Methadone Licensure Rules Part Three
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1. Download or print attachments from your control panel.
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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
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

Licensure & Certification Staff

Central Office (Columbus)
- Denise Cole, Private Psychiatric Hospitals Administrator & Surveyor Supervisor
- Calvin Daniels, Surveyor
- Barb Dietz, Surveyor
- Rosland Hawkins, Program Administrator
- Jill Hay, Surveyor (Incident Reports)
- Teri Hill, Surveyor
- Greg Lewis, Program Administrator, Supervisor
- Robert Nugen, Surveyor Supervisor
- Janel M. Pequignot, Chief
- Kisha Stewart, Mental Health Administrator
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- Chris Dunlevy, Surveyor

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
Ohio Revised Code


OAC Rule 5122-40-09
Non-Medication Services
Key Concepts

✓ Methadone without additional treatment services is not effective
✓ Specifies the additional services a methadone provider must make available, and where
✓ Identifies those services which may be available by another entity and the process for doing so
✓ Requires patients receive med info, informed consent, and orientation, including naloxone kit
✓ Specifies patients receive counseling, frequency and duration during first 90 days, and counselor to patient ratio

5122-40-09 (A)

(A) Methadone programs shall provide at a minimum, the following services:

(1) Prior to July 1, 2017 the assessment, individual counseling, group counseling, medical/somatic, crisis intervention, and case management services pursuant to rule 3793:2-1-08 of the Administrative Code;

(2) After July 1, 2017 the general services, case management services, and crisis intervention services pursuant to Chapter 5122-29 of the Administrative Code.
(A) Methadone programs shall provide at a minimum, the following services:

(3) Vocational rehabilitation, education and employment services for patients who either request these services or who have been determined by the program staff to be in need of these services.

(B) All services shall be provided at the methadone program site. The exception is vocational rehabilitation, education and employment services when the program has entered into a written agreement with another entity to provide these services. The program sponsor shall document that these services are fully and reasonably available to all patients.
Upon admission, each patient shall receive the following information both written and verbally:

1. Signs and symptoms of overdose and when, where and how to seek emergency assistance;
2. An explanation of the medication, including:
   a. Medication administration;
   b. Potential drug interactions;
   c. Medical issues related to detoxification from opioid treatment medications;
   d. Characteristics of the medications administered or prescribed by the program;

(C) Upon admission, each patient shall receive the following information both written and verbally:

2. An explanation of the medication, including:
   e. Drug safety issues;
   f. Dispensing procedures and dosage restrictions;
   and,
   g. Side effects of medications administered or prescribed by the program.
5122-40-09 (C) (continued)

(C) Upon admission, each patient shall receive the following information both written and verbally:

(3) An explanation of alternative methods that are available for treatment of opioid addiction, whether offered by the program or not, and the potential benefits, risks and costs of each treatment;

(4) A formal agreement of informed consent to be signed by the patient and a copy retained by him or her;

5122-40-09 (D)

(D) Every person admitted to a methadone program shall receive program orientation within two weeks of admission. The orientation shall be made verbally at the earliest opportunity at which the patient is stable and capable of understanding and retaining the information presented. Orientation shall include the following:

(1) An explanation of the patient's rights and right to file a grievance and applicable appeal procedures, in accordance with rule 5122-26-18 of the Administrative Code;
Every person admitted to a methadone program shall receive program orientation within two weeks of admission. The orientation shall be made verbally at the earliest opportunity at which the patient is stable and capable of understanding and retaining the information presented. Orientation shall include the following:

(2) An explanation of the services and activities provided by the opioid treatment program, including:
   (a) Expectations and rules;
   (b) Hours of operation;
   (c) Access to crisis services;
   (d) Confidentiality policy;
   (e) Toxicological screening and random testing policies;
   (f) Administrative withdrawal criteria, pursuant to rule 5122-40-14 of the Administrative Code;
   (g) Interventions;
   (h) Incentives, if offered; and,
   (i) Various discharge criteria.

(3) An explanation about obtaining reports from the prescription drug monitoring program database; how the reports are used to treat and monitor the patient and the requirement that the reports be maintained in the patient files;

(4) An explanation of any and all financial obligations of the patient; all fees charged by the methadone treatment program; and any financial arrangements for services provided by the methadone treatment program;

(5) Familiarization with the methadone treatment programs facility and premises;
5122-40-09 (D) (continued)

Every person admitted to a methadone program shall receive program orientation within two weeks of admission. The orientation shall be made verbally at the earliest opportunity at which the patient is stable and capable of understanding and retaining the information presented. Orientation shall include the following:

(6) Provision of a naloxone kit including the nasal atomizer or other device furnished by the methadone treatment program, or a prescription for such kit.

(a) The methadone treatment program shall provide instruction on the kits use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in overdose situations.

