Methadone Licensure Rules
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How to Participate in Today’s Webinar

1. Download or print attachments from your control panel.
2. Type questions in the “Question” box of your control panel and send them.
3. For questions about specific rules, it is helpful to include the rule and paragraph - ex: 02 (B)(2)(i).
4. At end of each section, MHAS will read and answer questions submitted in writing.
5. Time permitting, all questions will be answered.
6. Time permitting, will allow individuals to ask questions or make comments verbally at end of webinar. You will need to “raise your hand” on your control panel. You must be connected to audio via phone or microphone.
What This Webinar Will and Will Not Cover

Will Cover
1. OAC Chapter 5122-40 Methadone License Regulations
   - Effective Date 1 June 2017

Will NOT Cover
1. Review of OAC Chapters 5122-24 through 5122-29 (Certification standards)
2. Federal or other state agency regulations & processes
3. How to use Methadone to treat opiate addiction
4. Clinical practices
5. BH Redesign

Licensure vs. Certification

OhioMHAS Licenses the following provider types:
1. Methadone programs
2. Private psychiatric inpatient hospitals
3. MH residential facilities
4. Adult care facilities
5. Adult foster homes

OhioMHAS Certifies the following provider types:
1. SUD & MH Outpatient treatment
2. SUD Residential
3. Prevention
4. Driver Intervention Programs
Rule Status

1. Rules were filed with JCARR 3/17/2017
   ➢ Available at the Register of Ohio
2. Revised Filed (not all) April 18, 2017
3. Public Hearing April 25, 2017
4. Final Filed May 22, 2017
5. Effective June 1, 2017

Big Ticket Changes

1. Removes requirement for providers to be certified for outpatient or residential treatment for two years prior to applying for licensure
   ➢ Does not remove OAC 5122-25-05 requirement for providers applying for certain non-methadone services to offer those to at least 10 clients for at least 2 months prior to submitting an application
2. Removes requirement limiting licensure to non-profits and government agencies
3. Significant updating of rules to improve and assure quality
**Ohio Revised Code**


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**Who Else Regulates Methadone?**

(when prescribed for opiate treatment)

1. Board of Pharmacy (TDDD)
2. SAMSHA
3. DEA
4. CARF/TJC/COA
OAC Rule 5122-40-01
Definitions and Applicability

Key Concepts

- Definitions used through Chapter 5122-40
- Who must apply for methadone tx licensure
- Who is exempt from methadone tx licensure
- Existing methadone tx providers remain licensed
5122-40-01 (A) continued

(A) In addition to the definitions listed in rule 5122-24-01 of the Administrative code, the following definitions apply to Chapter 5122-40 of the Administrative Code.

(1) "Administration" means the direct application of methadone medication to a client.

(2) "Department" mean the Ohio department of mental health and addiction services.

(3) "Detoxification" means the administering of methadone medication in decreasing doses to an individual to alleviate adverse physiological or psychological effects of withdrawal from the continuous use of a narcotic drug and as a method of bringing the individual to an opiate drug-free state.
(A) In addition to the definitions listed in rule 5122-24-01 of the Administrative code, the following definitions apply to Chapter 5122-40 of the Administrative Code.

(4) "Dispense", means the final association of Methadone medication for take home doses with a particular patient pursuant to the prescription, drug order or other lawful order of the prescriber and the professional judgment of and responsibility for: interpreting, preparing, compounding, labeling and packaging of methadone medication.

(5) “Good standing” means that the program, program owner, program sponsor, medical director, program administrator, or principal shall not have been denied a license, certificate, or similar approval to operate a methadone program by an appropriate issuing body of any state or jurisdiction; or been the subject of the following by any appropriate issuing body of any state or jurisdiction:
(a) An action that resulted in the suspension, proposed revocation, or revocation of the program or person’s license or registration; or
(b) A disciplinary action that was based, in whole or in part, on the program or person’s inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
(6) "Interim maintenance" means maintenance provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance.

(7) "Long-term detoxification" means the administering of Methadone medication for detoxification of a patient for a period of more than thirty days but not in excess of one hundred eighty days.

