



Promoting Wellness and Recovery

John R. Kasich, Governor
Tracy J. Plouck, Director

Methadone Licensure Rules Part Two

**Janel M. Pequignot, Chief
Licensure and Certification
OhioMHAS**

Janel.Pequignot@mha.ohio.gov

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

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
- Holly Stone, Surveyor
- Kelly Taynor-Arledge, Surveyor
- Tina Weller (June), Surveyor

Licensure & Certification Staff

Cincinnati

- LaTaunia Pitts-Wilson, Surveyor
- Joy Sherer, Surveyor

Cleveland

- Cheryl Casto (June), Surveyor
- Donna Sabo, Surveyor
- Vacant, Surveyor

Massillon

- Jim Budimlic, Surveyor
- Laura Schering, Surveyor
- Susan Sekely, Surveyor

Toledo

- 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

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

[5119.391 \[Effective 6/1/2017\] Methadone treatment license.](#)

[5119.392 \[Effective 6/1/2017\] Methadone treatment facility locations.](#)

Who Else Regulates Methadone? (when prescribed for opiate treatment)

1. Board of Pharmacy (TDDD)
2. SAMSHA
3. DEA
4. CARF/TJC/COA



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OAC Rule 5122-40-06 Methadone Administration

Key Concepts

- ✓ Standards for prescribing, administering and dispensing methadone in accordance with state and federal laws
- ✓ Take-home doses
- ✓ Guest dosing
- ✓ Interim methadone maintenance
- ✓ Pregnant patients

5122-40-06 (A)

(A) Methadone administration shall consist of face-to-face interactions with patients, and methadone medication shall only be administered or dispensed in oral, liquid doses.

5122-40-06 (B)

(B) Methadone medication administration shall be provided in a manner to ensure privacy.

5122-40-06 (C)

(C) Methadone medication shall only be administered orally.

5122-40-06 (D)

(D) Methadone medication programs are permitted to establish medication units following the guidelines of 42 CFR part 8 subsection 8.11(i)(1).

5122-40-06 (E)

(E) Methadone administration shall be provided by individuals who have one or more of the following credentials from the applicable state of Ohio board:

- (1) Licensed physician;
 - (2) 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;
 - (3) Registered nurse;
 - (4) Licensed practical nurse who has proof of completion of a course in medication administration approved by the Ohio board of nursing;
- or,
- (5) Physician assistant who has proof of completion of a course in medication administration approved by the state medical board of Ohio.

5122-40-06 (F)

(F) Dispensing or personally furnishing methadone shall be performed in accordance with rules adopted by the state board of pharmacy and may only be done by individuals who have one or more of the following credentials from the applicable state of Ohio board:

- (1) Licensed physician; or,
- (2) Pharmacist pursuant to section 4729.39 of the Revised Code.

5122-40-06 (G)

(G) Providers of methadone administration services shall be supervised by individuals who have one of the following credentials from the applicable state of Ohio board:

- (1) Licensed physician; or,
- (2) Registered nurse.

5122-40-06 (H)

(H) A written, signed, and dated physician's order shall be required and a copy maintained in the patient's record, for all methadone administered, personally furnished, or dispensed. The prescribing physician must be a staff member or contract employee of the methadone program.

5122-40-06 (I)

(I) Labels for dispensing or personally furnishing methadone shall be prepared in accordance with 21 C.F.R. 1306.14 and section 3719.08 of the Revised Code and in accordance with Chapter 4729 of the Administrative Code.

5122-40-06 (J)

(J) Methadone orders shall be written by a program physician who is licensed by the Ohio state medical board and registered with the U.S. drug enforcement administration to order methadone. The following procedures shall be followed in writing physician orders for methadone.

- (1) A physician's order for methadone shall be valid for a maximum time period of ninety days.
- (2) A physician's order for methadone shall be reviewed at least every ninety days and adjusted, reordered, or a notation made that methadone is to be discontinued.

5122-40-06 (K)

(K) Methadone programs shall be open and administer medication at least six days per week every week, except that programs may close on federal holidays indicated in paragraph (N) of this rule.