(b) The methadone treatment program shall provide a new naloxone kit or prescription upon expiration or use of the old kit.

(c) The methadone treatment program shall be exempt from this requirement for one year if the client refuses the naloxone kit or already has a naloxone kit.

5122-40-09 (E)

Documentation that the patient has completed the orientation training and received the written information required in paragraphs (C) and (D) of this rule, shall be completed and signed by the program and the patient and maintained in the patient's chart.
Each methadone treatment program shall make available substance use disorder counseling, individual or group, to every patient as is clinically necessary.

(1) The ratio of full-time equivalent individual counselors to patients shall be no greater than one to sixty-five; and any currently licensed methadone program with a ratio above that limit shall have until June 1, 2018 to meet this requirement.

(2) Counselor to patient ratios shall be individually determined by the specific needs of the patient and allow patients access to their primary counselor if more frequent contact is merited by need or is requested by the patient.

(3) The counselor caseload shall:
(a) Allow the program to provide adequate psychosocial assessments, treatment planning and individualized counseling; and,
(b) Allow for regularly scheduled, documented individual counseling sessions.
(F) Each methadone treatment program shall make available substance use disorder counseling, individual or group, to every patient as is clinically necessary.

(4) Counseling sessions shall be provided according to generally accepted best practices and shall be offered:
(a) At least weekly during the first ninety days of treatment, for at least 50 minutes in duration.
(b) Thereafter, counseling duration and frequency should be established by counselor and documented in the treatment plan, with consideration given to the ability of the patient to participate, recovery status, treatment engagement, and laboratory results.

(5) Exceptions to frequency of counselor to patient contact shall be clinically justified and documented in client record.
OAC Rule 5122-40-10
Diversion

Key Concepts

✓ Requires diversion control plan that is approved by SOTA
✓ Requires pharmacy procedures
✓ Identifies who has access to methadone (and partial opioid agonists) throughout its “time” at the methadone program location, i.e. from delivery through dispensing
5122-40-10 (A)

(A) Each methadone program shall, as part of its quality improvement plan, have a diversion control plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility for implementing the plan to the medical and administrative staff of the program.

(1) The diversion control plan shall be reviewed and approved by the state authority.

5122-40-10 (A) (continued)

(A) Each methadone program shall, as part of its quality improvement plan, have a diversion control plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility for implementing the plan to the medical and administrative staff of the program.

(2) Diversion control plans shall minimize the diversion of opioid agonist and partial opioid agonist to illicit use. The plan shall include:

(a) Clinical and administrative continuous monitoring of the potential for and actual diversion including an investigation, tracking and monitoring system of incidents of diversion; and,

(b) Proactive planning and procedures for problem identification, correction and prevention.
(D) Each provider shall develop a written performance improvement plan and document its performance improvement activities. The provider shall include in its performance improvement plan the frequency of data collection and analysis.

The provider shall collect and analyze data as required by its accrediting body, if applicable, or for a provider without behavioral health accreditation, at least annually.

(B) Each methadone program shall have written pharmacy procedures that include:
(1) Requirement that accurate records for opioid agonist medication administered and dispensed, or partial opioid agonist medication if administered, be traceable to specific patients and show the date, quantity and batch or lot number of the medication bottle used for preparing individual doses of medication. These records shall be maintained for at least seven years from the last date of administering or dispensing the medication;
(B) Each methadone program shall have written pharmacy procedures that include:

(2) Requirement that the methadone program meet the security standards for the distribution and storage of controlled substances as required by the United States drug enforcement administration as outlined in 21 CFR 1301.72 to 21 CFR 1301.76 and pursuant to rule 4729-9-11 of the Administrative Code;

(3) Requirement that the acceptance of delivery of opioid agonist and partial opioid agonist medications shall only be made by a physician, pharmacist, registered nurse or licensed practical nurse who has proof of completion of a course in medication administration approved by the Ohio board of nursing and does so under the direction of a licensed physician;
   (a) The person accepting delivery of opioid agonist and partial opioid agonist medications must be an employee of the methadone program.
   (b) The methadone program shall maintain a current list of those employees who are authorized to receive delivery of opioid agonist and partial opioid agonist medications. The list shall indicate the name and license number of each person and be signed and dated by the medical director of the methadone program.
(B) Each methadone program shall have written pharmacy procedures that include:

(4) Requirement that the program shall not employ a physician or other employee who has access to controlled substance, including opioid agonist and partial opioid agonist medications, who has had an application for registration with the U.S. drug enforcement administration (DEA) denied or has had their registration revoked at any time;