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(8) "Medical director" is a physician, licensed to practice medicine in Ohio by the state of Ohio medical board, who assumes the responsibility for the administration of all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

(9) "Medication unit" means a unit established by a methadone medication maintenance program solely to dispense methadone medication for observed ingestion.
(10) "Methadone maintenance" means the administering or dispensing of methadone medication at stable dosage levels for a period in excess of twenty-one days in the treatment of a patient for opioid addiction.

(11) "Methadone treatment program" or "program" means a community addiction services provider engaged in the treatment of individuals with opioid dependence through on-site administration or dispensing of an opioid treatment medication in the form of methadone medication.

(12) "Partial opioid agonist" means buprenorphine products or combination products approved by the federal food and drug administration for maintenance or detoxification of opioid dependence, or any other partial agonists federally approved, controlled substances used for the purpose of narcotic replacement treatment. These medications are used as an alternative to opioid agonists in the treatment of opioid addiction. At certain dosages, a partial agonist can both activate and block the effects of opioid medications or receptors, thereby assisting in control of opioid addiction. Partial agonists bind to the receptors and activate them, but not to the same degree as full agonists.
(A) In addition to the definitions listed in rule 5122-24-01 of the Administrative code, the following definitions apply to Chapter 5122-40 of the Administrative Code.

(13) "Physician extender" means a medical staff person other than a physician, functioning within his or her scope of practice to provide medical services to patients admitted to opioid treatment programs.

(14) “Program administrator” is a person who is responsible for the day-to-day operation of the methadone treatment program in a manner consistent with the laws and regulations of the United States department of health and human services, United States drug enforcement administration, and the laws and rules of the state of Ohio.

(15) "Program sponsor" is a person or representative of the program, who is responsible for the operation of the methadone medication program and who assumes responsibility for all of its employees, including any practitioners, agents or other persons providing medical, rehabilitative or counseling services at the program.

(16) "SAMHSA" means the federal substance abuse and mental health services administration.

(17) "Short-term detoxification" means the administering of a methadone medication for detoxification of a patient for a period not to exceed thirty days.
(18) "State authority" or "state opioid treatment authority" means the agency or individual designated by the Ohio department of mental health and addiction services to exercise the responsibility and authority of the state for governing the treatment of opiate addiction with medication assisted treatment. The state authority shall act as the state's coordinator for the development and monitoring of opioid treatment programs and shall serve as a liaison with the appropriate federal, state and local agencies.

(19) "State oversight agency" means the agency or office of state government identified by the governor to provide regulatory oversight of opioid treatment programs on behalf of the state of Ohio. The designated state oversight agency is responsible for licensing, monitoring and investigating complaints or grievances regarding opioid treatment programs. The Ohio department of mental health and addiction services is the agency designated by the governor to provide regulatory oversight on behalf of the state of Ohio.
(B) This Chapter is applicable to any community addiction services provider subject to methadone medication licensure in accordance with section 5119.391 of the Revised Code, which includes any program that employs methadone medication treatment; or prescribes, dispenses, or administers methadone for the treatment of opioid addiction.

(C) Programs licensed as methadone medication program at the time of the effective date of this rule shall remain licensed until the expiration of their current licensure. If a program wants to continue to operate as a licensed methadone medication program, then it is required to apply to the department for licensure in accordance with this Chapter.
(D) A methadone program directly operated by the department of veterans affairs, the Indian health service or any other department or agency of the United States is not required to obtain a state license.
Poll Question

Key Concepts

- Duties of State Opiate Treatment Authority (SOTA)
- Requirements in rule are not applicable to providers, although they do correlate with other rules in this chapter, and state and federal requirements
State Opiate Treatment Authority aka “SOTA”

Every state is required to have one if permitting methadone treatment.

http://dpt2.samhsa.gov/regulations/smalist.aspx

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5122-40-02

The department shall designate an individual within the department to serve as the state authority to provide technical assistance to opioid treatment programs and the state oversight authority. The powers and duties of the state authority include, but are not limited to, the following:
5122-40-02 (A)

(A) Assist in the development and implementation of rules, regulations, standards and best practice guidelines to assure the quality of services delivered by opioid treatment programs.

