

5122-40-01

Definitions and applicability.

(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 assisted treatment to a client.
- (2) "Department" mean the Ohio department of mental health and addiction services.
- (3) "Detoxification" means the administering of any ~~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.
- (4) "Dispense", means the final association of any ~~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 any ~~methadone~~ medication used for medication assisted treatment.
- ~~(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)~~(5) "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)~~(6) "Long-term detoxification" means the administering of ~~Methadone~~ medication assisted treatment for detoxification of a patient for a period of more than thirty days but not in excess of one hundred eighty days.

- (7) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code."
- (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~~ delivery of all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and qualified healthcare professionals functioning under the medical director's direct supervision.
- (9) "Medication unit" means any center for substance abuse treatment (CSAT) approved facility established as part of, but geographically separate from, an opioid treatment program from which medication assisted treatment is administered or dispensed.~~a unit established by a methadone medication maintenance program solely to dispense methadone medication for observed ingestion.~~
- (10) "~~Methadone~~ Medication maintenance" means the administering or dispensing of ~~methadone~~ medication assisted treatment at stable dosage levels for a period in excess of twenty-one days in the treatment of a patient for opioid addiction.
- (11) "~~Methadone~~ Opioid 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~~that engages in supervised assessment and treatment, using any form of medication assisted treatment for individuals who have opioid use disorders. Services include medically supervised withdrawal and/or maintenance treatment, along with various levels of medical, psychiatric, psychosocial, and other types of supportive care.
- (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~~ opioid 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.
- (13) "Permanent patient transfer" means the transfer of a patient from one opioid treatment program to another opioid treatment program.

- (13)(14) "Physician extender" means a qualified 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.
- (15) "Principal" means a person who has controlling authority or is in a leading position, e.g., executive director, chief financial officer, chief clinical officer, chief operating officer.
- (14)(16) "Program administrator" is a person who is responsible for the day-to-day operation of the ~~methadone~~-opioid 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)(17) "Program sponsor" is a person or representative of the program, who is responsible for the operation of the ~~methadone medication program~~opioid treatment 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)(18) "SAMHSA" means the federal substance abuse and mental health services administration.
- (17)(19) "Short-term detoxification" means the administering of a ~~methadone~~ medication assisted treatment for detoxification of a patient for a period not to exceed thirty days.
- (18)(20) "State authority" or "state opioid treatment authority" (SOTA) 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~~by an opioid treatment program. 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)(21) "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 as an opioid treatment program in accordance with section 5119.391 of the Revised Code ~~through June 29, 2019~~ and section 5119.37 of the Revised Code after June 29, 2019, which includes any opioid treatment program requiring certification, as certification is defined in 42 C.F.R. 8.2, ~~program that employs methadone medication treatment; or prescribes, dispenses, or administers methadone for the treatment of opioid addiction.~~
- (C) Programs licensed as ~~methadone medication~~ an opioid treatment 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~~ opioid treatment program, then it is required to apply to the department for licensure in accordance with this Chapter.
- (D) ~~A methadone~~ An opioid treatment 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.

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State opioid treatment authority.

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:

- (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.
- (B) Act as a liaison between relevant state and federal agencies.
- (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.
- (D) Coordinate initial licensure between the department and other licensing, accrediting, and certifying entities as required in this paragraph.
- (E) Assure delivery of technical assistance and informational materials to opioid treatment programs as needed.
- (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.
- (H) Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate.
- (I) Review program monitoring activities pursuant to rule 5122-40-08 of the Administrative Code.
- (J) Review diversion control plan pursuant to rule 5122-40-10 of the Administrative Code
- (K) Review opioid treatment programs' disaster planning efforts pursuant to rule 5122-40-12 of the Administrative Code.
- (L) Review opioid treatment programs' evaluation activities efforts pursuant to rule 5122-40-13 of the Administrative Code.
- (M) Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed opioid treatment program.

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

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Issuance of licenses.

- (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~~ an opioid treatment program by demonstrating compliance with the licensure requirements set forth in section 5119.391 of the Revised Code through June 29, 2019 and section 5119.37 of the Revised Code after June 29, 2019 and Chapter 5122-40 of the Administrative Code.

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.