5122-40-06 (L)

(L) The take-home supply for patients enrolled in the methadone program during the first ninety days of treatment is limited to a single dose each week. The patient shall ingest all other doses under appropriate supervision in accordance with 42 CFR 8.12 (i)(3). At the discretion of the medical director or other authorized program physician, a patient may receive one additional take-home dose for those holidays listed in paragraph (N) of this rule if the methadone program is closed in observance of the holiday.

5122-40-06 (M)

(M) Take-home doses of medication shall not be permitted for clients who are on short-term opiate detoxification except on federal holidays and Sundays if the program is closed.

5122-40-06 (N)

(N) If the methadone treatment program is closed for any of the following federal holidays, all patients may be given a one-day take-home dose at the discretion of the medical director.

- (1) Thanksgiving day.
- (2) Christmas day.
- (3) New year's day.
- (4) Martin Luther King day.
- (5) President's day
- (6) Memorial day
- (7) Fourth of July
- (8) Labor day
- (9) Columbus day
- (10) Veteran's day

5122-40-06 (O)

(O) The program shall have written procedures for take-home methadone doses that include:

- (1) Statement that the methadone program decisions on dispensing take-home doses of methadone medication shall be determined by the medical director or other authorized program physician;
- (2) Statement that a take-home dose of methadone medication is an earned privilege and not a right;
- (3) Requirement that take-home doses of methadone medication shall be given only to a methadone patient, who, in the opinion of the medical director or other authorized program physician, is responsible in handling opiate drugs;

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

- (4) Except during program closure on Sundays and federal holidays listed in paragraph (N) of this rule, a statement that before a medical director or other authorized program physician authorizes take-home doses of methadone medication, the medical director or other authorized program physician shall record the rationale for this decision in the patient's clinical record and consider, at a minimum, the following criteria:
 - (a) Absence of recent abuse of opioid or other drugs and alcohol;
 - (b) Regularity of clinic attendance for methadone medication administration;

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(4) Except during program closure on Sundays and federal holidays listed in paragraph (N) of this rule, a statement that before a medical director or other authorized program physician authorizes take-home doses of methadone medication, the medical director or other authorized program physician shall record the rationale for this decision in the patient's clinical record and consider, at a minimum, the following criteria:

- (c) Regularity of clinic attendance for counseling sessions;
- (d) Absence of serious behavioral problems at the clinic;
- (e) Absence of known recent criminal activity, for example, drug dealing;
- (f) Stability of the patient's home environment;
- (g) Stability of the patient's social relationships;
- (h) Length of time in comprehensive maintenance treatment;

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(4) Except during program closure on Sundays and federal holidays listed in paragraph (N) of this rule, a statement that before a medical director or other authorized program physician authorizes take-home doses of methadone medication, the medical director or other authorized program physician shall record the rationale for this decision in the patient's clinical record and consider, at a minimum, the following criteria:

- (i) Assurance that take-home doses of methadone can be safely stored within the patient's home;
- (j) Determination if the rehabilitation benefit to the patient by receiving a take-home dose of methadone medication outweighs the potential risks of diversion; and,
- (k) Employment status of patient.

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(5) Statement that physician orders for take-home methadone medication shall expire every ninety days;

(6) Requirement that education on the proper safe storage and disposal of take-home medication be provided to patients prior first take-home dose.

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(7) Requirement that child-resistant packaging and caps be used for take-home doses of methadone medication; and,

(a) If a take-home bottle is returned by a patient for refills, the methadone program shall accept the bottle and dispose of it.

(b) Bottles used for take-home doses of methadone medication shall only be used once.

(c) Under no circumstance is methadone medication to be placed in a container provided by a patient (including previous take-home bottle).

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(8) Requirement that each take-home bottle of methadone medication dispensed or personally furnished have a label that contains the following information:

- (a) The methadone program's name, address and telephone number;
- (b) Name of patient;
- (c) Name of program physician prescribing the methadone medication;
- (d) The name of the methadone medication;

5122-40-06 (O) (continued)

(O) The program shall have written procedures for take-home methadone doses that include:

(8) Requirement that each take-home bottle of methadone medication dispensed or personally furnished have a label that contains the following information:

- (e) The dosing instructions and schedule;
- (f) Date that the take-home methadone dose was prepared;
- (g) The label shall contain the following warning "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."; and,
- (h) Any other requirements pursuant to rules adopted by the state board of pharmacy.