5122-40-02 (B)

(B) Act as a liaison between relevant state and federal agencies.
5122-40-02 (C)

(C) Review opioid treatment guidelines, rules, regulations and recovery models for individualized treatment plans of care developed by the federal government and other nationally recognized authorities approved by the department.

5122-40-02 (D)

(D) Coordinate initial licensure between the department and other licensing, accrediting, and certifying entities as required in this paragraph.
5122-40-02 (E)

(E) Assure delivery of technical assistance and informational materials to opioid treatment programs as needed.

5122-40-02 (F)

(F) Perform both scheduled and unscheduled site visits to opioid treatment programs in cooperation with the identified state oversight office when necessary and appropriate.
(G) Consult with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate.
https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/submit-exception-request

(H) Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate.
5122-40-02 (I)

(I) Review program monitoring activities pursuant to rule 5122-40-08 of the Administrative Code.

5122-40-02 (J)

(J) Review diversion control plan pursuant to rule 5122-40-10 of the Administrative Code.
5122-40-02 (K)

(K) Review opioid treatment programs’ disaster planning efforts pursuant to rule 5122-40-12 of the Administrative Code.

5122-40-02 (L)

(L) Review opioid treatment programs’ evaluation activities efforts pursuant to rule 5122-40-13 of the Administrative Code.
5122-40-02 (M)

(M) Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed opioid treatment program.

5122-40-02 (N)

(N) Notify the substance abuse and mental health services administration, the United States drug enforcement administration, the Ohio board of pharmacy, and the Ohio medical board of any official action taken against an opioid treatment program.
5122-40-02 (O)

(O) The state authority shall approve medication exception requests for methadone programs operated by the department of veterans affairs, the Indian health service or any other department or agency of the United States.

Who do I Contact?

Q: Do I contact my lead surveyor in Licensure and Certification (Lic/Cert) for questions about methadone licensure, or do I contact the SOTA?

A: It depends. Questions about regulations, licensure processes, licensure status are directed to your lead surveyor. Application components that are reviewed by SOTA (e.g. diversion control plan) are sent to Lic/Cert with the rest of the application. Questions about federal requirements, e.g. exception requests, best practices, etc., are directed to SOTA. Lic/Cert or SOTA forward or share communications with each other as needed.
OAC Rule 5122-40-03
Issuance of Licenses

Key Concepts

✓ Providers must be in compliance with standards in order for MHAS to issue Methadone license
✓ License issued for one year
✓ License is not transferable
✓ Surveys, MHAS access to records and program areas, Plans of Corrections (POC)
✓ Provider must re-apply for renewal
✓ Conditions under which MHAS may propose to deny or revoke licensure
(A) The department may issue a license for the program only if it has been determined to the department’s satisfaction that the program is adequately staffed and equipped to maintain methadone treatment by demonstrating compliance with the licensure requirements set forth in section 5119.391 of the Revised Code and Chapter 5122-40 of the Administrative Code.

(A) ...The department shall not issue a license if program cannot affirmatively demonstrate that it will maintain strict compliance with section 3719.61 of the Revised Code, all other laws relating to drug abuse, or this Chapter.
Nothing in the laws dealing with drugs of abuse shall be construed to prohibit treatment of narcotic drug dependent persons by the continuing maintenance of their dependence through the administration of methadone in accordance with the rules adopted by the department of mental health and addiction services under section 5119.391 of the Revised Code, when all of the following apply:

(A) The likelihood that any person undergoing maintenance treatment will be cured of dependence on narcotic drugs is remote, the treatment is prescribed for the purpose of alleviating or controlling the patient's drug dependence, and the patient's prognosis while undergoing treatment is at least a partial improvement in the patient's asocial or antisocial behavior patterns;

(B) In the case of an inpatient in a hospital or clinic, the amount of the maintenance drug dispensed at any one time does not exceed the quantity necessary for a single dose, and the dose is administered to the patient immediately;

(C) In the case of an outpatient, the amount of the maintenance drug dispensed at any one time shall be determined by the patient's treatment provider taking into account the patient's progress in the treatment program and the patient's needs for gainful employment, education, and responsible homemaking, except that in no event shall the dosage be greater than the amount permitted by federal law and rules adopted by the department pursuant to section 5119.391 of the Revised Code;
ORC 3719.61
Methadone Maintenance Treatment

(D) The drug is not dispensed in any case to replace or supplement any part of a supply of the drug previously dispensed, or when there is reasonable cause to believe it will be used or disposed of unlawfully;
(E) The drug is dispensed through a program licensed and operated in accordance with section 5119.391 of the Revised Code.

