

5122-40-10

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 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.

Effective: 1/1/2019

Five Year Review (FYR) Dates: 6/1/2022

CERTIFIED ELECTRONICALLY

Certification

11/05/2018

Date

Promulgated Under: 119.03
Statutory Authority: 5119.391
Rule Amplifies: 5119.391
Prior Effective Dates: 07/01/2001, 10/01/2003, 06/01/2017