- (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~~ operate a methadone an opioid treatment program is for a one-year time period.
- (D) A license is not transferable to any other site or property.
- (E) A license is valid only for the ~~applicant~~ licensed provider named in the application, and is not transferable to or assumable by any other person, corporation, or entity, including any person or entity which purchases the licensed program or the licensed program's corporate or managing entity, or enters into any similar purchase agreement.
- (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~~ opioid treatment 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~~opioid treatment 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 ~~an~~ an ~~methadone~~opioid treatment program for one or more of the following reasons:
- (1) ~~Until June 29, 2019, the~~ 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)~~ After June 29, 2019, the program does not meet the requirements of division (C) of section 5119.37 of the Revised Code and rule 5122-40-04 of the Administrative Code;
- ~~(2)~~(3) The program fails to achieve or retain certification in accordance with Chapter 5122-25 of the Administrative Code;
- ~~(3)~~(4) The program is not in compliance with the requirements for licensure as set forth by the rules in this chapter;
- ~~(4)~~(5) 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)~~(6) The program presents or submits false or misleading information as part of a license application, renewal, or investigation;
- ~~(6)~~(7) The program permits an employee to falsify information on patient records;

- (7)(8) 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)(9) The program fails to provide timely access to its records as requested by the department;
- (9)(10) 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)(11) The program, provider, owner, sponsor, medical director, administrator, or principal of the provider is not in good standing in any other jurisdiction in which the ~~methadone provider~~opioid treatment program currently provides services, or was not in good standing at all times within the past ~~five~~three years in any other jurisdiction in which the program previously provided substance use treatment services, that are comparable to the ~~methadone opioid treatment program~~services authorized under section 5119.391 of the Revised Code until June 29, 2019 or section 5119.37 of the Revised Code after June 29, 2019; or,
- (11)(12) The applicant, operator, owner, ~~sponsor, or~~medical director, administrator, or principal is or has been a principal with a ~~methadone opioid treatment 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~~three 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 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.
- (13) The program fails to timely notify the department of any adverse action or proposed adverse action as required by rule 5122-40-04.
- (M) The refusal to issue or withdrawal of a license shall be subject to proceedings governed by Chapter 119. of the Revised Code.
- (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 until June 29, 2019 or section 5119.37 of the Revised Code after June 29, 2019.
- (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 ninety days 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.
- (P) ~~A methadone~~ An opioid treatment 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.
- (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.

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General licensure requirements.

(A) An alcohol and drug addiction program desiring to obtain an initial license or renew a license as ~~a methadone medication~~ an opioid treatment 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) General services in accordance with rule 5122-29-03 of the Administrative Code;

(b) SUD case management services in accordance with rule 5122-29-13 of the Administrative Code; and,

~~(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) Submit a renewal application at least ninety days prior to the expiration of the current license.

~~(3)~~(4) When applying for renewal licensure, be accredited as an opioid treatment program by an accreditation body that has been approved by SAMHSA;

~~(4)~~(5) Be certified by SAMHSA pursuant to "certification of opioid treatment programs," 42 C.F.R. Part 8.11;

~~(5)~~(6) Have a category III terminal distributor of dangerous drugs license from the state board of pharmacy pursuant to Chapter 4729. of the Revised Code;

~~(6)~~(7) Have a security and alarm system that is approved by the United States drug enforcement administration;

~~(7)~~(8) 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)~~(9) 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)~~(10) 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)~~(11) Be in good standing with the state board of pharmacy, ~~department of medicaid, medicare~~centers for medicare & medicaid services, Ohio department of medicaid, and the United States drug enforcement administration;
- ~~(11)~~(12) 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~~as defined by division (C)(1) of section 5119.391 of the Revised Code until June 29, 2019 and division (C)(1) of section 5119.37 of the Revised Code after June 29, 2019;
- ~~(12)~~(13) Demonstrate the ability to meet the standards of medical care for opioid treatment services established by the American society of addiction medicine (ASAM) criteria, third edition (2013), or other nationally recognized standards organization selected by the director;

(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~~the provider is requesting an initial license for a particular location that is located on a parcel of real estate that is within a radius of five hundred linear feet of the boundaries of a parcel of real estate having situated on it a public or private school, child day-care center licensed under Chapter 5104. of the Revised Code, or child-serving agency regulated by the department under Chapter 5119 of the Revised Code.
- (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~~opioid treatment program is to operate.