(5) Requirement that the program notifies the field division of the United States drug enforcement administration for its geographical area of any theft or significant loss of any controlled substance, including opioid agonist medication upon the discovery of the loss or theft;
   (a) The program shall complete DEA form 106 regarding any loss or theft.
   (b) The Ohio state board of pharmacy, in accordance with rule 4729-9-15 of the Administrative Code, the Ohio department of mental health and addiction services, and the local law enforcement authorities shall be immediately notified of any loss or theft.
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(B) Each methadone program shall have written pharmacy procedures that include:

(6) Statement that adequate precautions shall be taken to store medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security;
(7) Requirement that patients be required to wait in an area physically separated from the opioid agonist and partial opioid agonist storage and dispensing area; and,

(8) Requirement that opioid agonist and partial opioid agonist storage and dispensing areas shall:
(a) Be located where personnel will not be unduly interrupted when handling drugs;
(b) Be maintained in a clean and orderly manner; and,
(c) Not be cleaned by a current patient of the program.
OAC Rule 5122-40-11
Toxicology

Key Concepts

- Requires written procedures for toxicology screenings
- Toxicology test are scheduled throughout treatment
- Minimize ability for patient to “cheat” the test
- Test for specified drugs
- Assure accuracy of testing
- Share all results with patients
Each methadone program shall have written procedures for toxicology screening that include, at a minimum:

(A) Requirement that an initial toxicology screening be performed for each prospective methadone patient as part of the documented physical evaluation completed by a physician prior to admission. The results of all tests must be received within fourteen days following admission.
5122-40-11 (B)

(B) Requirement that a toxicology screening be performed monthly for each methadone patient.
(1) This requirement may be reduced to two toxicology screenings per quarter if the patient has had more than twenty-four consecutive months of negative screens.
(2) The failure of a toxicology screening due to illicit drug use shall result in a return to monthly screening.

5122-40-11 (C)

(C) Requirement that programs shall have a standing physician's order for patient toxicology screening.
5122-40-11 (D)

(D) Requirement that any urine screen sent in for confirmation be performed by a laboratory that is in compliance with all Clinical Laboratory Improvement Amendments per 42 C.F.R. 493.

5122-40-11 (E)

(E) Requirement that toxicology screening be conducted in a manner to minimize falsification and that sample collection procedures include the following:
(1) Each specimen collection will be monitored.
(2) Each sample shall be labeled to reflect the identification of the person from whom it was obtained and reflect the date the sample was obtained.
5122-40-11 (F)

(F) Requirements that each toxicology screening include, at a minimum analysis for the following:
(1) Opiates, including prescription opioid analgesics as defined in section 3719.01 of the Revised Code, heroin, and fentanyl;
(2) Methadone;
(3) Amphetamines;
(4) Cocaine;
(5) Barbiturates;
(6) Marijuana;
(7) Benzodiazepines, as defined in section 3719.01 of the Revised Code; and,
(8) Buprenorphine.

5122-40-11 (G)

(G) Results of toxicology screening shall be reviewed by the program staff with the patient with documentation of such and a copy of the results placed in the patient's file, in accordance with the requirements of rule 5122-27-04 of the Administrative Code.
5122-40-11 (H)

(H) Provisions for ensuring that presumptive laboratory results are distinguished from confirmatory laboratory results.

5122-40-11 (I)

(I) The program shall have a policy for the discontinuation of methadone maintenance for individuals who test positive for illicit drugs, which shall include provisions for continuing to provide counseling and other rehabilitation services, or referral to another provider.
OAC Rule 5122-40-12
Disaster Plan

Key Concepts

- Licensed methadone providers expected to assist in event of temporary or permanent closure of a methadone program
- Health and Safety Committee engages in disaster planning
- Maintain supply of methadone to be able to guest dose “large numbers” of patients from other methadone programs
5122-40-12 (A)

(A) Each methadone treatment program shall maintain an up-to-date disaster plan that addresses emergency situations including fire emergencies, tornadoes, earth quakes, flooding, winter storms, and involuntary temporary or permanent facility closure.

5122-40-12 (B)

(B) Methadone treatment programs shall establish a health and safety committee that initiates planning actions for disaster scenarios. This committee shall: (1) Identify internal resources and areas of need that shall include at minimum: (a) personnel training; (b) equipment needs; (c) evacuation plans; (d) backup systems for payroll, billing records, and patient records; and, (e) communications;
(B) Methadone treatment programs shall establish a health and safety committee that initiates planning actions for disaster scenarios. This committee shall:

(2) Identify external resources and areas of need that shall include at minimum:
   (a) suppliers of methadone;
   (b) other opioid treatment programs; and,
   (c) alternative dosing locations;

(3) Develop a communication plan for the disaster scenario to inform patients, the state authority, SAMHSA, the United States drug enforcement administration, and any other parties deemed necessary; and,

(4) Develop disaster documentation procedures for guest patients that shall include at minimum:
   (a) temporary chart and client identification number;
   (b) identity verification; and,
   (c) medication verification.
5122-40-12 (C)

(C) Each methadone treatment program shall provide the state authority with the emergency contact information for at least one member of the organization.