5122-40-03 (B)

(B) The state authority shall coordinate the licensure process among the licensing authorities including the department, SAMHSA, the United States drug enforcement administration, and the state board of pharmacy.
(C) A license to conduct a methadone treatment program is for a one-year time period.

(D) A license is not transferable to any other site or property.
5122-40-03 (E)

(E) A license is valid only for the applicant named in the application, and is not transferable to or assumable by any other person or entity, including any person or entity which purchases the licensed program.

5122-40-03 (F)

(F) The license must be posted in an area visible to residents and visitors at the program facility at all times and made available for inspection to any person who requests it.
(G) The department may conduct surveys or inspections of licensed programs, as it deems necessary and appropriate, to determine initial or continued compliance with requirements or to determine whether deficiencies have been corrected, or upon complaint or allegation of licensure violations. Inspections or surveys may be unscheduled and unannounced. The department shall conduct inspections of all licensed methadone medication programs at least once every twelve months.

(H) The department shall have access to all records, accounts, and other documents relating to the operation of the program, as well as access to all areas in the program facility and to the staff, and all patients, as the department deems necessary and appropriate.
(I) The program shall be responsible for notifying the department of any changes or proposed changes concerning the information submitted and attested to in the application, or in the operation of the program, or the continued compliance of the facility with the requirements for licensure.

(J) The department may permit the methadone medication program to develop a plan of correction to address any noted violations or deficiencies.
(K) The department may grant a waiver or variance to the provisions of this chapter. However, requests for waivers and variances that would adversely affect the quality of services or the health and safety of patients will not be granted.  
(1) A provider shall submit a written request to the department for a waiver or variance. The written request shall state clearly the rationale and need for the requested waiver or variance.  
(2) The waiver shall be for a period of time determined by the department, not to exceed the expiration date of the current license and is not renewable.

(L) The department may refuse to issue or revoke a license of a methadone program for one or more of the following reasons:  
(1) The program does not meet the requirements of division (C) of section 5119.391 of the Revised Code and rule 5122-40-04 of the Administrative Code;  
(2) The program fails to achieve or retain certification in accordance with Chapter 5122-25 of the Administrative Code;
(L) The department may refuse to issue or revoke a license of a methadone program for one or more of the following reasons:

(3) The program is not in compliance with the requirements for licensure as set forth by the rules in this chapter;

(4) The program has been cited for a pattern of serious noncompliance or repeated violations of statutes or rules during the period of current or previous licenses;

(5) The program presents or submits false or misleading information as part of a license application, renewal, or investigation;

(6) The program permits an employee to falsify information on patient records;

(7) The program is aware of an employee who has abused or neglected a patient and has failed to take appropriate disciplinary action to correct the situation;

(8) The program fails to provide timely access to its records as requested by the department;
The department may refuse to issue or revoke a license of a methadone program for one or more of the following reasons:

(9) The program is in violation of any provision of section 3719.61 of the Revised Code, or any other state or federal law or rule relating to drug abuse;
(10) The program is not in good standing in any other jurisdiction in which the methadone provider currently provides services, or was not in good standing at all times within the past five years in any other jurisdiction in which the program previously provided substance use treatment services, that are comparable to the methadone treatment services authorized under section 5119.391 of the Revised Code; or,

(11) The applicant, operator, owner, or medical director is or has been a principal with a methadone program that has had a previous license to operate in Ohio revoked or denied renewal for any reason other than nonpayment of the license fee unless:
(a) A minimum period of three years has passed from the date of the director's order denying the issuance of an initial license or a minimum period of five years has passed from the date of the director's order revoking a license or denying the renewal of a license; and,
(b) The licensure revocation or non-renewal was not due to any act or omission that is a violation of any provision of section 3719.61 of the Revised Code, or any other state or federal law or rule relating to drug abuse.
5122-40-03 (M)

(M) The refusal to issue or withdrawal of a license shall be subject to proceedings governed by Chapter 119. of the Revised Code.