- (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 until June 29, 2019 or section 5119.371 of the Revised Code after June 29, 2019, 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 regulated by the department under Chapter 5119 of the Revised Code 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 until June 29, 2019 or section 5119.371 of the Revised Code after June 29, 2019.
 - (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 until June 29, 2019, or section 5119.37 of the Revised Code after June 29, so long as the program remains continuously licensed.
- (C) An opioid treatment provider shall inform the department of any adverse action or proposed adverse action that is issued to the provider or owner, or is issued to any other program, corporation, entity or partnership with which the opiate treatment program's sponsor, medical director, administrator or a principal is associated. Adverse action is defined as a notice issued by a state, province federal or similar licensing or regulatory authority to deny, revoke, suspend, place on probation or take similar action against a provider's license, certificate or other approval to operate an opioid treatment program. Notice provided to the department shall consist of a copy of the notice of adverse action or proposed adverse action, and all of that opioid treatment program's compliance or monitoring reports issued for the prior three-year period. The opioid treatment provider shall provide this information to the Department at the following times:
- (1) At the time of initial or renewal application; and,
 - (2) Within seven days of receipt of notice.
- (D) Upon receipt of an application, the department shall review the materials to determine if they are complete. If an application is incomplete, the department shall notify the applicant of corrections or additions needed, and may return the materials to the applicant. Incomplete materials shall not be considered an application for licensure, and return of the materials or failure to issue a license shall not constitute a denial of an application for licensure.

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Personnel.

- (A) Each licensed ~~methadone~~opioid treatment program shall have a program sponsor, who is the person that assumes responsibility for the operation of and the employees of the ~~methadone~~opioid treatment component of a community addiction services provider. The program sponsor shall agree on behalf of the ~~methadone~~opioid 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~~use disorder.
- (1) The program sponsor is responsible for the general establishment, certification, licensure, and operation of the ~~methadone~~opioid treatment program.
 - (2) The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the ~~methadone~~opioid treatment program shall employ a licensed physician for the position of medical director.
- (B) Each ~~methadone~~opioid 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) Certification from the American academy of health care providers in the addictive disorders as a certified addiction specialist; or,
 - ~~(e)~~(d) 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~~opioid 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.

- (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.
 - (v) The department may request periodic documentation of progress towards completion of the training plan.
 - (vi) The program administrator of the ~~methadone~~-opioid 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.
- (2) The medical director shall maintain authority over the medical aspects of treatment offered by the ~~methadone~~-opioid 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~~-opioid treatment program is in compliance with all applicable federal, state and local laws, rules and regulations;
 - (f) Ensuring that evidence of current physiologic dependence on an ~~opiate~~opioid, length of ~~opiate~~-opioid dependence, and exceptions to admission criteria are documented in the patient's clinical record before the patient receives the initial dose of ~~methadone~~-medication used in medication assisted treatment;
 - (g) Ensuring that a medical history and a physical examination have been done before a patient receives the initial dose of ~~methadone~~-medication used in medication assisted treatment;

- (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 used for medication assisted treatment;
 - (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~~ opioid treatment program;
 - (m) Ensuring all medical services are appropriately performed by the ~~methadone~~ opioid treatment program;
 - (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,
- (3) Each ~~methadone~~ opioid treatment program shall have at least one medical director per program location. These site-level medical directors shall be present at the ~~methadone~~ opioid treatment program at least ~~fifty~~ forty 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~~ opioid treatment programs at least ~~fifty~~ forty percent of the time that the program administers or dispenses medication and can satisfactorily discharge all of their duties for each program.
- (a) Opioid treatment programs may appoint one additional person who meets the qualifications in (B)(1) of this rule to be a co-medical director. Co-medical director's may both contribute to the organization's requirements to be on staff for at least forty percent of the time that the program administers or dispenses medication.
 - (b) Opioid treatment programs that employ co-medical directors shall inform the department of such an arrangement in writing.