5122-40-12 (D)

(D) Each methadone treatment program shall keep at least a ten-day supply based on average caseload of methadone on site to prepare to receive clients from other facilities in disaster scenarios.
OAC Rule 5122-40-13
Evaluation Activities

Key Concepts

✓ The Central Registry shall make data available to the Department
✓ If certain data cannot be transferred via OHBH, then the provider shall submit it to the Central Registry, in addition to the data that it is required to submit in accordance with 5122-40-08
✓ Nothing in rule is applicable to routine L/C Methadone survey process, or provider PI processes/requirements.
5122-40-13 (A)

(A) The department shall collect from the central registry system described in rule 5122-40-08 of the Administrative Code, on a regular basis the information listed in paragraph (B) of this rule for continuous quality improvement purposes.

5122-40-13 (B)

(B) The central registry system shall collect and make available to the department the following data:
(1) The total number of patients;
(2) The type of medication assisted treatment used for each patient;
(3) The patient’s admission date;
(4) The state residency of each patient;
(5) The housing status of the patient at admission and discharge;
(6) The employment status of the patient at admission and discharge;
5122-40-13 (B) (continued)

(B) The central registry system shall collect and make available to the department the following data:

(7) The pregnancy status of the patient;
(8) The patient's discharge date;
(9) The date on which the patient is no longer actively receiving treatment, if different than the discharge date;
(10) The patient's discharge reason;
(11) The number and type of administrative and medical withdrawals from the opioid treatment program.

5122-40-13 (C)

(C) The central registry vendor shall facilitate automatic data collection for the required data in paragraph (B) of this rule through the program's local implementation of the Ohio behavioral health system (OHBH). Programs that are unable to transfer data through OHBH shall enter data for paragraphs (B)(5), (B)(6), and (B)(10) of this rule directly into the central registry system on an at least quarterly basis.
Ohio Behavioral Health Data (OHBH)

- Collection of TEDS mandated by SAMHSA
  ✓ SUD TX clients
- Transitioning to OBHIS (Ohio Behavioral Health Information System)
  ✓ SUD and Mental health TX clients


Contact: Carol.Carstens@mha.ohio.gov
5122-40-13 (D)

(D) Programs shall enter data for paragraph (B)(11) directly into the central registry system on at least a quarterly basis.

5122-40-13 (E)

(E) Data collected from the central registry system and used for publicly available reports and publications will be presented in aggregate form, so that no individual patient or opioid treatment program may be identified.
OAC Rule 5122-40-14
Program Withdrawal

Key Concepts

✓ Individuals may be withdrawn from a program for administrative or medical reasons
✓ Provider needs to taper medication in a safe manner
✓ Administrative withdrawal of a pregnant patient requires notification to and consultation with MHAS Medical Director and SOTA
(A) Administrative withdrawal is an involuntary withdrawal or administrative discharge from a methadone treatment program. The schedule of withdrawal may be brief, less than thirty days if necessary.

(1) Administrative withdrawal may result from any of the following:
(a) Disruptive conduct or behavior considered to have an adverse effect on the program, staff or patient population of such gravity as to justify the involuntary withdrawal and discharge of a patient. Such behaviors may include violence, threat of violence, dealing drugs, diversion of pharmacological agents, repeated loitering, or flagrant noncompliance resulting in an observable, negative impact on the program, staff and other patients; or,
(b) Incarceration or other confinement.

(2) The methadone treatment program shall document in the patient's individualized treatment plan of care and chart all efforts regarding referral or transfer of the patient to a suitable, alternative treatment program.

(3) Methadone treatment programs wishing to use administrative withdrawal procedures with a pregnant patient must notify and consult the department’s medical director and state authority for case review before initiating administrative withdrawal procedures.
(B) Medical withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and patient in accordance with approved national guidelines. In some cases, the withdrawal may be against the advice of clinical staff (against medical advice).

1. The methadone treatment program shall supply a schedule of dose reduction well tolerated by the patient.
2. The program shall offer supportive treatment, including increased counseling sessions and referral to a self-help group or other counseling provider as appropriate.

3. If the patient is readmitted, the program shall document attempting to assist the patient in any issues which may have triggered his or her abrupt departure.
4. The methadone treatment program shall make provisions for continuing care for each patient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the patient should reconsider withdrawal.
5. Female patients of child bearing age shall have a negative pregnancy screen prior to the onset of medically-supervised withdrawal.
(C) For either withdrawal scenario, the program shall have in place a detailed relapse prevention plan developed by the counselor in accordance with best practices and in conjunction with the patient. The prevention plan shall be given to the patient in writing prior to the administration of the final dose.