5122-40-03 (N)

(N) The revocation of a license pursuant to paragraph (L)(9) of this rule shall be subject to proceedings governed by division (L) of section 5119.391 of the Revised Code.
(O) Termination of licenses
(1) A license shall be considered terminated and invalid in the following circumstances:
(a) The program has voluntarily discontinued operations; or,
(b) An application for renewal has not been received by the department prior to the expiration of the license.

(2) The termination of a license, as specified in paragraph (O)(1) of this rule, shall not be considered a denial or revocation of a license and shall not be subject to proceedings governed by Chapter 119. of the Revised Code. If the department determines that circumstances exist as specified in paragraph (O)(1) of this rule, it shall issue a letter to the operator specifying the date of termination of the license.
5122-40-03 (P)

(P) A methadone program directly operated by the department of veterans affairs, the Indian health service or any other department or agency of the United States is not required to obtain a state license.

5122-40-03 (Q)

(Q) Regardless of whether the department takes action to deny, withdraw, revoke a license for the reasons listed in paragraph (L) of this rule, it may refer matters to local, state or federal officials as appropriate.
OAC Rule 5122-40-04
General Licensure Requirements

Key Concepts

✓ Licensure requirements
  ➢ MHAS
  ➢ Federal
  ➢ Accreditation
✓ Program cannot be within radius of 500 linear feet of certain entities specified in law
(A) An alcohol and drug addiction program desiring to obtain an initial license or renew a license as a methadone medication program shall:

(1) Be certified as a provider pursuant to Chapter 5122-25 of the Administrative Code at a minimum for the following services:
   (a) Prior to July 1, 2017 the assessment, counseling, medical/somatic, and case management services pursuant to rule 3793:2-1-08 of the Administrative Code.
   (b) After July 1, 2017 the general services and case management services pursuant to Chapter 5122-29 of the Administrative Code.
   (c) Crisis intervention in accordance with rule 5122-29-10 of the Administrative Code.

(2) Submit with the application for initial license or license renewal a licensure fee as set by paragraph (B)(2) of rule 5122-40-08 of the Administrative Code;

(3) When applying for renewal licensure, be accredited as an opioid treatment program by an accreditation body that has been approved by SAMHSA;

(4) Be certified by SAMHSA pursuant to "certification of opioid treatment programs," 42 C.F.R. Part 8.11;

(5) Have a category III terminal distributor of dangerous drugs license from the state board of pharmacy pursuant to Chapter 4729. of the Revised Code;
(A) An alcohol and drug addiction program desiring to obtain an initial license or renew a license as a methadone medication program shall:

(6) Have a security and alarm system that is approved by the United States drug enforcement administration;

(7) Meet the security requirements for the distribution and storage of controlled substances as required by 21 C.F.R. 1301.72 to 21 C.F.R. 1301.76;

(8) Operate the program in accordance with 21 C.F.R. 291.505, conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (Oct. 27, 1970);

(9) Have a program sponsor who has signed and submitted SAMHSA form SMA-162, application for certification to use opioid drugs in a treatment program under 42 CFR 8.11;

(10) Be in good standing with the state board of pharmacy, department of medicaid, medicare, and the United States drug enforcement administration;
5122-40-04 (A) (continued)

(A) An alcohol and drug addiction program desiring to obtain an initial license or renew a license as a methadone medication program shall:

(11) Be in good standing in any other jurisdiction in which the methadone provider currently provides services or was in good standing at all times in any other jurisdiction in which the methadone provider previously provided services within the past five years, that are comparable to the methadone treatment services authorized under section 5119.391 of the Revised Code;

(12) Demonstrate the ability to meet the standards of medical care for opioid treatment services established by the American society of addiction medicine criteria, third edition (2013), or other nationally recognized standards organization selected by the director;

5122-40-04 (B)

(B) Geographic restrictions:

(1) A program applying for an initial license shall not be issued a license if there is a public or private school, licensed child day-care center, or other child-serving agency within a radius of five hundred linear feet of the location where the methadone treatment program is to operate.