- (4) Opioid treatment programs in the first sixty days of operation may reduce the time requirement medical directors must be present on site to at least twenty percent of the time that the program administers or dispenses medication. On the sixty-first day of operation the program shall be subject to the requirements of paragraph (B)(3) of this rule.
- ~~(4)~~(5) The medical director must have a current U.S. drug enforcement administration (DEA) registration for prescribing, administering, or dispensing controlled substances, and the medical director must have a DEA waiver if they or any other healthcare professional they supervise prescribes, administers, or dispenses partial opioid agonists.
- ~~(5)~~(6) 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 paragraph (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~~ opioid treatment programs located outside the state of Ohio
- (C) Each licensed ~~methadone~~ opioid 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~~ opioid 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 and enforcement 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.
- (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~~-opioid treatment programs located outside the state of Ohio.
- (D) The ~~methadone~~-opioid 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~~-opioid 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.
- (1) All physicians and physician extenders employed by the ~~methadone~~-opioid 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.
- (2) During all hours of operation, every ~~methadone~~ opioid treatment program shall have a licensed physician on call and available for consultation with other staff members at any time.
- (3) During all hours of operation when medication is being administered, every ~~methadone~~ opioid 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.
- (4) The medical director or a program physician at the opioid treatment program shall meet with each patient within seventy-two hours of the assessment and at least once every six months thereafter during treatment. Each meeting shall be documented in the patient's record.
- (5) Opioid treatment programs that utilize certified nurse practitioners to personally furnish medication assisted treatment shall have certified nurse practitioners meet with their patients at least once every three months during treatment. Each meeting shall be documented in the patient's record.
- (a) Certified nurse practitioners personally furnishing medication assisted treatment shall have a standard care arrangement with the opioid

treatment programs medical director pursuant section 4723.431 of the Revised Code. If the medical director has five existing certified nurse practitioners with a standard of care arrangement, then the standard of care arrangement shall be between a certified nurse practitioner and a program physician employed by the opioid treatment program.

(b) Use of a certified nurse practitioner to personally furnish medication assisted treatment does not remove the obligation of a medical director or program physician to meet with patients.

- (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~~ any form of medication. 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 form of medication to any person who has been convicted of a felony relating to controlled substances.

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Methodone Medication assisted treatment administration.

- (A) ~~Methodone Medication~~ administration shall consist of face-to-face interactions with patients, and methadone medication shall only be administered or dispensed in oral, liquid doses.
- (B) ~~Methodone medication~~Medication assisted treatment administration shall be provided in a manner to ensure privacy.
- (C) Methadone medication shall only be administered orally.
- (D) ~~Methodone medication~~Opioid treatment programs are permitted to establish medication units following the guidelines of 42 CFR part 8 subsection 8.11(i)(1).
- (E) ~~Methodone administration~~Administration of medication assisted treatment 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.
- (F) Dispensing or personally furnishing ~~methodone medication assisted treatment~~ 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; or,
 - (3) Certified nurse practitioner with an exemption request approved by SAMHSA and the state authority.

- (G) Providers of ~~methadone-medication~~ 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.
- (H) A written, signed, and dated physician's order shall be required and a copy maintained in the patient's record, for all ~~methadone-medication~~ administered, personally furnished, or dispensed. The prescribing physician must be a staff member or contract employee of the methadone program.
- (I) Labels for dispensing or personally furnishing ~~methadone-medication assisted treatment~~ 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.
- (J) ~~Methadone-Medication assisted treatment~~ orders shall be written by a ~~program physician~~ prescriber 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~~ prescriber's order for ~~methadone-medication assisted treatment~~ shall be valid for a maximum time period of ninety days.
 - (2) A ~~physician's~~ prescriber's order for ~~methadone-medication assisted treatment~~ shall be reviewed at least every ninety days and adjusted, reordered, or a notation made that ~~methadone~~ the medication is to be discontinued.
- (K) ~~Methadone-Opioid treatment~~ 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. Upon approval of an exception request from the state authority and SAMHSA, opioid treatment programs may close for one business day twice per year for administrative planning purposes. Closure dates may not be within the same sixth month period.
- (L) The take-home supply for patients enrolled in ~~the methadone program~~ an opioid treatment program receiving methadone 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~~ opioid treatment program is closed in observance of the holiday.

(M) The take-home supply for patients enrolled in an opioid treatment program receiving partial opioid agonist during the first ninety days of treatment is limited to a 14 days' supply. After the first 90 days of treatment, the amount of take-home supply may never exceed one month.

