TO BE RESCINDED

5122-29-35 **Licensure to conduct an opioid agonist program.**

(A) The purpose of this rule is to state the minimum requirements that a program must meet in order to be licensed to conduct an opioid agonist program by the department.

(B) Definitions:

(1) "Administration" means the direct application of an opioid agonist medication to a client. Opioid agonists shall only be administered orally.

(2) "Detoxification" means the administering of an opioid agonist treatment 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.

(3) "Dispense", as used in this Chapter means the final association of an opioid agonist medication for take home doses with a particular client 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 opioid agonist medication.

(4) "Interim opioid agonist maintenance" means maintenance provided in conjunction with appropriate medical/somatic services while a client is awaiting transfer to a program that provides comprehensive maintenance.

(5) "Long-term detoxification" means the administering of an opioid agonist medication for detoxification of a client for a period of more than thirty days but not in excess of one hundred eighty days.

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

(7) "Medication unit" means a unit established by an opioid agonist maintenance program solely to dispense opioid agonist medication for observed ingestion.

(8) Opioid agonist means methadone or levomethadyl acetate hydrochloride (LAAM).

(9) " Opioid agonist maintenance" means the administering or dispensing of opioid agonist medication at stable dosage levels for a period in excess of twenty-one days in the treatment of a client for opioid addiction.

(10) "Program sponsor" is a person or representative of the program, who is responsible for the operation of the opioid agonist 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.

(11) "Short-term detoxification" means the administering of an opioid agonist medication for detoxification of a client for a period not to exceed thirty days.

(C) This rule is applicable to any program subject to opioid agonist program licensure in accordance with section 3793.11 of the Revised Code, which includes:

(1) Any program that administers or dispenses an opioid agonist medication for the treatment of opioid addiction.

(2) Any physician who administers or dispenses an opioid agonist medication for the treatment of opioid addiction. A physician is considered a program if she/he administers or dispenses an opioid agonist medication for the treatment of narcotic addiction and is required to meet the requirements of this rule to be licensed as an opioid agonist program.

(D) An alcohol and drug addiction program desiring to be licensed as an opioid agonist program shall apply to the department for licensure in accordance with rule 3793:2-1-01 of the Administrative Code, program certification process. A license to conduct an opioid agonist program is for a one-year time period.

(E) The provision of an interim opioid agonist maintenance program is prohibited under this rule.

(F) Each site applying for or maintaining a license to conduct an opioid agonist program shall:

(1) Be owned and operated by an agency that has owned and operated an alcohol and drug addiction treatment program that has been certified by the Ohio

department of alcohol and drug addiction services for a minimum of two years.

(2) Be accredited as an opioid treatment program by an accreditation body that has been approved by the substance abuse and mental health services administration.

(3) Be certified by the Ohio department of alcohol and drug addiction services as an:

(a) Alcohol and drug addiction outpatient program in accordance with rule 3793:2-2-01 of the Administrative Code or

(b) Alcohol and drug addiction residential program in accordance with rule 3793:2-5-01 of the Administrative Code.

(4) Have a current certification from the substance abuse and mental health services administration to use an opioid agonist in the maintenance treatment of opioid addiction.

(5) Have a terminal distributor of dangerous drugs license from the Ohio state board of pharmacy.

(6) Have a security and alarm system that is approved by the U.S. drug enforcement administration.

(7) Meet the security requirements for the distribution and storage of controlled substances as required by 21 CFR 1301.72 through 1301.76.

(8) Have a program sponsor who has signed and submitted form SMA-162, application for certification to use opioid drugs in a treatment program under 42 C.F.R. 4095, to the substance abuse and mental health services administration.

(9) Have a physician who is the medical director for the program.

(a) The physician must be licensed by the Ohio state medical board.

(b) The physician must have a current U.S. drug enforcement administration registration certificate for prescribing controlled substances.

(10) Operate the program in accordance with 21 CFR 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."

(G) An alcohol and drug addiction program that provides opioid agonist administration services must be licensed by the department as an opioid agonist program.