5122-40-06 (P)

(P) An individual must be a patient of a methadone program licensed by the department in order to receive methadone medication under the provisions of this rule except as otherwise provided in this rule.

5122-40-06 (Q)

(Q) A patient may attend a different opioid treatment program if prior approval is obtained from the patient's medical director or program physician to receive services on a temporary basis from another opioid treatment program licensed under this Chapter or by SAMHSA. The approval shall be noted in the patient's record and shall include the following documentation:

(1) The patient's signed and dated consent for disclosing identifying information to the program which will provide services on a temporary basis;

5122-40-06 (Q) (continued)

(Q) A patient may attend a different opioid treatment program if prior approval is obtained from the patient's medical director or program physician to receive services on a temporary basis from another opioid treatment program licensed under this Chapter or by SAMHSA. The approval shall be noted in the patient's record and shall include the following documentation:

- (2) A medication change order by the referring medical director or program physician permitting the patient to receive services on a temporary basis from the other program for a length of time not to exceed 30 days; and,
- (3) Evidence that the medical director or program physician for the program contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with his or her dosage schedule, and supervises the administration of the medication.

5122-40-06 (R)

(R) The provision of interim methadone maintenance is prohibited under this rule unless the methadone treatment program has a waiver from the department in addition to authorization from SAMHSA in accordance with 42 C.F.R. 8.11(g).

- (1) All of the requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions: no take-home doses are permitted except on Sundays and federal holidays if the program is closed on those days; an initial and periodic treatment plan are not required; a primary counselor is not required; and the rehabilitative and other services described in 42 C.F.R. 8.12(f)(4), (f)(5)(i), and (f)(5)(iii) are not required.

5122-40-06 (R) (continued)

(R) The provision of interim methadone maintenance is prohibited under this rule unless the methadone treatment program has a waiver from the department in addition to authorization from SAMHSA in accordance with 42 C.F.R. 8.11(g).

(2) Interim maintenance cannot be provided to an individual for more than one hundred and twenty days in any twelve month period.

(3) To receive interim maintenance, a patient must be fully eligible for admission to comprehensive maintenance.

(4) Interim maintenance treatment is for those patients who cannot be enrolled in comprehensive maintenance treatment in a reasonable geographic area within fourteen days of application for admission.

5122-40-06 (R) (continued)

(R) The provision of interim methadone maintenance is prohibited under this rule unless the methadone treatment program has a waiver from the department in addition to authorization from SAMHSA in accordance with 42 C.F.R. 8.11(g).

(5) During interim maintenance, the initial toxicology and at least two additional toxicology screening tests should be obtained.

(6) Programs offering interim maintenance must develop clear policies and procedures governing the admission to interim maintenance and transfer of patients to comprehensive maintenance.

5122-40-06 (S)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(1) Requirement that each woman admitted to the methadone program be informed of the possible risks to herself or to her unborn child from the use of methadone medication;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(2) Statement that a pregnant woman, regardless of age, who has a documented past opioid dependency and who may be in direct jeopardy of returning to opioid dependency with all of its attendant dangers during pregnancy, may be placed on a methadone regimen.

