Ohio Administrative Code

Rule 5122-40-06 Medication assisted treatment administration.

Effective: June 10, 2022

(A) 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) Medication administration shall be provided in a manner to ensure privacy.

(C) Methadone medication shall only be administered orally.

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

(E) Medication shall be administered 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 medication 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;

(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 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 prescriber's order shall be required and a copy maintained in the patient's record, for all medication administered, personally furnished, or dispensed. The prescriber must be a staff member or contract employee of the opioid treatment program.

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

(J) Medication orders shall be written by a prescriber who is appropriately licensed and registered with the U.S. drug enforcement administration to order medications for opioid use disorder. The following procedures shall be followed in writing prescriber orders for these medications.

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

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

(K) 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 (O) 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 of medication for patients enrolled in 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 prescriber, a patient may receive one additional take-home dose for those holidays listed in paragraph (O) of this rule if the opioid treatment program is closed in observance of the holiday.

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

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

(O) If the opioid treatment program is closed for any of the federal holidays set forth in 5 U.S. Code 6103 including but not limited to the following 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) Juneteenth National Independence day

(8) Fourth of July

(9) Labor day

(10) Columbus day

(11) Veteran's day

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

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

(2) Statement that the dispensing of medication for home administration is permitted only when such dispensing is found to be safe, outweighs potential risks, and is beneficial for the patient. Such dispensing is not a right and is not automatic. Rather it is subject to medical-legal considerations on an individual case by case basis .

(3) Requirement that take-home doses of medication shall be given only to a patient, who, in the opinion of the medical director or other authorized prescriber, is responsible in handling medication;

(4) Except during program closure on Sundays and federal holidays listed in paragraph (O) of this rule, a statement that before a medical director or other authorized prescriber authorizes take-home doses of medications, the medical director or other authorized prescriber shall record the individualized 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 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 medication 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 medication outweighs the potential risks of diversion; and,

(k) Employment status of patient.

(5) Statement that prescriber orders for take-home doses of medication shall expire every ninety days;

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

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

(a) If a take-home bottle or other form of packaging is returned by a patient for refills, the 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 -shall only be used once.

(c) Under no circumstance is 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 medication packaging used have a label that contains the following information:

(a) The opioid treatment program's name, address and telephone number;

(b) Name of patient;

(c) Name of practitioner prescribing the medication;

(d) The name of the medication;

(e) The dosing instructions and schedule;

(f) Date that the take-home 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.

(9) Condition that any take-home policies and procedures be individualized to each patient's treatment needs.

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

(R) A patient may attend a different opioid treatment program if prior approval is obtained from the patient's medical director or prescriber 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 prescriber 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 prescriber 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.

(S) A patient may receive medication at a community mental health services or addiction services provider certified for the residential and withdrawal management substance use disorder services as defined in rule 5122-29-09 of the Administrative Code, long-term care provider, or skilled nursing provider from an opioid treatment program. A temporary medication request will be submitted through the SAMHSA extranet and approved by the state authority. Medication orders are to be renewed every seven days. Medication approval will be noted in the patient's record and will 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; and

(2) A chain of custody document showing that any medication used for medication assisted treatment is transferred from medical staff of the opioid treatment program to medical staff of the partnering

provider.

(T) The provision of interim maintenance with medication is prohibited under this rule unless the 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; 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.

(U) Each opioid treatment program shall have written procedures for pregnant patients that include at least the following:

(1) Requirement that each pregnant person admitted to the opioid treatment program be informed of the possible risks to themselves or to their unborn child from the use of medication assisted

treatment, and be informed that abrupt withdrawal from these medications may adversely affect the unborn child;

(2) Statement that a pregnant person, regardless of age, who has a documented opioid use disorder and who may be in direct jeopardy of resuming illicit opioid use with all of its attendant dangers during pregnancy, may be placed on a medication assisted treatment regimen.

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

(3) Requirement that the admission of each pregnant person to an opioid treatment program be approved by the medical director or other authorized prescriber prior to admitting the person to the program;

(4) Requirement that opioid treatment programs develop a form for release of information between themselves and the healthcare provider providing obstetrical care. This voluntary form should be offered for coordination of medical care;

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

(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 person cannot afford care or refuses prenatal care services on-site or by referral, 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 person refuses the offered on-site or referred prenatal services, the medical director or treating prescriber must use informed consent procedures to have the person formally acknowledge, in writing, refusal of these services;

(b) Requirement that if a person 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 treatment program, the clinical record shall include documentation to reflect services provided;

(d) Requirement that if a person is referred outside of the agency for prenatal services, the provider to whom they have been referred shall be notified that the person is taking medication for an opioid use disorder; however, such notice shall only be given after the patient has signed a release of information;

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

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

(g) Recommendation that blood serum levels of methadone be monitored once a trimester prior to delivery. Post-partum, the patient's withdrawal symptoms and clinical status should be re-evaluated every three days for two weeks to determine the appropriate dose of MAT by the appropriate healthcare professional. The medical director or other authorized prescriber shall request and review serum levels to determine whether any changes to treatment are indicated; and,

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

(7) Statement that if a person refuses prenatal service by the opioid treatment program and by an outside provider:

(a) The medical director or other authorized prescriber 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 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 opioid treatment program. I refuse to permit the 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 prescriber shall indicate in the signature block that "patient refused to sign" and affix their signature and the date on the statement.

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