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

~~(N)~~(O) If the ~~methadone~~-opioid treatment program is closed for any of the following federal holidays, all patients receiving methadone 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

~~(O)~~(P) The opioid treatment program shall have written procedures for take-home ~~methadone~~-medication assisted treatment doses that include:

- (1) Statement that the ~~methadone~~-opioid treatment 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~~ medication;

- (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~~ medications used for medication assisted treatment, 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;
 - (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;
 - (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 assisted treatment outweighs the potential risks of diversion; and,
 - (k) Employment status of patient.
- (5) Statement that physician orders for take-home ~~methadone~~ medication for substance use disorders 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 to the first take-home dose.
- (7) Requirement that child-resistant packaging ~~and or~~ caps be used for take-home doses of ~~methadone medication~~ medications for substance use disorders; and,

- (a) If a take-home bottle or other form of packaging is returned by a patient for refills, the ~~methadone~~ opioid treatment program shall accept the bottle or other form of packaging and dispose of it.
 - (b) If a take-home bottle or other form of packaging is utilized for take home doses, the medication bottles ~~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).
- (8) Requirement that each take-home bottle or other form of ~~methadone~~ medication packaging used for medication assisted treatment dispensed or personally furnished have a label that contains the following information:
- (a) The ~~methadone~~ opioid treatment 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;
 - (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.
- ~~(P)~~(Q) An individual must be a patient of a ~~methadone~~ opioid treatment program licensed by the department in order to receive ~~methadone~~ medication assisted treatment under the provisions of this rule except as otherwise provided in this rule.
- ~~(Q)~~(R) 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;
- (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 thirty 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.

~~(R)~~(S) The provision of interim ~~methadone~~ maintenance with medication assisted treatment is prohibited under this rule unless the ~~methadone-opioid~~ 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 for patients receiving methadone: 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.
- (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.
- (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.

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

(1) Requirement that each woman admitted to the ~~methadone~~-opioid treatment program be informed of the possible risks to herself or to her unborn child from the use of ~~methadone~~-medication assisted treatment, and be informed that abrupt withdrawal from these medications may adversely affect the unborn child;

(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~~-medication assisted treatment 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~~-medication assisted treatment is justified in their clinical opinion;

(3) Requirement that the admission of each pregnant woman to a ~~methadone~~-opioid treatment 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)~~(4) Requirement that ~~methadone~~-opioid 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;

~~(6)~~(5) Requirement that each pregnant woman be given education on recognizing the symptoms of neonatal abstinence syndrome near the time of delivery;

~~(7)~~(6) 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~~an opioid treatment 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;

- (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~~ opioid treatment 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~~ on medication assisted treatment; however, such notice shall only be given after the patient has signed a release of information;
- (e) Requirement that any changes in ~~methadone~~ medication assisted 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~~ medication dose carefully throughout the pregnancy, moving rapidly to supply increased or split dose if it becomes necessary;
- (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;
- (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,
- (8)(7) Statement that if a patient refuses prenatal service by the ~~methadone~~ opioid treatment program and by an outside provider:
 - (a) The medical director or other authorized program physician shall note this in the clinical record; and,
 - (b) The patient will be asked to sign a statement that says "I have been offered the opportunity for prenatal care by the ~~methadone~~ opioid

treatment 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~~ opioid treatment program. I refuse to permit the ~~methadone~~ opioid treatment 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.

(U) If a patient desires to be permanently transferred, medication assisted treatment administration shall continue until the patient completes the admission process at the admitting program.

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Program policies and patient records.

- (A) Each ~~methadone~~opioid treatment 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~~medication 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;
 - (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~~opioid treatment program within the last two years; and,
 - (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.
 - (2) Admission procedures for ~~methadone~~medication 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) Policies and procedures for the frequency of testing someone with new or increased risk factors for tuberculosis, sexually transmitted diseases, hepatitis type B and C, and HIV disease.
 - ~~(4)~~(5) 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.
 - ~~(5)~~(6) 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)(7) Procedures for the ordering, delivery, receipt and storage of ~~methadone~~any medication used for medication assisted treatment;
- (7)(8) 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)(9) Policy or procedure which specifies which staff will have access to the program's ~~methadone~~medication assisted treatment supply;
- (9)(10) Procedures for administering ~~methadone~~medication assisted treatment in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (10)(11) Procedures for dispensing ~~methadone~~medication assisted treatment, including days and hours, in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (11)(12) Policy or procedure for days and hours for non-medication dispensing program services;
- (12)(13) 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)(14) 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)(15) Policies and procedures for take-home doses of ~~methadone~~medication assisted treatment in accordance with the requirements of rule 5122-40-06 of the Administrative Code;
- (15)(16) Policy or procedure for urinalysis for ~~methadone~~ patients in accordance with the requirements of rule 5122-40-11 of the Administrative Code;
- (16)(17) Policies and procedures for urinalysis for employees of the ~~methadone~~opioid treatment program;