Statement that for such pregnant women, evidence of current physiological dependence on opioid drugs is not needed if the medical director or other authorized program physician certifies the pregnancy, determines and documents that the woman may resort to the use of opioid drugs and determines that methadone treatment is justified in their clinical opinion;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

- (3) Requirement that the admission of each pregnant woman to a methadone program be approved by the medical director or other authorized program physician prior to admitting the woman to the program;
- (4) Statement that abrupt withdrawal from these medications may adversely affect the unborn child;
- (5) Requirement that methadone treatment programs develop a form for release of information between themselves and the healthcare provider in care of obstetrical care. This voluntary form should be offered to all pregnant women for coordination of medical care;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

- (6) Requirement that each pregnant woman be given education on recognizing the symptoms of neonatal abstinence syndrome near the time of delivery;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(7) Procedures for prenatal care that include:

(a) Provisions for providing prenatal care by the program or by referral to an appropriate health care provider. If appropriate prenatal care is neither available on-site or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services on-site or by referral, a methadone program, at a minimum, should offer basic prenatal instruction on maternal, physical, and dietary care as part of its counseling services. If a pregnant patient refuses the offered on-site or referred prenatal services, the medical director or treating physician must use informed consent procedures to have the patient formally acknowledge, in writing, refusal of these services:

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(7) Procedures for prenatal care that include:

(b) Requirement that if a woman is referred to prenatal care outside the agency, the name, address and telephone number of the health care provider shall be recorded in the woman's clinical record;

(c) If prenatal care is provided by the methadone program, the clinical record shall include documentation to reflect services provided;

(d) Requirement that if a patient is referred outside of the agency for prenatal services, the provider to whom she has been referred shall be notified that she is in methadone treatment; however, such notice shall only be given after the patient has signed a release of information:

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(7) Procedures for prenatal care that include:

(e) Requirement that any changes in methadone treatment be communicated to the appropriate healthcare provider if the woman has prenatal care outside the agency if the woman allows communication among providers;

(f) Requirement that the program monitor the methadone dose carefully throughout the pregnancy, moving rapidly to supply increased or split dose if it becomes necessary;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(7) Procedures for prenatal care that include:

(g) Recommendation that blood serum levels for methadone agonist be monitored once a trimester, and every three days for two weeks after delivery to ensure appropriate level of medication before and after delivery by the appropriate healthcare professional. The medical director shall request and review serum levels to determine whether any changes to treatment need to be made;

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(7) Procedures for prenatal care that include:

(h) Requirement that the program shall offer on-site parenting education and training to all male and female patients who are parents or shall refer interested patients to appropriate alternative services for the training; and,

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(8) Statement that if a patient refuses prenatal service by the methadone program and by an outside provider:

(a) The medical director or other authorized program physician shall note this in the clinical record; and,

5122-40-06 (S) (continued)

(S) Each methadone program shall have written procedures for pregnant female patients that include at least the following:

(8) Statement that if a patient refuses prenatal service by the methadone program and by an outside provider:

(b) The patient will be asked to sign a statement that says "I have been offered the opportunity for prenatal care by the methadone program or by a referral to a prenatal clinic or by a referral to the physician of my choice. I refuse prenatal counseling by the methadone program. I refuse to permit the methadone program to refer me to a physician or prenatal clinic for prenatal services." If the patient refuses to sign the statement, the medical director or other authorized program physician shall indicate in the signature block that "patient refused to sign" and affix their signature and the date on the statement.



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OAC Rule 5122-40-07 Program Policies and Patient Records

Key Concepts

- Expands on policy & procedures requirements contained in 5122-40-06
- Establishes policy & procedures requirements not contained in 5122-40-10 and 5122-40-11
- Some require developing P&P in accordance with other chapter 5122-40 rules; other allow provider to set the standard
- Clinical records requirements
- Must store clinical records 7 years after administering/dispensing last methadone dose

Policy vs. Procedure

“Policy”

- Guiding principle
- “What” and/or “Why”

“Procedure”

- Step-by-step instructions
- How we accomplish
- “How”, “When”, “Who”, sometimes “What”

Do

- ✓ Read the standards
- ✓ Determine how a standard fits your organization
- ✓ Develop policies and procedures that describe and reflect YOUR mission and how YOU operate

Don't

- ✓ Copy/repeat the standards and consider it a policy and/or procedure
- ✓ Purchase standards, hire someone to write, borrow from the last agency you worked at, or otherwise obtain policies and procedures without ensuring they fit YOUR mission and how YOU operate

Example

Policy: Licensed staff will maintain competency to perform their job.

