Ohio Administrative Code

Rule 5122-40-06 Medication administration.

Effective: January 31, 2025

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

(B) Medication administration is to be provided in a manner to ensure privacy.

(C) Opioid treatment programs are permitted to establish medication units following the guidelines of 42 C.F.R. 8.11(h).

(D) Medication is to be administered only by the following individuals:

(1) A physician;

(2) 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;

(3) A registered nurse;

(4) A licensed practical nurse; or

(5) A physician assistant .

A provider of medication administration is to be supervised in their medication administration if such supervision is required by statute or rules adopted by the Ohio licensing board that issued such provider's license or certification.

(E) Dispensing medication is only to be performed by pharmacists in accordance with Chapter 4729. of the Revised Code. Personally furnishing medication is to be performed in accordance with rules

adopted by the state of Ohio board of pharmacy and may only be done by the following individuals:

(1) A physician;

(2) A pharmacist pursuant to section 4729.39 of the Revised Code;

(3) A certified nurse practitioner :

(4) A physician assistant; or

(5) An individual to whom a program prescriber has delegated the act of personally furnishing as authorized by the state of Ohio board of pharmacy in accordance with Chapter 4729:5-21 of the Administrative Code.

(F) A written, signed, and dated order from a program prescriber is required for all medication admininistered, personally furnished, or dispensed . A copy of each order is to be maintained in the patient's record.

(G) Labels for dispensing or personally furnishing medication are to be prepared in accordance with 21 C.F.R. 1306.14 and section 3719.08 of the Revised Code and in accordance with Chapter 4729:5-21 of the Administrative Code.

(H) Medication orders are to be written by a program prescriber who is appropriately licensed and registered with the United States drug enforcement administration to order medications for opioid use disorder. The following procedures are to be followed in writing prescriber orders for these medications.

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

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

(I) Opioid treatment programs are to be open and administer medication at least six days per week

every week, except that programs may close on federal holidays indicated in paragraph (L) 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 are not to be within the same sixth month period.

(J) An opioid treatment program will enter into agreements with one or more alternate programs under which the opioid treatment program arranges for such programs to administer medication used in medication-assisted treatment in the event the opioid treatment program is closed due to emergency and unable to administer medication as required by paragraph (I) of this rule. Such agreements will cover any costs associated with the patient receiving the medication at the alternate site and are not to lead to any additional costs incurred by the patient.

(K) The take-home supply of medications for medication-assisted treatment for patients enrolled in an opioid treatment program receiving partial opioid agonist is limited to a one month supply. The take-home supply of such medication for patients enrolled in an opioid treatment program receiving methadone is limited to a one month supply and is to be in accordance with federal regulations.

(L) If the opioid treatment program is closed for any of the federal holidays set forth in 5 U.S.C. 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

(M) The opioid treatment program is to have written procedures for take-home medication doses that include:

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

(2) A 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) A requirement that take-home doses of medication are to be given only to:

(a) A patient, who, in the opinion of the medical director or other authorized prescriber, is responsible in handling medication; or

(b) A trusted third party in accordance with federal drug enforcement administration regulations, when the pickup is approved in advance by the SOTA.

(4) A statement that prescriber orders for take-home doses of medication expire every ninety days;

(5) A 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.

(6) RequirementA 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 is to 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 -are only to be used once.

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

(7) A requirement that each take-home bottle or other form of medication packaging used have a label that complies with section 3719.08 of the Revised Code and rule 4729:5-21-02 of the Administrative Code.

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

(N) An individual is to be a patient of an opioid treatment program licensed by the department to receive medication under the provisions of this rule except under the circumstances in paragraph (O) of this rule.

(O) A patient may attend a different opioid treatment program if prior approval is obtained from the patient's medical director or program prescriber to receive services on a temporary basis from another opioid treatment program licensed under this chapter or by SAMHSA. The approval is to be noted in the patient's record and 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.

(P) A patient may receive medication from an opioid treatment program while the patient is at or admitted to any of the following: a correctional facility or a community mental health services or addiction services provider certified for residential and withdrawal management substance use disorder services as defined in rule 5122-29-09 of the Administrative Code, a long-term care provider, a skilled nursing facility, or any other inpatient or residential facility. A temporary medication request will be submitted through the SAMHSA extranet and approved by the state authority. 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 or appropriate law enforcement staff.

(Q) An opioid treatment program may admit patients for interim treatment in accordance with 21 C.F.R. 8.12(j)..

(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 eighty

days in any twelve month period.

(3) To receive interim maintenance, a patient is to 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 are to develop clear policies and procedures governing the admission to interim maintenance and transfer of patients to comprehensive maintenance.

(R) Each opioid treatment program is to have written procedures for pregnant patients that include at least the following:

(1) A requirement that each pregnant patient admitted to the opioid treatment program be informed of the possible risks to themselves or to their unborn child from the use of medications used in medication-assisted treatment, and be informed that abrupt withdrawal from these medications may adversely affect the unborn child;

(2) A statement that a pregnant patient, 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 regimen of medications used in medication-assisted treatment.

A statement that for such pregnant patient, 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 the use of medications used in medication-assisted treatment is justified in their clinical opinion;

(3) A requirement that the admission of each pregnant patient to an opioid treatment program be

approved by the medical director or other authorized prescriber prior to admitting the person to the program;

(4) A 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) A requirement that each pregnant patient 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 patient 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 patient refuses the offered on-site or referred prenatal services, the medical director or treating prescriber is to use informed consent procedures to have the person formally acknowledge, in writing, refusal of these services;

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

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

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

(e) A 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) A 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) A 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 medications used in medication-assisted treatment by the appropriate healthcare professional. The medical director or other authorized prescriber is to request and review serum levels to determine whether any changes to treatment are indicated; and

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

(7) A 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 is to 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 is to indicate in the signature block that "patient refused to sign" and affix their signature and the date on the statement.

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