- (17)(18) Procedure for cleaning the ~~methadone~~-medication areas;
- (18)(19) Policies and procedures for missed ~~methadone~~-medication administration appointments;
- (19)(20) Policies and procedures stating that ~~methadone~~-medication assisted treatment shall not be provided to a patient who is known to be currently receiving ~~methadone~~-medication assisted treatment from another ~~methadone~~ opioid treatment program with the exception of guest dosing patients whose need for ~~methadone~~-medication maintenance has been verified by the medical director or other authorized program physician of both the ~~methadone~~ maintenance opioid treatment program where the patient is currently enrolled and at the program where the patient is requesting to receive services;
- (20)(21) Policies and procedures related to disaster planning, pursuant to rule 5122-40-12 of the Administrative Code;
- (21)(22) Policies and procedures relating to a diversion control plan, pursuant to rule 5122-40-10 of the Administrative Code; and,
- (22)(23) 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.
- (24) Policies and procedures relating to permanent patient transfer, pursuant to rules 5122-40-08 of the administrative code.
- (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 for serological tests for hepatitis type B and C performed by the program or a copy of results when performed by another entity. The program may accept results from tests performed within the past six months;

- (6) Result of a serological test for HIV performed by the program or a copy of results when performed by another entity within the past six months. The program may accept results from tests performed within the past six months;
- ~~(5)~~(7) Results of a serological test for syphilis performed by the program or a copy of results when performed by another entity within the past six months. The program may accept results from tests performed within the past six months;
- ~~(6)~~(8) Results of tubercular skin test or interferon gamma release assay (IGRA) blood test performed by the program or a copy of results when performed by another entity within the past six months. The program may accept results from tests performed within the past six months;
- ~~(7)~~(9) Results of a urinalysis for drug determination at the time of admission and the results of each subsequent urinalysis;
- ~~(8)~~(10) Assessment in accordance with Chapter 5122-29 of the Administrative Code;
- ~~(9)~~(11) Individualized treatment plan in accordance with Chapter 5122-27 of the Administrative Code;
- ~~(10)~~(12) Progress notes in accordance with Chapter 5122-27 of the Administrative Code;
- ~~(11)~~(13) Documentation of counseling on preventing exposure to tuberculosis, hepatitis type B and C, and the transmission of human immunodeficiency virus (HIV) disease;
- ~~(12)~~(14) 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:
- (a) Vocational rehabilitation services;
 - (b) Employment services; and.
 - (c) Education services.
- ~~(13)~~(15) 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 treatment program. This documentation may be stored in either the client record or the central registry system;

- ~~(14)~~(16) Documentation to reflect verification by the medical director or other authorized program physician of the need for ~~opioid agonist~~ medication assisted treatment for guest dosing patients;
- ~~(15)~~(17) Information required by Chapter 5122-27 of the Administrative Code; and,
- ~~(16)~~(18) Documentation of any check of the prescription drug monitoring program data pursuant to rule 5122-40-08 of the Administrative Code.
- (C) ~~Methadone patient~~Patient records shall be maintained for at least seven years from the last date of administering or dispensing a controlled substance.

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Monitoring program.

- (A) Each ~~methadone~~-opioid treatment program shall review state's drug database as described in section 4729.75 of the Revised Code (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;
 - (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.
- (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 section 4729.86 of the Revised Code.
- (B) All ~~methadone~~-opioid treatment 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~~-opioid 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 first of each year.
- (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~~
Within 24 hours of patient admission or discharge, the program shall report to the central registry, patient admission 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,
- (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.

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.

- (4) A patient's medication and dosage shall be updated within the central registry system at least once a week for disaster planning efforts.
- (C) ~~Methadone-Opioid~~ 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~~ medication assisted treatment to a patient who is simultaneously receiving ~~opioid agonist or partial opioid agonist~~ medication assisted treatment from another program;
- (b) Require the patient to sign a written statement documenting whether they are currently receiving ~~opioid agonist or partial opioid agonist~~ medication assisted 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;
- (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.
- (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 central registry system and within a radius of two one hundred statute miles to determine if the patient is simultaneously receiving opioid agonist or partial opioid agonist therapy from another program; and,
- (f) Document in the patient record all information provided and authorizations of release of information signed pursuant to this rule.