Procedure:

1. Staff will obtain 30 hours of continuing education every two calendar years.
2. HR Director will schedule 30 hours of CE approved training courses every year.
3. HR Staff will place a copy of the CE Certificate in each staff person's personnel file.
4. Each staff person is permitted \$100/year staff development funds to obtain training outside the agency. HR will submit a request for reimbursement to payroll after receiving a copy of the CE Certificate, to be included in the paycheck within one month.

Example

Policy: Licensed staff will maintain competency to perform their job.

Procedure:

5. Staff that attend training outside the agency must submit a copy of the CE Certificate to his/her supervisor and the HR Director within 7 days of attendance.
6. HR staff will maintain a log of training attended by each staff person and the total number of hours.
7. HR Director will notify an employee that does not yet have 30 hours of training at least 90 days prior to the end of the 2nd calendar year, and copy his/her supervisor.

5122-40-07 (A)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

(1) Admission criteria for adolescents and adults for methadone maintenance and detoxification, including at a minimum:

(a) Determination by an individual qualified to diagnose by their scope of practice that the patient is currently dependent on an opioid drug according to the current diagnostic and statistical manual for mental disorders or the international statistical classification of diseases and related health problems;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

(1) Admission criteria for adolescents and adults for methadone maintenance and detoxification, including at a minimum:

(b) The patient became dependent on an opioid drug at least one year before admission to the opioid program. This requirement may be waived by the medical director or other authorized program physician if the patient has been released from a penal institution within the past six months, is pregnant (as verified by the medical director or other authorized program physician) or has been discharged from a methadone program within the last two years; and,

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

(1) Admission criteria for adolescents and adults for methadone maintenance and detoxification, including at a minimum:

(c) A patient under eighteen years of age shall have two documented unsuccessful attempts at short-term detoxification or alcohol and other drug treatment within a twelve-month period and must have written consent for maintenance from a parent or legal guardian.

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

(2) Admission procedures for methadone maintenance and detoxification;

(3) Procedures for providing counseling on preventing exposure to and the transmission of tuberculosis, hepatitis type B and C, and human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment;

(4) Policy or procedure that establish ratios of primary counselors to patients that are in accordance with the requirements for counselors in rule 5122-40-09 of the Administrative Code.

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (5) Policies and procedures that treatment will meet the standards of medical care for opioid treatment services established by the American society of addiction medicine, 2015 edition, or other nationally recognized standards organization selected by the director.
- (6) Procedures for the ordering, delivery, receipt and storage of methadone medication;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (7) Policy or procedure for the security alarm system that includes, but is not limited to, the following:
 - (a) Provisions for testing the alarm system; and,
 - (b) Provisions for documenting the testing of the alarm system.
- (8) Policy or procedure which specifies which staff will have access to the program's methadone supply;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (9) Procedures for administering methadone medication in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (10) Procedures for dispensing methadone medication, including days and hours, in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (11) Policy or procedure for days and hours for non-medication dispensing program services;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (12) Policies and procedures for the involuntary termination of methadone patients in accordance with the requirements of rule 5122-40-14 of the Administrative Code;
- (13) Procedures for referring or providing prenatal services to pregnant methadone patients in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (14) Policies and procedures for take-home doses of methadone medication in accordance with the requirements of rule 5122-40-06 of the Administrative Code;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (15) Policy or procedure for urinalysis for methadone patients in accordance with the requirements of rule 5122-40-11 of the Administrative Code;
- (16) Policies and procedures for urinalysis for employees of the methadone program;
- (17) Procedure for cleaning the methadone medication areas;
- (18) Policies and procedures for missed methadone administration appointments;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (19) Policies and procedures stating that methadone medication shall not be provided to a patient who is known to be currently receiving methadone medication from another methadone program with the exception of guest dosing patients whose need for methadone maintenance has been verified by the medical director or other authorized program physician of both the methadone maintenance program where the patient is currently enrolled and at the program where the patient is requesting to receive services;

5122-40-07 (A) (continued)

(A) Each methadone program shall have written policies or procedures that include, but are not limited to, the following:

- (20) Policies and procedures related to disaster planning, pursuant to rule 5122-40-12 of the Administrative Code;
- (21) Policies and procedures relating to a diversion control plan, pursuant to rule 5122-40-10 of the Administrative Code; and,
- (22) Policies and procedures for accessing the state's drug database pursuant to section 4729.75 of the Revised Code, pursuant to rule 5122-40-08 of the Administrative Code.