(H) Opioid agonist administration services shall consist of face-to-face interactions with clients, and opioid agonist medication shall only be administered or dispensed in oral, liquid doses.

(I) An individual must be a client of an opioid agonist program licensed by the department in order to receive opioid agonist medication under the provisions of this rule except as otherwise provided in this rule.

(J) Opioid agonist administration services shall be provided in a manner to ensure privacy.

(K) Opioid agonist administration services 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) Registered nurse.

(3) Licensed practical nurse who has proof of completion of a course in medication administration approved by the Ohio board of nursing.

(L) Dispensing of opioid agonist medication shall only be done by individuals who have one or more of the following credentials from the applicable state of Ohio board:

(1) Licensed physician.

(2) Pharmacist.

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

(1) Licensed physician.

(2) Registered nurse.

(N) The program's opioid agonist medical services component shall be supervised by an individual who:

(1) Is a physician licensed by the state of Ohio medical board.

(2) Is identified as the "medical director" of the opioid agonist program as required by 42 C.F.R. 4096.

(O) A written, signed, and dated physician's order shall be required and a copy maintained in the client's record, for all opioid agonist medication administered or dispensed. The prescribing physician must be a staff member or contract employee of the opioid agonist program.

(P) Labels for dispensing opioid agonist medication shall be prepared in accordance with 21 C.F.R. 1306.14 and section 3719.08 of the Revised Code.

(Q) Opioid agonist client records shall be maintained for at least seven years from the last date of administering or dispensing a controlled substance.

(R) Each opioid agonist program shall have written policies and/or procedures that include, but are not limited to, the following:

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

(a) Determination by an individual qualified to diagnose per rule 3793:2-1-08 of the Administrative Code that the client is currently dependent on an opioid drug according to the current diagnostic and statistical manual for mental disorders.

(b) The client 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 client 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 an opioid agonist

program within the last two years.

(c) A client 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 opioid agonist 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 client admitted or readmitted to maintenance or detoxification treatment.

(4) Procedures for the ordering, delivery, receipt and storage of opioid agonist medication.

(5) Policy and/or procedure for the security alarm system that includes, but is not limited to, the following:

(a) Provisions for testing the alarm system.

(b) Provisions for documenting the testing of the alarm system.

(6) Procedures for administering opioid agonist medication.

(7) Procedures for dispensing opioid agonist medication.

(8) Policy and/or procedure for the involuntary termination of opioid agonist clients.

(9) Policy and/or procedure for referring or providing prenatal services to pregnant opioid agonist clients.

(10) Policy and/or procedure for take-home doses of opioid agonist medication if dispensed.

(11) Policy and/or procedure for urinalysis for methadone clients.

(12) Policy and/or procedure for urinalysis for employees of the opioid agonist

program.

(13) Policy and/or procedure for cleaning the opioid agonist medication areas.

(14) Policy and/or procedure for missed opioid agonist administration appointments.

(15) Policy and/or procedure stating that opioid agonist medication shall not be provided to a client who is known to be currently receiving opioid agonist medication from another opioid agonist program with the exception of transient clients whose need for opioid agonist maintenance has been verified by the medical director or other authorized program physician of both the opioid agonist maintenance program where the client is currently enrolled and at the program where the client is requesting to receive services.

(S) Opioid agonist programs shall provide the following services in addition to those services required by an outpatient program in accordance with rule 3793:2-2-01 and/or a residential program in accordance with rule 3793:2-5-01 of the Administrative Code:

(1) Opioid agonist administration which meets the requirements of rule 3793:2-3-01 of the Administrative Code, opioid agonist administration.

(2) Urinalysis services which meet the requirements of rule 3793:2-3-01 of the Administrative Code, urinalysis services.

(3) Medical/somatic services.

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

(T) All services shall be provided at the opioid agonist program site unless the program sponsor has entered into a written agreement with another entity to provide certain services (e.g., vocational, educational, etc.) for clients enrolled in the opioid agonist program. The program sponsor shall document that these services are fully and reasonably available to all clients.

(U) Each opioid agonist maintenance program shall, as part of its quality improvement plan, conduct ongoing assessment of client outcomes.