(2) The five-hundred foot restriction may be waived if the program obtains a letter of support from each public or private school, licensed child day-care center, or other child-serving agency within the five hundred linear foot radius of the location where the methadone treatment program is to operate.
Database

Child Care Centers:
http://www.ODJFS.state.oh.us/cdc/query.asp

5122-40-04 (B) (continued)

(B) Geographic restrictions:
(3) Programs will perform their due diligence to evaluate this criterion before submitting the application for licensure.
(4) If a determination was not applied for and made by the program prior to submitting a license application pursuant to section 5119.392 of the Revised code, the department, upon receiving a license application, shall proceed to make the determination if there is such a public or private school, licensed child day-care center, or other child-serving agency within the five-hundred foot radius of the location listed on the application and issue a declaration of its findings in accordance with section 5119.392 of the Revised Code.
5122-40-04 (B) (continued)

(B) Geographic restrictions:

(5) For license renewals, the geographic restrictions of this paragraph shall not apply pursuant to division (K) of section 5119.391 of the Revised Code so long as the program remains continuously licensed.
**Key Concepts**

- Program Sponsor
- Medical Director
  - Site level and, if applicable, regional
- Program Administrator
  - Site level and, if applicable, regional
- Counselor to patient ratio 1:65

**5122-40-05 (A)**

(A) Each licensed methadone treatment program shall have a program sponsor, who is the person that assumes responsibility for the operation of and the employees of the methadone treatment component of a community addiction services provider. The program sponsor shall agree on behalf of the methadone treatment program to adhere to all requirements set forth in federal or state laws, rules, or regulations regarding the use of methadone treatment medications in the treatment of opioid addiction.
5122-40-05 (A) continued

(A) Each licensed methadone treatment program shall have a program sponsor, who is the person that assumes responsibility for the operation of and the employees of the methadone treatment component of a community addiction services provider. The program sponsor shall agree on behalf of the methadone treatment program to adhere to all requirements set forth in federal or state laws, rules, or regulations regarding the use of methadone treatment medications in the treatment of opioid addiction.

(1) The program sponsor is responsible for the general establishment, certification, licensure, and operation of the methadone treatment program.

(2) The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the methadone treatment program shall employ a licensed physician for the position of medical director.

5122-40-05 (B)

(B) Each methadone treatment program shall have a designated medical director.

(1) The medical director shall be a physician licensed to practice medicine or osteopathy in the state of Ohio and shall have either:

(a) Certification from the American board of addiction medicine;

(b) Certification from a member board of medical subspecialties with an addiction subspecialty; or,

(c) A written plan to attain competence in opioid treatment within a probationary time period.
5122-40-05 (B) (continued)

(B) Each methadone treatment program shall have a designated medical director.
(1) The medical director shall be a physician licensed to practice medicine or osteopathy in the state of Ohio and shall have either:
(c) A written plan to attain competence in opioid treatment within a probationary time period.
(i) The medical director may submit a written plan to attain competence in opioid treatment to the department for approval at least two weeks prior to employment at a methadone treatment program.
(ii) The time for completion of the plan may not exceed twenty-four months from the date of the appointment as medical director. The physician may work as a medical director during this probationary time period, subject to the supervision and reporting requirements of this rule. Waivers may be granted by the department if there are problems scheduling certification examinations.

5122-40-05 (B) (continued)

(B) Each methadone treatment program shall have a designated medical director.
(1) The medical director shall be a physician licensed to practice medicine or osteopathy in the state of Ohio and shall have either:
(c) A written plan to attain competence in opioid treatment within a probationary time period.
(iii) During the probationary time period, the medical director shall be directly supervised at least once a week by a physician who holds an appropriate medical certification in the field of opioid treatment pursuant to paragraph (B)(1) of this rule.
(iv) Consultation with and supervision of a medical director during the probationary time period may be provided by telephone or video conferencing and shall be documented, signed, and dated by both the supervising physician and the supervised physician.
Each methadone treatment program shall have a designated medical director. The medical director shall be a physician licensed to practice medicine or osteopathy in the state of Ohio and shall have either:

(c) A written plan to attain competence in opioid treatment within a probationary time period.

(v) The department may request periodic documentation of progress towards completion of the training plan.