5122-40-07 (B)

(B) An individual client record shall be maintained for each client, and contain the following:

- (1) Date of each visit that the patient makes to the program;
- (2) Date, time, and amount of methadone medication administered or dispensed along with the printed name and original signature of the service provider;
- (3) Medical history;
- (4) Documentation of physical examination and results;
- (5) Results of a serological test for syphilis;

5122-40-07 (B) (continued)

(B) An individual client record shall be maintained for each client, and contain the following:

- (6) Results of tubercular skin test;
- (7) Results of a urinalysis for drug determination at the time of admission and the results of each subsequent urinalysis;
- (8) Assessment in accordance with chapter 5122-29 of the Administrative Code;
- (9) Individualized treatment plan in accordance with chapter 5122-27 of the Administrative Code;
- (10) Progress notes in accordance with chapter 5122-27 of the Administrative Code;

5122-40-07 (B) (continued)

(B) An individual client record shall be maintained for each client, and contain the following:

- (11) Documentation of counseling on preventing exposure to tuberculosis, hepatitis type B and C, and the transmission of human immunodeficiency virus (HIV) disease;
- (12) Documentation of provision of the following when the individual has been assessed as in need of these services, either directly or through referral to adequate and reasonably accessible community resources:
 - Vocational rehabilitation services;
 - (b) Employment services; and
 - (c) Education services.

5122-40-07 (B) (continued)

(B) An individual client record shall be maintained for each client, and contain the following:

- (13) Documentation to reflect that the program has attempted to determine whether or not the patient is enrolled in any other opioid agonist or partial opioid agonist maintenance program. This documentation may be stored in either the client record or the central registry system;
- (14) Documentation to reflect verification by the medical director or other authorized program physician of the need for opioid agonist medication for guest dosing patients;

5122-40-07 (B) (continued)

(B) An individual client record shall be maintained for each client, and contain the following:

- (15) Information required by Chapter 5122-27 of the Administrative Code; and,
- (16) Documentation of any check of the prescription drug monitoring program data pursuant to rule 5122-40-08 of the Administrative Code.

5122-40-07 (C)

(C) Methadone patient records shall be maintained for at least seven years from the last date of administering or dispensing a controlled substance.



Promoting Wellness and Recovery

John R. Kasich, Governor
Tracy J. Plouck, Director

OAC Rule 5122-40-08 Monitoring Program

Key Concepts

- ✓ Check for other controlled substances prescribed to patient
- ✓ Check for dual enrollment
- ✓ Goal to prevent abuse, diversion and trafficking
- ✓ Check OARRS at specified intervals
- ✓ Report to and check methadone central registry aka “Lighthouse”
- ✓ Patient must provide specified info and consent to a check of central registry, or program cannot admit

5122-40-08 (A)

(A) Each methadone treatment program shall review state’s drug database as described in section 4729.75 (the prescription drug monitoring program) database maintained by the state board of pharmacy.

(1) Program physicians, or their designees as allowed by the Ohio board of pharmacy, shall review a patient’s information in the database:

- (a) At the patient's intake;
- (b) At the initiation of treatment;
- (c) After the initial thirty days of treatment;

5122-40-08 (A) (continued)

(A) Each methadone treatment program shall review state's drug database as described in section 4729.75 (the prescription drug monitoring program) database maintained by the state board of pharmacy.

(1) Program physicians, or their designees as allowed by the Ohio board of pharmacy, shall review a patient's information in the database:

- (d) Prior to any take-home medication being granted excluding take home medication for program closure and federal holidays;
- (e) When the number of take home doses is increased;
- (f) Every ninety days;
- (g) When a patient refuses to participate in a drug screen; and,
- (h) After any positive drug test indicating any drug screen inconsistent with the patient's treatment plan.