- (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.
- (3) If the patient states that they are currently receiving ~~opioid agonist or partial opioid agonist therapy~~ medication assisted treatment 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~~ medication assisted treatment;
 - (b) Provide patient education materials about the transfer process, including but not limited to the length of time associated with the transfer process, responsibilities of the patient, responsibilities of each agency; and client rights to be re-admitted to the transferring agency if space is available;
 - ~~(b)~~(c) Contact the previous program by telephone and notify the program that the individual has applied for admission for ~~methadone~~ medication assisted treatment;
 - (d) Request information to be transferred from the previous program to the admitting program within 72 hours that includes medication type; medication dosage; length of time in treatment; current take home regimen or phase level; and most recent urine drug screen results;
 - ~~(e)~~(e) Request the program to cease providing ~~opioid agonist or partial opioid agonist~~ medication assisted treatment if it has not already done so, and only if the admitting program has documentation to verify medication type and dosage;
 - ~~(e)~~(f) 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,

~~(e)~~(g) 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.

(4) If the patient states that they are a visiting patient approved to receive services on a temporary basis, before providing ~~methadone~~ medication assisted 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~~ medication assisted treatment 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.

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

(6) When a program determines that it is providing ~~methadone~~ medication assisted 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.
- (7) The program which agrees to accept sole responsibility for a patient with multiple enrollments shall continue to provide ~~methadone~~ medication assisted 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 seventy-two 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 seventy-two hours of the discharge.
- (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) of this rule.
- (D) ~~A methadone~~ An opioid treatment program that has followed the requirements of paragraph (C) of this rule 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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Non-medication services.

- (A) ~~Methodone~~Opioid treatment 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)~~(1) After July 1, 2017 the ~~The~~ general services, SUD case management services, and crisis intervention services pursuant to Chapter 5122-29 of the Administrative Code.
 - ~~(3)~~(2) 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 ~~methodone-opioid treatment 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. Services provided through medication units are subject to rule 5122-40-15 of the Administrative Code.
- (C) 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;
 - (e) Drug safety issues;
 - (f) Dispensing procedures and dosage restrictions; and,

- (g) Side effects of medications administered or prescribed by the program.
 - (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;
- (D) Every person admitted to a ~~methadone~~ opioid treatment 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;
 - (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; and,
 - ~~(h) Incentives, if offered; and,~~
 - ~~(i)~~ (h) 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~~-opioid treatment program; and any financial arrangements for services provided by the ~~methadone~~-opioid treatment program;
 - (5) Familiarization with the ~~methadone~~-opioid treatment programs facility and premises;
 - (6) Provision of a naloxone kit including the nasal atomizer or other device furnished by the ~~methadone~~-opioid treatment program, or a prescription for such kit.
 - (a) The ~~methadone~~-opioid 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~~-opioid treatment program shall provide a new naloxone kit or prescription upon expiration or use of the old kit.
 - (c) The ~~methadone~~-opioid treatment program shall be exempt from this requirement for one year if the client refuses the naloxone kit or already has a naloxone kit.
- (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.
- (F) Each ~~methadone~~-opioid 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.

- (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 the counselor in collaboration with the patient 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.

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Diversion.

(A) Each ~~methadone~~-opioid treatment 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.

(2) Diversion control plans shall minimize the diversion of ~~opioid agonist and partial opioid agonist~~medications used for medication assisted treatment 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.

(B) Each ~~methadone~~-opioid treatment program shall have written pharmacy procedures that include:

(1) Requirement that accurate records for ~~opioid agonist medication~~medications used for medication assisted treatment 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;

(2) Requirement that the ~~methadone~~-opioid treatment 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~~medications used for medication assisted treatment 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~~ medications used for medication assisted treatment must be an employee of the ~~methadone~~ opioid treatment program.
 - (b) The ~~methadone~~ opioid treatment program shall maintain a current list of those employees who are authorized to receive delivery of ~~opioid agonist and partial opioid agonist medications~~ medications used for medication assisted treatment. The list shall indicate the name and license number of each person and be signed and dated by the medical director of the ~~methadone~~ opioid treatment program.
- (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~~ medications used for medication assisted treatment, 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~~ medications used for medication assisted treatment 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.
- (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~~ medication assisted treatment storage and dispensing area; and,
- (8) Requirement that ~~opioid agonist and partial opioid agonist~~ medications used for medication assisted treatment 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.

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Toxicology.