(V) Each opioid agonist maintenance 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.

(W) Each opioid agonist program shall have a medical director whose responsibilities include, but are not limited to, the following:

(1) Ensuring that the opioid agonist program is in compliance with all federal, state and local laws and regulations regarding the medical treatment of opiate addiction.

(2) Ensuring that evidence of current physiologic dependence on an opiate, length of opiate dependence and exceptions to admission criteria are documented in the client's clinical record before the client receives the initial dose of opioid agonist medication.

(3) Ensuring that a medical history and a physical examination have been done before a client receives the initial dose of opioid agonist medication.

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

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

(6) Developing a policy and procedures for take-home doses of opioid agonist medication.

(7) Ensuring that justification for take-home doses is recorded in the client's clinical record.

(8) Ensuring individuals are appropriately admitted to the opioid agonist program.

(9) Ensuring all medical/somatic services are appropriately performed by the opioid agonist program.

(X) Each opioid agonist program shall have a program sponsor who is the person named

in the application for certification described in 42 C.F.R. 4095 as responsible for the operation of the opioid agonist treatment program and who assumes responsibility for all its employees, including any practitioners, agents or other persons providing medical, rehabilitative or counseling services at the program. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

(Y) Opioid agonist programs are prohibited from establishing medication units as described in 42 CFR Part 8 Subsection 8.11.

(Z) The requirements of this rule apply to short-term and long-term opiate detoxification.

(1) Short-term opiate detoxification shall not exceed thirty calendar days.

(2) Long-term opiate detoxification shall not exceed one hundred eighty calendar days.

(3) Take-home doses of opioid agonist medication shall not be permitted for clients who are on short-term opiate detoxification.

(AA) Each opioid agonist program shall have written pharmacy procedures that include:

(1) Requirement that accurate records for opioid agonist medication administered and dispensed be traceable to specific clients and show the date, quantity and batch or lot number of the opioid agonist medication bottle used for preparing individual doses of opioid agonist medication. These records shall be maintained for at least seven years from the last date of administering or dispensing the methadone.

(2) Requirement that the opioid agonist program meet the security standards for the distribution and storage of controlled substances as required by the U.S. drug enforcement administration as outlined in 21 CFR 1301.72 through 1301.76.

(3) Requirement that opioid agonist medication be stored in accordance with 21 CFR 1301.72.

(a) Opioid agonist medication shall be stored in a safe having the following specifications or the equivalent: thirty man-minutes against surreptitious entry, ten man-minutes against forced entry, twenty man-hours against lock manipulation and twenty man-minutes against radiological techniques.

(b) If the safe weighs less than seven hundred fifty pounds, it shall be bolted or cemented to the floor or to a wall in such a way that it cannot be readily removed.

(c) The safe shall be equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond.

(d) The safe shall be housed in a room equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection agency or a local or state police agency which has a duty to respond.

(4) Requirement that the acceptance of delivery of opioid agonist medication 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 medication must be an employee of the opioid agonist program.

(b) The opioid agonist program shall maintain a current list of those employees who are authorized to receive delivery of opioid agonist medication. The list shall indicate the name and license number of each person and be signed and dated by the medical director of the opioid agonist program.

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

(6) Requirement that the program notify the field division of the U.S. drug enforcement administration for its geographical area of any theft or significant loss of any controlled substance, including , opioid agonist medication upon the discovery of the loss or theft.

(a) The program shall complete DEA form 106 regarding any loss or theft.

(b) The Ohio state board of pharmacy, in accordance with rule 4729-9-15 of the Administrative Code, the Ohio department of alcohol and drug addiction services and the local law enforcement authorities shall be immediately notified of any loss or theft.

(7) Statement that adequate precautions shall be taken to store medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security.

(8) Requirement that clients be required to wait in an area physically separated from the opioid agonist storage and dispensing area.

(9) Requirement that opioid agonist storage and dispensing areas shall:

(a) Be located where personnel will not be unduly interrupted when handling drugs.

(b) Be maintained in a clean and orderly manner.

(c) Not be cleaned by a current client of the program.