5122-40-08 (A) (continued)

(A) Each methadone treatment program shall review state's drug database as described in section 4729.75 (the prescription drug monitoring program) database maintained by the state board of pharmacy.

(2) The physician, or their designees as allowed by the Ohio board of pharmacy, shall review information in the drug database in order to ensure that the patient is not seeking prescription medication from multiple sources. The results obtained from the database shall be maintained with the patient records in accordance with chapter 4729.86 of the Revised Code.

5122-40-08 (B)

(B) All methadone programs shall participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts.

(1) The central registry will be administered by the state authority.

(2) The central registry shall be paid for by the methadone treatment programs through an annual licensing fee that shall be no more than the cost of the central registry. The amount of the fee shall be set by the department on a state fiscal year basis and shall be announced on or before July 1 of each year.

5122-40-08 (B) (continued)

(B) All methadone programs shall participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts.

(3) By the sixth working day of the month following the month in which the program admits or discharges a patient the program shall report to the central registry, for purposes of evaluation, patient admission and discharge data which shall include:

(a) Provider identification, including program name, county, and address;

(b) Patient identification, including:

(i) Patient name or initials;

(ii) Sex;

(iii) Month, day, and year of birth; and,

(iv) Race,

5122-40-08 (B) (continued)

(B) All methadone programs shall participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts.

(3) By the sixth working day of the month following the month in which the program admits or discharges a patient the program shall report to the central registry, for purposes of evaluation, patient admission and discharge data which shall include:

- (c) The month, day, and year of admission;
- (d) The month, day, and year of discharge, if applicable;
- (e) The type of admission (e.g. initial admission, transfer from another program, change in treatment service, etc.);
- (f) The type of treatment provided (e.g. detoxification or maintenance);
- (g) The type of medication prescribed;
- (h) The dose of medication; and,
- (i) Medicaid identification, if available.

5122-40-08 (B) (continued)

(B) All methadone programs shall participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts.

(3) By the sixth working day of the month following the month in which the program admits or discharges a patient the program shall report to the central registry, for purposes of evaluation, patient admission and discharge data which shall include:

Programs licensed on June 1, 2017 shall enter the patient information required by this paragraph for current patients by July 1, 2018 or within thirty days of the central registry system being installed by the vendor at the program site, whichever is later.

5122-40-08 (B) (continued)

(B) All methadone programs shall participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts.

(4) A patient's medication and dosage shall be updated within the central registry system at least once a week for disaster planning efforts.

5122-40-08 (C)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(1) Before a program admits a patient for treatment, the program shall:

(a) Notify the patient that it cannot provide methadone treatment to a patient who is simultaneously receiving opioid agonist or partial opioid agonist treatment from another program;

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(1) Before a program admits a patient for treatment, the program shall:

(b) Require the patient to sign a written statement documenting whether they are currently receiving opioid agonist or partial opioid agonist treatment from another program and retain the statement in the patient record. If the patient refuses to sign this statement, the program shall not admit the patient for treatment;

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(1) Before a program admits a patient for treatment, the program shall:

(c) Require the patient to provide the following information:

- (i) Full name and any aliases;
- (ii) Month, day, and year of birth;
- (iii) Mother's maiden name;
- (iv) Sex;
- (v) Race;
- (vi) Height;
- (vii) Weight;
- (viii) Color of hair;
- (ix) Color of eyes; and
- (x) Distinguishing markings, such as scars or tattoos.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(1) Before a program admits a patient for treatment, the program shall:

(d) Request the patient to voluntarily provide their Social Security number;

(e) Require the patient to sign an authorization for disclosure of confidential information, pursuant to 42 C.F.R. 2.34 for the limited purpose of authorizing the program to contact each opioid treatment program within a radius of two hundred statute miles to determine if the patient is simultaneously receiving opioid agonist or partial opioid agonist therapy from another program; and.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(1) Before a program admits a patient for treatment, the program shall:

