

Connecticut Department of Public Health
Regulation Concerning
Mobile Narcotic Treatment Programs

Section 1. The Regulations of Connecticut State Agencies are amended by adding section 19a-495-22-1 to 19a-495-22-6 as follows:

Sec. 19a-495-22-1. Definitions

Sec. 19a-495-22-2. Approval procedures

Sec. 19a-495-22-3. Mobile narcotic treatment program vehicles

Sec. 19a-495-22-4. Mobile narcotic treatment program & policies

Sec. 19a-495-22-5. Record keeping

Sec. 19a-495-22-6. Diversion

Sec. 19a-495-22-1. Definitions.

1. “Admission” means admission for maintenance treatment for opioid use disorder according to the criteria in 42 CFR 8.12.
2. “Advanced practice registered nurse” means an advanced practice registered nurse (APRN) licensed pursuant to Chapter 378 of the Connecticut General Statutes.
3. “Authorized healthcare provider” means a physician licensed pursuant to Chapter 370 of the Connecticut General Statutes, a physician assistant licensed pursuant to Chapter 370 of the Connecticut General Statutes, or an advanced practice registered nurse (APRN) licensed pursuant to Chapter 378 of the Connecticut General Statutes. For the purposes of this section, authorized healthcare providers are those who can prescribe or dispense schedule II through V medications and maintain an active controlled substance registration pursuant to chapter 420c of the Connecticut General Statutes.
4. “Commissioner” means the Commissioner of the Department of Public Health or the commissioner’s designee.
5. “Department” means the Connecticut Department of Public Health.
6. “Drug Enforcement Administration” or DEA means the United States Drug Enforcement Administration including local DEA administration.
7. “Mobile Narcotic Treatment Program” means a program as defined in 21 CFR 1300 that provides schedule II through V maintenance or detoxification medications or other treatments to individuals with opioid use disorder using a mobile narcotic treatment vehicle and is a multicare institution licensed as free-standing facility for the care or treatment of substance abusive or dependent persons that maintains a controlled substance registration.

8. "Mobile narcotic treatment vehicle" means a motor vehicle as defined in 21 CFR 1300.001(b) that is used in the operation of a mobile narcotic treatment program and is considered a satellite unit of a multicare institution licensed as free-standing facility for the care or treatment of substance abusive or dependent persons.
9. "Multicare institution" has the same meaning as in Section 19a-490 of the Connecticut General Statutes.
10. "Pharmacist" means a pharmacist licensed pursuant to Chapter 400j of the Connecticut General Statutes.
11. "Physician assistant" means a physician assistant licensed pursuant to Chapter 370 of the Connecticut General Statutes.
12. "Registered nurse" means a registered nurse licensed pursuant to Chapter 378 of the Connecticut General Statutes.
13. "Satellite unit" has the same meaning as in Section 19a-490(n) of the Connecticut General Statutes.

Sec. 19a-495-22-2. Approval Procedures

- (a) Pursuant to 19a-493c(1) of the Connecticut General Statutes, a licensed multicare institution may, under the terms of its existing license as a free-standing facility for the care or treatment of substance abusive or dependent persons, provide medication or other treatments to individuals with opioid use disorder through a mobile narcotic treatment program outside of the licensed institution using a mobile narcotic treatment vehicle. Each mobile narcotic treatment vehicle shall require a separate application and approval.
- (b) Issuance and renewal of approval to provide services from a mobile narcotic treatment program.
 - (1) Any multicare institution licensed as a free-standing facility for the care or treatment of substance abusive or dependent persons pursuant to section 19a-493 of the Connecticut General Statutes that has a license in good standing that intends to offer services through a mobile narcotic treatment program, shall submit an application to the Department of Public Health for approval of the mobile narcotic treatment program to offer services at off-site locations as a satellite unit.
 - (2) Application for approval shall be made to the Department of Public Health upon forms provided by the department.
 - (3) The application, specific to the mobile narcotic treatment program and vehicle, shall include, but not be limited to, the following:
 - (A) A description of proposed services which shall include the maximum number of individuals to be served and the duration of services;
 - (B) Insurance certificate or rider or both for workers compensation;