(BB) Opioid agonist medication orders shall be written by a program physician who is licensed by the Ohio state medical board and registered with the U.S. drug enforcement administration to order opioid agonist treatment medications. The following procedures shall be followed in writing physician orders for opioid agonist medication.

(1) A physician's order for opioid agonist medication shall be valid for a maximum time period of ninety days.

(2) A physician's order for opioid agonist medication shall be reviewed at least every ninety days and adjusted, reordered or a notation made that opioid agonist medication is to be discontinued.

(CC) Opioid agonist programs shall be open at least six days per week every week, except that programs may close on state holidays indicated in paragraph (II) of this rule.

(DD) The take-home supply for clients enrolled in the opioid agonist program during the first ninety days of treatment is limited to a single dose each week. The client shall

ingest all other doses under appropriate supervision in accordance with this rule. At the discretion of the medical director or other authorized program physician, a client may receive one additional take-home dose for those holidays listed in paragraph (II) of this rule if the opioid agonist program is closed in observance of the holiday.

(EE) Clients enrolled in the opioid agonist program in the second ninety days of treatment are eligible for consideration by the medical director or other authorized program physician for a maximum of two take-home doses per week including the holidays listed in paragraph (II) of this rule.

(FF) Clients enrolled in the opioid agonist program in the third ninety days of treatment are eligible for consideration by the medical director or other authorized program physician for a maximum of three take-home doses per week including the holidays listed in paragraph (II) of this rule.

(GG) Clients enrolled in the opioid agonist program in the remaining months of the first year of treatment are eligible for consideration by the medical director or other authorized program physician for a maximum of a six-day supply of take-home medication per week including the holidays listed in paragraph (II) of this rule.

(HH) Clients enrolled in the opioid agonist program after one year of continuous treatment are eligible for consideration by the medical director or other authorized program physician for a maximum two-week supply of take-home medication per week including the holidays listed in paragraph (II) of this rule.

(II) If the opioid agonist program is closed for any of the following state holidays, all clients may be given a one day take-home dose of opioid agonist at the discretion of the medical director.

(1) Thanksgiving day.

(2) Christmas day.

(3) New year's day.

(4) Martin Luther King day.

(5) Presidents' day

(6) Memorial day

(7) Fourth of July

(8) Labor day

(JJ) The program shall have written procedures for take-home opioid agonist doses that include:

(1) Statement that the opioid agonist program decisions on dispensing take-home doses of opioid agonist medication shall be determined by the medical director or other authorized program physician.

(2) Statement that a take-home dose of opioid agonist medication is an earned privilege and not a right.

(3) Requirement that take-home doses of opioid agonist medication shall be given only to an opioid agonist client, who, in the opinion of the medical director or other authorized program physician, is responsible in handling opiate drugs.

(4) Statement that before a medical director or other authorized program physician authorizes take-home doses of opioid agonist medication, the medical director or other authorized program physician shall record the rationale for this decision in the client'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 opioid agonist 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 client's home environment.

(g) Stability of the client's social relationships.

(h) Length of time in comprehensive maintenance treatment.

(i) Assurance that take-home doses of opioid agonist can be safely stored within the client's home.

(j) Determination if the rehabilitation benefit to the client by receiving a take-home dose of opioid agonist medication outweighs the potential risks of diversion.

(k) Employment status of client.

(5) Statement that physician orders for take-home opioid agonist medication shall expire every ninety days.

(6) Requirement that child-proof bottles and caps be used for take-home doses of opioid agonist medication.

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

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

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

(7) Requirement that each take-home bottle of opioid agonist medication have a label that contains the following information:

(a) The opioid agonist program's name, address and telephone number.

(b) Name of client.

(c) Name of program physician prescribing the opioid agonist medication.

(d) The name of the opioid agonist medication.

(e) The dosing instructions and schedule.

(f) Date that the take-home opioid agonist 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 client for whom it was prescribed."

(KK) Each opioid agonist program shall have written procedures for urinalysis that include, at a minimum:

(1) Requirement that an initial urinalysis be performed for each prospective opioid agonist client 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.

(2) Requirement that a urinalysis be performed monthly for each opioid agonist client.