(vi) The program administrator of the methadone treatment program is responsible for maintaining documentation regarding the medical director's training and experience in a file which is current and readily available at all times. The program administrator is also responsible for ensuring that the plan of development is completed within the approved time lines.

The medical director shall maintain authority over the medical aspects of treatment offered by the methadone treatment program. The medical director is responsible for:

(a) All medication treatment decisions;
(b) Operation of all medical aspects of the treatment program;
(c) Administration and supervision of all medical services;
(d) Medication storage and review of safe handling of medications;
(e) Ensuring that the methadone treatment program is in compliance with all applicable federal, state and local laws, rules and regulations;
(B) Each methadone treatment program shall have a designated medical director.

(2) The medical director shall maintain authority over the medical aspects of treatment offered by the methadone treatment program. The medical director is responsible for:

(f) Ensuring that evidence of current physiologic dependence on an opiate, length of opiate dependence, and exceptions to admission criteria are documented in the patient's clinical record before the patient receives the initial dose of methadone medication;

(g) Ensuring that a medical history and a physical examination have been done before a patient receives the initial dose of methadone medication;

(h) Ensuring that appropriate laboratory studies have been performed and reviewed. The initial dose of methadone medication may be administered before the results of the laboratory tests are reviewed;

(i) Ensuring all medical orders are signed as required by federal, state, or local laws and regulations;

(j) Developing or approving policy and procedures for take-home doses of methadone medication;

(k) Ensuring that justification for take-home doses is recorded in the patient's clinical record;

(l) Ensuring individuals are appropriately admitted to the methadone program;

(m) Ensuring all medical services are appropriately performed by the methadone treatment program;
Each methadone treatment program shall have a designated medical director. The medical director shall maintain authority over the medical aspects of treatment offered by the methadone treatment program. The medical director is responsible for:

(n) Obtaining and maintaining their own continuing medical education in the field of addiction on a documented and ongoing basis;
(o) Determining the ability of the program physicians or physician extenders to work independently within the applicable scope of practice; and,

Each methadone treatment program shall have one medical director per program location. These site-level medical directors shall be present at the methadone treatment program at least fifty percent of the time that the program administers or dispenses medication. Site-level medical directors may serve in their same capacity at additional sites as long as they are present at the ancillary methadone treatment programs at least fifty per cent of the time that the program administers or dispenses medication and can satisfactorily discharge all of their duties for each program.
Each methadone treatment program shall have a designated medical director.

(4) The medical director must have a current U.S. drug enforcement administration (DEA) registration for prescribing controlled substances, and the medical director must have a DEA waiver if they or any other healthcare professional they supervise prescribes partial opioid agonists.

(5) If a program utilizes regional medical directors, they are expected to supervise site-level medical directors. The regional medical director must be present at each methadone program each week, but is exempted from the time requirements in paragraph (B)(3) of this rule. The regional medical director must meet the requirements in paragraphs (B)(1)(a) or (B)(1)(b) of this rule. A regional medical director may take on some of the roles of the site level medical director if an organization has multiple programs in different locations. The program must inform the department of such an arrangement in writing, including:
(5) If a program utilizes regional medical directors, they are expected to supervise site-level medical directors. The regional medical director must be present at each methadone program each week, but is exempted from the time requirements in paragraph (B)(3) of this rule. The regional medical director must meet the requirements in paragraphs (B)(1)(a) or (B)(1)(b) of this rule. A regional medical director may take on some of the roles of the site level medical director if an organization has multiple programs in different locations. The program must inform the department of such an arrangement in writing, including:

(a) The schedule, including total hours per week the regional medical director will spend at each methadone program location.
(b) The division of responsibilities between the regional and site-level medical director.
(c) If the regional medical director serves in this or a similar capacity for any methadone programs located outside the state of Ohio.

(C) Each licensed methadone treatment program shall have a program administrator, who shall have at minimum either a master's degree in any field or a bachelor's degree and two years work experience in a related healthcare field.