- (D) Insurance certificate or rider or both for general liability;
 - (E) Directory and resume of all professional staff providing services through the mobile narcotic treatment program;
 - (F) Affirmative evidence of ability to comply with reasonable standards and regulations prescribed under the provisions of Chapter 368v of the Connecticut General Statutes and all other applicable state and federal laws and regulations as it relates to the proposed satellite unit outside of the licensed institution, to include, but not be limited to, patient confidentiality and the privacy and security of patient protected information;
 - (G) The type of mobile narcotic treatment vehicle;
 - (H) The schedule of location or locations where the mobile narcotic treatment vehicle will be serving, and the overnight parking location for the mobile narcotic treatment vehicle to be registered with the DEA; and
 - (I) Any other information required by the department.
- (4) The commissioner may in the commissioner's discretion deny, suspend, or revoke any approval for a mobile narcotic treatment program for reasons including, but not limited to, the following:
- (A) The multicare institution has been found by the authority with jurisdiction to be noncompliant with applicable federal, state, local or administrative laws;
 - (B) The multicare institution has been subject to any criminal, civil or administrative actions; or
 - (C) A material misstatement of fact is made on an initial or renewal application.
- (5) Not later than forty-five days after receipt of such application, the commissioner shall notify the multi-care institution of the approval or denial of such application.
- (6) Subsequent to initial approval, a timely announced inspection of the mobile narcotic treatment program may be conducted for compliance with all applicable state and federal laws and regulations. The multicare institution is subject to biennial renewal pursuant to section 19a-493(a) of the Connecticut General Statutes, and the mobile narcotic treatment program approval may be renewed as a satellite unit at that time.
- (7) Notice to the public. A copy of the multicare institution's license, listing the mobile narcotic treatment program, shall be posted in a conspicuous location accessible to the public in the mobile narcotic treatment program vehicle.
- (8) The multicare institution shall notify the department at least thirty days prior to any changes in services provided by the mobile narcotic treatment program, including, but not limited to, termination of mobile services. The multicare institution shall provide notice to patients of changes to or termination of mobile services in accordance with all applicable regulations.

Sec. 19a-495-22-3. Mobile narcotic treatment program vehicles

- (a) The multicare institution shall register all vehicles being used as a mobile narcotic treatment program with the Connecticut Department of Motor Vehicles pursuant to Chapter 246 of the Connecticut General Statutes. Such vehicles may not be a trailer in accordance with 21 CFR 1300.01. The multicare institution shall present the vehicle registration to the Department upon request.
 - (1) The multicare institution shall ensure all mobile narcotic treatment program vehicles comply with the following requirements:
 - (A) A safe is installed in the mobile narcotic treatment program vehicle to store narcotic drugs in schedules II to V utilized for maintenance or detoxification treatment. The safe shall be secured to the floor or wall so that it cannot be moved in accordance with 21 CFR 1301.72;
 - (B) An alarm system is installed that will alert upon unauthorized entry in accordance with 21 CFR 1301.72;
 - (C) The area used for storage of any medications or treatment supplies is not accessible from the outside of the vehicle;
 - (D) The controlled substance area is only accessible to authorized multicare institution employees;
 - (E) The vehicle has a bathroom facility;
 - (F) The vehicle has handwashing capacity;
 - (G) A refrigerator is installed;
 - (H) The vehicle has the capacity for adequate storage for both clean and utility purposes; and
 - (I) The vehicle has a door that physically separates the areas between narcotic dispensing and patient waiting area. If the vehicle is not equipped with a door that physically separates the area, patients shall wait outside the vehicle.

Sec. 19a-495-22-4. Mobile narcotic treatment program and policies

- (a) The mobile narcotic treatment program shall only dispense or administer medication in a form and manner as prescribed in Sec.19a-495-570 (m)(9) of the Regulations of Connecticut State Agencies, as applicable. The mobile narcotic treatment program shall have the ability to respond to any adverse medication reactions or overdose in accordance with standards of practice.
- (b) The mobile narcotic treatment vehicle shall not transport patients for any purpose, and shall not cross state lines.

(c) All patient and controlled substance records for the mobile narcotic treatment program shall be in compliance with the record requirements outlined in sections 19a-495-570 of the Regulations of Connecticut State Agencies and shall be stored and maintained at the licensed multicare institution in accordance with Sec. 19a-495-22-5 and 21 CFR 1304.24.

(d) A multicare institution that provides services with an approved mobile narcotic treatment program shall implement and maintain written policies and protocols for each service offered. Proposed services may include but not be limited to admission, counseling, induction, and dispensing take-home treatment.

(d) If the mobile component offers admission services, the mobile component shall be staffed with a physician, physician assistant, or APRN.

(e) If the multicare institution opts to offer counseling services from the mobile component, the mobile narcotic treatment program shall ensure confidentiality in the provision of such services to patients in accordance with applicable state and federal laws and regulations.

(f) If the multicare institution opts to offer take-home narcotic treatments, the following requirements shall be met:

(1) The mobile narcotic treatment program shall adopt and implement a written policy on dispensing take-home treatment; and

(2) The mobile narcotic treatment program shall make lockboxes available as needed to patients initiating take-home treatment.

