CARF) or the [Joint Commission](#)). Treatment programs must first obtain accreditation and then seek certification. Opioid treatment programs also must register with the federal [Drug Enforcement Administration](#).

Under state law, substance abuse treatment facilities must be licensed by the Department of Public Health (DPH). Under DPH regulations, methadone clinics are licensed as a subcategory of “private, freestanding facilities for the care or the treatment of substance abusive or dependent persons.” The DPH regulations require these facilities, when applying for licensure, to show compliance with local zoning ordinances.

In addition, methadone clinics seeking Department of Mental Health and Addiction Services (DMHAS) funding must meet other requirements in state regulations.

As of July 1, 2022, methadone dispensing or administration directly to a patient must be reported to the state's prescription drug monitoring program if (1) the patient has consented to the disclosure and (2) it complies with federal substance abuse confidentiality regulations ([CGS § 21a-254\(j\)](#)), as amended by [PA 21-192](#), § 5).

Below, we provide a broad overview of the SAMHSA certification requirements and state regulations. For more information on Connecticut's methadone clinics, including a list and map of the methadone clinics in the state, see DMHAS's [website](#).

SAMHSA Certification

SAMHSA's certification requirements for opioid treatment programs are found in [42 C.F.R. § 8.1 et seq.](#) Under the certification regulations, programs are evaluated in the following areas:

1. administrative and organizational structure (e.g., requiring a medical director);
2. continuous quality improvement, (e.g., annual policy and procedure reviews and ongoing assessment of patient outcomes);
3. staff credentials;
4. patient admission criteria (e.g., specific criteria for minors);
5. required services (e.g., counseling, drug testing, and initial and periodic assessments);
6. recordkeeping and patient confidentiality;
7. medication administration, dispensing, and use (e.g., must only use FDA-approved opioid agonist treatment medications);
8. unsupervised or "take home" use; and
9. interim maintenance treatment ([42 C.F.R. § 8.12](#)).

Methadone clinic medical directors and physicians at already approved clinics, under certain conditions, can request [exceptions](#) from the standard requirements, such as a request to allow a temporary increase in take-home medication.

Certificate of Need (CON) Approval

In addition to the other requirements outlined in this report, a party seeking to establish a new methadone clinic, or transfer ownership of a methadone clinic, may need to obtain CON approval from the Office of Health Strategy (OHS). But there are exceptions to this.

CON requirements generally apply to various types of health care facilities, including substance abuse treatment facilities. Among other exceptions, CON requirements generally do not apply to non-profit facilities that have a contract with a state agency for a service that would otherwise require CON approval.

For details on the CON process, see OHS's [website](#).

For more information on the SAMHSA regulations and certification process, see the agency's [website](#).

Federal Authority Delegated to DMHAS

State law designates DMHAS as the state methadone authority and specifies that as such, SAMHSA authorizes the department to (1) approve exceptions to federal opioid treatment protocols, (2) approve federal certification of all opioid treatment programs in the state, and (3) monitor those programs ([CGS § 17a-450\(d\)](#)).

DPH Licensure

In Connecticut, a drug rehabilitation facility, including a methadone clinic, must obtain a DPH license as a private, freestanding facility for the care or treatment of substance abusive or dependent persons ([Conn. Agencies Regs. § 19a-495-570](#)). Licenses must be renewed annually.

A drug rehabilitation clinic can be licensed to provide nine categories of services, including chemical maintenance treatment (such as methadone treatment).

DPH regulations require each facility to, among other things:

1. have a governing board, an executive director, and fiscal manager;
2. adopt written personnel policies and procedures covering staff work rules, including discipline, evaluation, and medical exams;
3. meet state and local codes (including zoning) and specific physical plant rules;
4. meet specific staffing requirements;
5. develop and implement emergency and disaster policies and procedures;
6. follow specified accident and injury reporting procedures;
7. develop individual service plans for clients and properly maintain client records; and
8. follow specific requirements regarding the storage and safeguarding of controlled substances.

The regulations contain numerous other requirements for facilities based on their specific types of services, including long-term treatment facilities. Among other requirements for methadone clinics (chemical maintenance treatment facilities):

1. each client must have an initial drug-screening urinalysis upon admission and at least eight additional random urinalyses during the first year while in a maintenance program and at least quarterly random urinalyses after that;
2. each client's individualized program plan must be reviewed every 90 days after the initial 30-day review for the first year and at least every 180 days thereafter;
3. a physician must be designated to direct the facility's medical services;
4. a nurse must be on duty during medication administration hours; and
5. the facility must develop and implement written policies and procedures protecting against the diversion of controlled substances within the program ([Conn. Agencies Regs. § 19a-495-570\(m\)](#)).

Clinics Seeking DMHAS Funding

State regulations establish requirements for methadone clinics seeking DMHAS funding ([Conn. Agencies Regs. § 17-226d-1 et seq.](#), particularly [§ 17-226d-7\(f\)](#)). The regulations require the clinics to comply with the federal methadone regulations, unless the state regulations impose more stringent requirements. In addition, the regulations set standards regarding:

1. admissions criteria,
2. required documentation,
3. hours of operation,
4. physical and laboratory examinations,
5. methadone dispensing,
6. counseling,
7. permissible off-premises consumption, and
8. detoxification procedures for clients expelled from the program.

For example:

1. outpatient maintenance programs must be open a minimum of six days per week;
2. each methadone program must provide a minimum of one counseling session per month for each client;
3. all dosages dispensed for off-premises consumption must be in child-proof containers with a warning label and clients must be advised about proper and safe home storage; and
4. programs that allow off-premises consumption must do so in accordance with a written procedure that meets certain requirements ([Conn. Agencies Regs. § 17-226d-7\(f\)](#)).

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