(f) Document in the patient record all information provided and authorizations of release of information signed pursuant to this rule.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(2) If the program receives the consent in paragraph (C)(1)(e) of this rule, it shall disclose to the central registry the information provided by the patient in paragraph (C)(1)(c) of this rule upon:

- (a) Accepting the patient for treatment;
- (b) Changing the dosage being administered or dispensed to the patient; or,
- (c) When the treatment is interrupted for a duration of greater than one week, resumed, or terminated.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(3) If the patient states that they are currently receiving opioid agonist or partial opioid agonist therapy from another program and the patient is not approved to receive services on a temporary basis before admitting the patient for treatment, the program shall:

- (a) Require the patient to sign an authorization of disclosure of confidential information, pursuant to 42 C.F.R. 2.34 for the limited purpose of authorizing the program to contact the previous program to notify it that the patient has applied for admission for methadone treatment;

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.
(3) If the patient states that they are currently receiving opioid agonist or partial opioid agonist therapy from another program and the patient is not approved to receive services on a temporary basis before admitting the patient for treatment, the program shall:

(b) Contact the previous program by telephone and notify the program that the individual has applied for admission for methadone treatment;

(c) Request the program to cease providing opioid agonist or partial opioid agonist if it has not already done so;

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.
(3) If the patient states that they are currently receiving opioid agonist or partial opioid agonist therapy from another program and the patient is not approved to receive services on a temporary basis before admitting the patient for treatment, the program shall:

(d) Request the previous program to provide the new program with written documentation (letter or discharge summary) that it has discharged the patient; and the previous program shall provide such information within seventy-two hours of receiving the request. If the previous program states that it has already discharged the patient, the new program may admit the patient for treatment; and,

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.
 (3) If the patient states that they are currently receiving opioid agonist or partial opioid agonist therapy from another program and the patient is not approved to receive services on a temporary basis before admitting the patient for treatment, the program shall:

(e) Document the following information in writing in the patient's record:

- (i) The name of the program contacted;
- (ii) The date and time of the contact;
- (iii) The name of the program staff member contacted; and,
- (iv) The results of the contact.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(4) If the patient states that they are a visiting patient approved to receive services on a temporary basis, before providing methadone treatment to the patient the program shall:

- (a) Contact the other program to determine that it has not already provided the patient with opioid agonist or partial opioid agonist therapy for the same time period and that it will not do so; and,
- (b) Document the following information in writing in the patient's medication orders:
 - (i) The name of the program contacted;
 - (ii) The date and time of the contact;
 - (iii) The name of the program staff member contacted; and,
 - (iv) The results of the contact.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(5) If the patient states that they are not currently receiving opioid agonist or partial opioid agonist therapy from another program, the program shall proceed with patient admission procedures.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(6) When a program determines that it is providing methadone treatment to a patient who is simultaneously receiving this therapy from one or more other programs, all of the involved programs shall immediately:

- (a) Confer to determine which program will accept sole responsibility for the patient;
- (b) Revoke the patient's take-home medication privileges; and,
- (c) Notify the state authority by telephone within seventy-two hours of such determination.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(7) The program which agrees to accept sole responsibility for a patient with multiple enrollments shall continue to provide methadone treatment. Each of the other programs involved shall:

- (a) Immediately discharge the patient from the program;
- (b) Document in the patient's record why the patient was discharged from the program;
- (c) Provide to the new program, within 72 hours of the discharge, written documentation (letter or discharge summary) that it has discharged the patient; and,
- (d) Send written notification of the discharge to the state authority within 72 hours of the discharge.

5122-40-08 (C) (continued)

(C) Methadone treatment programs shall verify new patients are not enrolled in another program through the central registry.

(8) If the state authority determines that there is patient who is enrolled in multiple programs, and none of the programs has accepted sole responsibility for the patient, the state authority shall:

- (a) Designate one program which shall accept sole responsibility for the patient; and,
- (b) Order the remaining programs to proceed in accordance with paragraph (C)(7).

5122-40-08 (D)

(D) A methadone treatment program that has followed the requirements of paragraph (C) has complied with the requirement to check for patient dual enrollment, regardless of whether or not the patient is actually dually enrolled in another program.



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Final Questions