(g) The multicare institution shall issue and implement written contingency policies and protocols for the mobile narcotic treatment program, including, but not limited to the following:

- (1) Vehicle malfunction;
- (2) Weather emergency;
- (3) Medical emergency;
- (4) Schedule changes; and
- (5) Staff illness or absence.

Contingency policies and protocols shall ensure the safety of staff and individuals, and shall ensure all controlled substances are accounted for in accordance with 21 CFR 1301.72(e)(1)

(h) All medication maintenance and disposal shall be conducted in compliance with Sections 19a-495-570(m)(9) and 21a-262-3 of the Regulations of Connecticut State Agencies as applicable, and with 21 CFR 1317.

Sec. 19a-495-22-5. Record keeping

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

- (1) The automated system maintains the information required in 21 CFR 1304.24(a);
 - (2) The automated system has the capability of producing a hard copy printout of the program's dispensing records;
 - (3) The mobile component prints a hard copy of each day's dispensing and administration log, which is then initialed appropriately by each person who dispensed or administered medication to the program's patients;
 - (4) The automated system is approved by DEA;
 - (5) The multicare institution or its mobile component maintains an off-site back-up of all computer-generated program information; and
 - (6) The automated system is capable of producing accurate summary reports for both the registered site of the multicare institution and any mobile component, for any timeframe selected by Department and 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 registered site of the multicare institution.
- (b) All records shall be maintained in accordance with Section 19a-14-40 to 19a-14-44 inclusive of the Regulations of Connecticut State Agencies.
- (c) Authorized healthcare providers may obtain written consent signed by the patient to share records with a prescription drug monitoring program in accordance with 42 CFR 2 Subpart B. No records shall be shared with a prescription drug monitoring program without such consent.

Sec. 19a-495-22-6. Diversion

- (a) The multicare institution shall ensure authorized healthcare providers comply with the following requirements pursuant to 21 CFR 1301.72 for transferring, transporting or dispensing controlled substances:
- (1) The authorized healthcare providers have control over all narcotic drugs in schedules II-V when transferring them from the free-standing facility for the care or treatment of substance abusive or dependent persons to the mobile narcotic treatment vehicle, and when dispensing at the location.
 - (2) Any narcotic drugs in schedules II-V transferred to the mobile narcotic treatment vehicle are secured in the safe when not dispensing.
 - (3) The mobile narcotic treatment vehicle has returned to the licensed multicare facility at the end of each day when the mobile narcotic treatment vehicle has finished providing services. The mobile narcotic treatment vehicle shall park at the existing registered location on file with the DEA and the Department. Authorized staff shall remove and secure all narcotic drugs in schedules II-V in the facility and park the mobile narcotic treatment vehicle in a secure area.
 - (4) Approved mobile narcotic treatment programs may apply for a waiver of the daily return requirement for DEA approval. The mobile narcotic treatment program shall notify the Department of any waiver approved.

(b) Authorized providers of the mobile narcotic treatment program shall not:

- (1) Receive controlled substances from other mobile narcotic treatment vehicles or any other entity;
- (2) Deliver controlled substances to other mobile narcotic treatment vehicle or any other entity; or
- (3) Conduct reverse distribution of controlled substances on a mobile narcotic treatment vehicle.

(c) The Department of Consumer Protection shall be notified of any loss, theft, diversion, or robbery of controlled substances from the mobile narcotic treatment program.

Statutory Authority for Section 1, adding 19a-495-22-1 to 19a-495-22-6 inclusive:

Section 19a-493 of the Connecticut General Statutes as amended by Section 4 of Public Act 22-108.

Statement of Purpose

The proposed regulations provide procedures for existing multicare institutions licensed by the Department of Public Health to obtain approval from the Department to operate a mobile narcotic treatment program, as defined under 21 CFR 1300.001(b), as a satellite unit of the multicare institution. These regulations implement the requirements of Public Act 22-108 to allow for the operating of mobile narcotic treatment programs by existing licensed multicare facilities. The purpose of this proposed regulation is to improve access to narcotic treatment programs, within the provisions of the federal Drug Enforcement Agency rule permitting mobile narcotic treatment programs as contingent activities of existing registered narcotic treatment programs. This proposed regulation sets forth the process for the Department's review and approval of the vehicle, staffing, program, and services for such mobile narcotic treatment programs by the Department, as a satellite units of licensed multicare facilities. The proposed regulation also sets forth requirements for contingency planning, required policies and procedures, record-keeping, and diversion. The proposed regulation will reduce transportation barriers for vulnerable patient populations.