5122-40-06 **Methadone administration.**

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

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

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

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

(1) Licensed physician;

(2) Pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code but only if specifically authorized by a consult agreement and to the extent specified in the agreement;

(3) Registered nurse;

(4) Licensed practical nurse who has proof of completion of a course in medication administration approved by the Ohio board of nursing; or,

(5) Physician assistant who has proof of completion of a course in medication administration approved by the state medical board of Ohio.

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

(1) Licensed physician; or,

(2) Pharmacist pursuant to section 4729.39 of the Revised Code..

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

(1) Licensed physician; or,

(2) Registered nurse.

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

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

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

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

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

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

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

(L) 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.

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

(1) Thanksgiving day.

(2) Christmas day.

(3) New year's day.

(4) Martin Luther King day.

(5) President's day

(6) Memorial day

(7) Fourth of July

(8) Labor day

(9) Columbus day

(10) Veteran’s day

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

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

(2) Statement that a take-home dose of methadone medication is an earned privilege and not a right;

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

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

(a) Absence of recent abuse of opioid or other drugs and alcohol;

(b) Regularity of clinic attendance for methadone medication administration;

(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 outweighs the potential risks of diversion; and,

(k) Employment status of patient.

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

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

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

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

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

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

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

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

(b) Name of patient;

(c) Name of program physician prescribing the methadone medication;

(d) The name of the methadone medication;

(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.

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

(P) 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 30 days; and,

(3) Evidence that the medical director or program physician for the program contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with his or her dosage schedule, and supervises the administration of the medication.

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

(1) All of the requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions: no take-home doses are permitted; 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 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.

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

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

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

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

(3) Requirement that the admission of each pregnant woman to a methadone program be approved by the medical director or other authorized program physician prior to admitting the woman to the program;

(4) Statement that abrupt withdrawal from these medications may adversely affect the unborn child;

(5) Requirement that methadone treatment programs develop a form for release of information between themselves and the healthcare provider in care of obstetrical care. This voluntary form should be offered to all pregnant women for coordination of medical care;

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

(7) Procedures for prenatal care that include:

(a) Provisions for providing prenatal care by the program or by referral to an appropriate health care provider. If appropriate prenatal care is neither available on-site or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services on-site or by referral, a methadone program, at a minimum, should offer basic prenatal instruction on maternal, physical, and dietary care as part of its counseling services. If

a pregnant patient refuses the offered on-site or referred prenatal services, the medical director or treating physician must use informed consent procedures to have the patient formally acknowledge, in writing, refusal of these services;

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

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

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

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

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

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

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

(b) The patient will be asked to sign a statement that says "I have been offered the opportunity for prenatal care by the methadone program or by a referral to a prenatal clinic or by a referral to the physician of my

choice. I refuse prenatal counseling by the methadone program. I refuse to permit the methadone program to refer me to a physician or prenatal clinic for prenatal services." If the patient refuses to sign the statement, the medical director or other authorized program physician shall indicate in the signature block that "patient refused to sign" and affix their signature and the date on the statement.

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