



Ohio Administrative Code

Rule 4729:5-21-05 Mobile opioid treatment programs.

Effective: January 20, 2022

(A) As used in this rule, "mobile opioid treatment program" has the same meaning as "mobile narcotic treatment program" as used in 21 CFR part 1301 (7/12/2021).

(B) For any opioid treatment program intending to operate a mobile opioid treatment program, the licensee shall notify the local drug enforcement administration (DEA) office, in writing, its intent to do so, and the opioid treatment program must receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program. The mobile opioid treatment program may only operate in the same state in which the opioid treatment program is registered with the DEA.

(1) Licensees are not required to obtain a separate terminal distributor of dangerous drugs license for conveyances (mobile components) utilized by the licensee to transport dangerous drugs away from licensed locations for use as part of a mobile opioid treatment program. Vehicles must possess valid county/city and state information (e.g., a vehicle identification number (VIN) or license plate number) on file at the licensed location of the opioid treatment program licensed by the board.

(2) A mobile opioid treatment program is not permitted to reverse distribute, share, or transfer dangerous drugs from one mobile component to another mobile component while deployed outside of the licensed location. These mobile components of opioid treatment programs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and shall not transport patients.

(C) For any conveyance operated as a mobile opioid treatment program, a securely locked safe must be installed and used to store dangerous drugs in schedules II-V for the purpose of maintenance or detoxification treatment, when not located at the licensee's licensed location.

(1) The safe must conform to the requirements set forth in paragraph (a)(1) of 21 CFR 1301.72 (7/12/2021).



- (2) The mobile component shall also be equipped with an alarm system that conforms to the requirements set forth paragraph (a)(1)(iii) of 21 CFR 1301.72 (7/12/2021).
- (3) The storage area of the mobile component must conform to the accessibility requirements in paragraph (d) of 21 CFR 1301.72 (7/12/2021).
- (4) The storage area for controlled substances in a mobile component of an opioid treatment program must not be accessible from outside of the vehicle.
- (a) Authorized personnel transporting the controlled substances on behalf of the mobile opioid treatment program are required to retain control over the controlled substances when transferring controlled substances between the licensed location and the conveyance, from the conveyance to the location where medication will be administered or personally furnished, and when administering or personally furnishing medication. At all other times during transportation, all controlled substances must be properly secured in the safe.
- (b) Upon completion of the operation of the conveyance on a given day, the conveyance must be immediately returned to the licensed location, and all controlled substances must be removed from the conveyance and secured within the licensed opioid treatment program. After the conveyance has returned to the registered location and the controlled substances have been removed, the conveyance may be parked until its next use at the licensed location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area.
- (c) A mobile opioid treatment program may apply to the DEA for an exception to the requirements in paragraph (C)(4)(b) of this rule.
- (i) The application for such an exception shall be submitted in accordance with 21 CFR 1301.72.
- (ii) If an exception is granted, the licensee shall comply with the security conditions set forth in the approval granted by the DEA. Any conveyance maintained in accordance with an exception granted under this rule shall be subject to inspection by a board of pharmacy agent.



(iii) If an exception is revoked or otherwise rescinded by the DEA, the licensee shall comply with the requirements in paragraph (C)(4)(b) of this rule.

(iv) All approvals from the DEA shall be maintained at the licensed location and made immediately available for inspection by an agent of the state board of pharmacy.

(d) All opioid treatment programs with mobile components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable (mechanical failure, accidents, fire, etc.), that the controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the licensed location.

(5) Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained by the mobile opioid treatment program.

(D) Persons enrolled in any opioid treatment program, including those receiving treatment at a mobile opioid treatment program, will be required to wait in an area that is physically separated from the medication storage area and areas used for administration or personally furnishing by a physical entrance such as a door or other entryway. Patients will need to wait outside of a mobile opioid treatment program if that unit does not have seating or a reception area that is separated from the medication storage area and areas used for administration or personally furnishing. This requirement shall be enforced by the terminal distributor of dangerous drugs and the licensee's employees.

(E) Any controlled substances being transported for disposal from the location where the drugs are administered or personally furnished shall be secured and disposed of in compliance with 21 CFR 1317 (7/12/2021) and rule 4729:5-3-01 of the Administrative Code.

(F) A conveyance used as part of a mobile opioid treatment program may only be supplied with controlled substance dangerous drugs by the licensed opioid treatment program that operates such conveyance. Persons permitted to administer or personally furnish controlled substances from mobile opioid treatment programs shall not:

(1) Receive controlled substances from other mobile opioid treatment program or any other entity;



(2) Deliver controlled substances to other mobile opioid treatment program or any other entity; or

(3) Conduct reverse distribution of controlled substances on a mobile opioid treatment program.

(G) A mobile opioid treatment program shall maintain records with the following information for each dangerous drug:

(1) Name of drug;

(2) Strength of drug;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Initials of the employee personally furnishing or administering a drug.

(H) The records required by paragraph (G) of this rule shall be maintained in a log at the licensed opioid treatment program.

(1) As an alternative to maintaining a paper log, an opioid treatment program may also use an automated/computerized data processing system for the storage and retrieval of the program's records, if the following conditions are met:

(a) The automated system maintains the information required in paragraph (G) if this rule;



(b) The automated system has the capability of producing a hard copy printout of the records required in paragraph (G) of this rule;

(c) The opioid treatment program or its mobile component prints a hard copy of each day's log, which is then initialed appropriately by each person who personally furnished/administered the medication to the program's patients;

(d) The automated system is approved by DEA;

(e) The opioid treatment program or its mobile component maintains an off-site back-up of all computer generated program information; and

(f) The automated system is capable of producing accurate summary reports for both the licensed site of the opioid treatment program and any mobile component, for any time-frame selected by DEA personnel during an investigation. If these summary reports are maintained in hard copy form, they must be kept in a systematically organized file located at the licensed opioid treatment program.

(2) The opioid treatment program must retain all records for any mobile component three years from the date of execution.

(I) A mobile opioid treatment program shall comply with all other applicable requirements of 21 CFR 1301 (7/12/2021).