Each ~~methadone~~-opioid treatment 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.
- (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.
- (C) Requirement that programs shall have a standing physician's order for patient toxicology screening.
- (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.
- (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.
- (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.
- (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.
- (H) Provisions for ensuring that presumptive laboratory results are distinguished from confirmatory laboratory results.
- (I) The program shall have a policy for the discontinuation of ~~methadone~~ medication 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.

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Disaster plan.

- (A) Each ~~methadone~~-opioid treatment program shall maintain an up-to-date disaster plan that addresses emergency situations including fire emergencies, tornadoes, earthquakes, flooding, winter storms, and involuntary temporary or permanent facility closure.
- (B) ~~Methadone~~-Opioid 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;
 - (2) Identify external resources and areas of need that shall include at minimum:
 - (a) Suppliers of ~~methadone~~medication used for treatment of substance use disorder;
 - (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.
- (C) Each ~~methadone~~-opioid treatment program shall provide the state authority with the emergency contact information for at least one member of the organization.

- (D) Each ~~methadone-opioid~~ 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.

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Evaluation activities.

- (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.
- (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~~;
 - (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;
 - (12) The number of overdose episodes experienced while in treatment;
 - (13) The patient's referral source; and,
 - (14) The patient's tobacco use.
- ~~(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 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.~~

~~(D)~~(C) Programs shall enter data for paragraph (B)~~(11)~~ of this rule directly into the central registry system ~~on at least a quarterly basis~~ by the sixth working day of each month.

~~(E)~~(D) 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.

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Program withdrawal.

(A) Administrative withdrawal is an involuntary withdrawal or administrative discharge from a ~~methadone~~-opioid 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;

(c) Absence from scheduled treatment appointments; or,

(d) Urine drug screens inconsistent with the patient's treatment plan.

(2) The ~~methadone~~-opioid 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~~-Opioid 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~~-opioid 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~~-opioid 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.

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5122-40-15**Medication units.**

- (A) Opioid treatment programs may voluntarily establish medication units with the appropriate licensure from the Ohio department of mental health and addiction services, the United States drug enforcement agency, the substance abuse and mental health services agency, and the Ohio board of pharmacy.
- (B) Medication units may be located in:
- (1) Homeless shelters, jails, prisons, or county or local boards of public health, located no further than ninety miles from the primary opioid treatment program;
 - (2) Federally qualified health centers, located no further than ninety miles from the primary opioid treatment program;
 - (3) Providers certified to provide ASAM level three residential substance use disorder services in accordance with rule 5122-29-09 of the Ohio administrative Code, located no further than ninety miles from the primary opioid treatment program;
or
 - (4) Appalachian counties, as defined by [https://www.arc.gov/appalachian region/CountriesinAppalachia.asp](https://www.arc.gov/appalachian_region/CountriesinAppalachia.asp). These medication units may be opened no closer than forty-five miles and no further than ninety miles to the primary opioid treatment program.
- (C) Medication units shall provide medication dosing and may provide urine screen collection, and shall adhere to all state and federal regulations for those services. Any other services provided at the medication unit shall have prior approval by Ohio department of mental health and addiction services and the substance abuse and mental health services agency.
- (D) The primary opioid treatment program is responsible for keeping all of the documentation on each patient, which may be accessed through electronic means by the medication unit. Original paper records generated by the medication unit shall be transferred to the hub after generation.
- (E) The initial patient intake, behavioral health assessment, and medical examination along with all other behavioral health assessments shall be at the primary opioid treatment program.
- (F) The medical director shall maintain authority over the medical aspects of treatment offered by the medication unit. The medical director shall not be expected to be present at the medication unit, they shall attend and document weekly calls with staff from the medication unit that cover the clinical care of patients at the medication unit.

The medical director shall visit the medication unit at least:

(1) Once per month; and

(2) After any patient death that is determined to be as a result of an overdose .

(G) The medication unit shall obtain its supply of approved controlled substance directly from the manufacturer and maintain its inventory in accordance with applicable state and federal regulations.

(H) The medication unit shall participate in the central registry system to prevent clients from dosing at the primary opioid treatment program and the medication unit in compliance with rule 5122-40-08 of the administrative code.

(I) If an opioid treatment program voluntarily decides to close the operation of a medication unit, it shall notify the Ohio department of mental health and addiction services, the United States drug enforcement agency, the substance abuse and mental health services agency, and the Ohio board of pharmacy at least ninety days before the planned closure of the program. The opioid treatment programs shall present a plan to transfer existing patients to similar opioid treatment programs or other suitable treatment programs at the time of the notification.

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