(3) Requirement that programs shall have a standing physician's order for client urinalysis.

(4) Requirement that urinalysis be performed by a laboratory that is in compliance with all applicable federal proficiency testing and licensing standards.

(5) Requirement that urine specimens be collected in a manner to minimize falsification and that urine collection procedures include the following:

(a) A program employee shall monitor each specimen collected.

(b) Each urine specimen shall be labeled to reflect the identification of the person from whom it was obtained and reflect the date the specimen was obtained.

(6) Chain of custody for urine specimens.

(7) Requirements that each urinalysis include, at a minimum analysis for the following:

(a) Opiates.

(b) Methadone.

(c) Amphetamines.

(d) Cocaine.

(e) Barbiturates.

(f) Marijuana

(8) Results of urinalysis testing shall be reviewed by the program staff with the client with documentation of such and a copy of the results placed in the client's file.

(9) Provisions for ensuring that presumptive laboratory results are distinguished from definitive laboratory results.

(10) Provisions for discontinuing opioid agonist maintenance if a person continues to use alcohol and/or other drugs. The policy shall include provisions for continuing to provide counseling and other rehabilitation services if opioid agonist maintenance is discontinued.

(LL) Each opioid agonist program shall have written procedures for pregnant female clients that include at least the following:

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

(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 an opioid agonist regimen.

(a) 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 opioid agonist treatment is justified in her/his clinical opinion.

(b) Requirement that the admission of each pregnant woman to an opioid

agonist program be approved by the medical director or other authorized program physician prior to admitting the woman to the program.

(3) Procedures for prenatal care that include:

(a) Provisions for providing prenatal care by the program or by referral to an appropriate health care provider.

(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 opioid agonist program, the clinical record shall include documentation to reflect services provided

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

(4) Statement that if a client refuses prenatal service by the opioid agonist program and by an outside provider:

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

(b) The client will be asked to sign a statement that says "I have been offered the opportunity for prenatal care by the opioid agonist 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 opioid agonist program. I refuse to permit the opioid agonist program to refer me to a physician or prenatal clinic for prenatal services." If the client refuses to sign the statement, the medical director or other authorized program physician shall indicate in the signature block that "client refused to sign" and affix her/his signature and the date on the statement.

(MM) Each client file shall contain the following:

(1) Date of each visit that the client makes to the program.

(2) Date, time, name and amount of opioid agonist medication administered or dispensed with the original signature of the service provider.

(3) Medical history.

(4) Documentation of physical examination and results.

(5) Results of a serological test for syphilis.

(6) Results of tubercular skin test.

(7) Results of a urinalysis for drug determination at the time of admission and the results of each subsequent urinalysis.

(8) Documentation of any significant psychological or physical disability.

(9) An individualized treatment plan shall be written for each client within seven days of completion of the assessment or at the time of the first face-to-face contact following assessment. Programs shall have written policies and procedures that specify criteria and time frames for reviewing and updating an individualized treatment plan, which take into account the client's changing clinical needs and response to treatment. The treatment plan shall be reviewed and counter-signed by a program physician at least once a year.

(10) An account of the client's progress.

(11) Documentation of counseling on preventing exposure to tuberculosis, hepatitis type B and C, and the transmission of human immunodeficiency virus (HIV) disease.

(12) Documentation of provision of the following either directly or through referral to adequate and reasonably accessible community resources:

(a) Vocational rehabilitation services.

(b) Employment services.

(c) Education services.

(13) Documentation to reflect that the program has attempted to determine whether or not the client is enrolled in any other opioid agonist maintenance program.

(14) Documentation to reflect verification by the medical director or other authorized program physician of the need for opioid agonist medication for transient clients.

(15) Information required by rule 3793:2-1-06 of the Administrative Code, client records.

(NN) Programs licensed as an opioid agonist program by the department at the time of the effective date of this rule shall remain licensed until the expiration of its current licensure. If it wants to continue to operate as a licensed opioid agonist program, then it is required to apply to the department for licensure in accordance with this rule and rule 3793:2-1-01 of the Administrative Code, program certification process.

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