(1) The program administrator is responsible for the day-to-day operation of the methadone treatment program in a manner consistent with the laws and regulations of the United States department of health and human services, United States drug enforcement administration, and the laws and rules of the state of Ohio, including, but not limited to assuring:
5122-40-05 (C) (continued)

(C) Each licensed methadone treatment program shall have a program administrator, who shall have at minimum either a master’s degree in any field or a bachelor’s degree and two years work experience in a related healthcare field. (1) The program administrator is responsible for the day-to-day operation of the methadone treatment program in a manner consistent with the laws and regulations of the United States department of health and human services, United States drug enforcement administration, and the laws and rules of the state of Ohio, including, but not limited to assuring:

(a) Development of policies and procedures for operation of the facility;
(b) Maintenance and security of the facility;
(c) Employment, credentialing, evaluation, scheduling, training and management of staff;
(d) Protection of patient rights;
(e) Conformity of the program with federal confidentiality regulations, namely, 42 CFR Part 2; and,
(f) Management of the facility budget.

5122-40-05 (C) (continued)

(C) Each licensed methadone treatment program shall have a program administrator, who shall have at minimum either a master’s degree or a bachelor’s degree and two years work experience in a related healthcare field.

(2) A regional program administrator may take on some of the roles of the site-level program administrator if an organization has multiple programs in different locations. The program must inform the department of such an arrangement in writing, including:

(a) The portion of the program administrator time spent with each program, and include mention of any competing priorities that might take away time allocated to the treatment programs.
(b) The division of responsibilities between the regional and site-level program administrator.
(c) If the regional program administrator serves in this or a similar capacity for any methadone programs located outside the state of Ohio.
5122-40-05 (D)

(D) The methadone treatment program may employ and use program physicians, physician extenders and other health care professionals working within their scope of practice who have received sufficient education, training and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses and other licensed professional care providers must comply with the credentialing requirements of their respective professions. The methadone treatment program may only employ...

5122-40-05 (D) (continued)

(D) ...The methadone treatment program may only employ certified nurse practitioners or clinical nurse specialists, physician 's assistants, certified addiction registered nurses, or board certified addiction specialist registered nurses as physician extenders. A pharmacist may be a physician extender if authorized to manage drug therapy pursuant section 4729.39 of the Revised Code and specifically authorized by a consult agreement and to the extent specified in the agreement.
All physicians and physician extenders employed by the methadone treatment program shall be actively licensed in Ohio and shall have:

(a) A minimum of one year's experience in an addiction treatment settings; or

(b) Completion within six months of a plan of education for obtaining competence in addiction treatment methods. The plan of education must be developed in consultation with and approved by the medical director. The medical director shall certify the individual's completion of the plan of education when, in the discretion of the medical director, it is satisfactorily accomplished. If the medical director is completing a plan of competency described in paragraph (B)(1)(c) of this rule, the medical director may assist the physician or physician extender develop a plan and the plan shall be approved by the medical director's supervising physician.
5122-40-05 (D) (continued)

(2) During all hours of operation, every methadone treatment program shall have a licensed physician on call and available for consultation with other staff members at any time.

5122-40-05 (D) (continued)

(3) During all hours of operation when medication is being administered, every methadone treatment program shall have present and on duty at the facility at least one of the following:
   (a) Physician assistant;
   (b) Registered nurse;
   (c) Licensed practical nurse who has proof of completion of a course in medication administration approved by the Ohio board of nursing; or,
   (d) A pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code but only if specifically authorized by a consult agreement and to the extent specified in the agreement.
(E) Counselors with less than one year of full time equivalent experience in the field of addiction treatment shall develop with their supervisor a plan to achieve competency prior to providing counseling services without their supervisor present during or constantly observing counseling sessions. The plan must specify the frequency of face-to-face clinical supervision meetings between the counselor and supervisor, and the time-frame for achieving competency which shall be no more than one year.

(F) Each program shall conduct a criminal records check of each staff who shall have access to methadone. All criminal records checks conducted in accordance with this rule shall consist of both a bureau of criminal identification and investigation to conduct (BCI&I) criminal records check and a federal bureau of investigations records check.
(F) Each program shall conduct a criminal records check of each staff who shall have access to methadone. All criminal records checks conducted in accordance with this rule shall consist of both a bureau of criminal identification and investigation to conduct (BCI&I) criminal records check and a federal bureau of investigations records check.

(1) The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "webcheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "webcheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

(2) A program shall not employ in a position which allows access to methadone any person who has been convicted of a felony relating to controlled substances.
Final Questions