

Secretary of the State File Number

6414

Regulation of the

Department of Public Health

Concerning

Mobile Narcotic Treatment Programs

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

Posted to the Connecticut eRegulations System on **August 1, 2024**

EFFECTIVE DATE

August 1, 2024

Approved by the Attorney General on

June 17, 2024

Approved by the Legislation Regulation Review Committee on

July 23, 2024

Electronic copy with agency head certification statement electronically submitted to and received by the Office of the Secretary of the State on

July 31, 2024

Form ICM-ECOPY (NEW 6/2015)
State of Connecticut
Secretary of the State



IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES
This form should be used only for regulations first noticed *on and after March 23, 2015*.

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the
Department of Public Health
Concerning
Mobile Narcotic Treatment Programs

Approved by the Legislative Regulation Review Committee: **July 23, 2024**

eRegulations System Tracking Number: **PR2023-010**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto
set my hand on **July 24, 2024**.

A handwritten signature in black ink, appearing to read "Manisha Juthani", written over a horizontal line.

Manisha Juthani, MD

Commissioner

Department of Public Health

State of Connecticut
Regulation of
Department of Public Health
Concerning

Mobile Narcotic Treatment Programs

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

(NEW) Sec. 19a-495-22-1. Definitions

As used in this section and sections 19a-495-22-2 to 19a-495-22-6, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Admission” means admission of a patient in accordance with patient admission criteria, as described in 42 CFR 8.12, for maintenance treatment using opioid agonist treatment medication to treat opioid use disorder;
- (2) “Advanced practice registered nurse” or “APRN” means an advanced practice registered nurse 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 licensed pursuant to Chapter 378 of the Connecticut General Statutes. Authorized healthcare providers are those who can prescribe or dispense narcotic drugs in DEA schedule II to V, inclusive, and maintain an active controlled substance registration pursuant to Chapter 420c of the Connecticut General Statutes;
- (4) “Commissioner” means the Commissioner of Public Health or the commissioner’s designee;
- (5) “DMHAS” means the Department of Mental Health and Addiction Services;
- (6) “DMHAS accreditation” means approval to operate a mobile narcotic treatment program issued by DMHAS as the State Opioid Treatment Authority and in accordance with 42 CFR 8;
- (7) “Department” means the Department of Public Health;
- (8) “Drug Enforcement Administration” or “DEA” means the United States Drug Enforcement Administration including local DEA administration;
- (9) “Mobile narcotic treatment program” means a mobile narcotic treatment program, as defined in 21 CFR 1300.01, that is operated by a multicare institution and maintains a controlled substance registration pursuant to Chapter 420c of the Connecticut General Statutes;
- (10) “Mobile narcotic treatment vehicle” means a motor vehicle, as defined in 21 CFR 1300.01(b), as amended from time to time, that is used in the operation of a mobile narcotic treatment program and is considered a satellite unit of a multicare institution;
- (11) “Multicare institution” has the same meaning as provided in Section 19a-490 of the Connecticut General Statutes;
- (12) “Physician assistant” means a physician assistant licensed pursuant to Chapter 370 of the Connecticut General Statutes;

- (13) “Registered nurse” means a registered nurse licensed pursuant to Chapter 378 of the Connecticut General Statutes; and
- (14) “Satellite unit” has the same meaning as provided in Section 19a-490(n) of the Connecticut General Statutes.

(NEW) Sec. 19a-495-22-2. Approval procedures

- (a) Pursuant to Section 19a-493(d) of the Connecticut General Statutes, a multicare institution may, under the terms of its existing license, provide medication or other treatments to individuals with opioid use disorder through a mobile narcotic treatment program outside of the multicare institution using a mobile narcotic treatment vehicle if approved by the commissioner. Each mobile narcotic treatment vehicle shall require a separate application and approval by the department.
- (b) Issuance and renewal of approval to provide services from a mobile narcotic treatment program.
- (1) Any multicare institution whose license is 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.
 - (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 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;
 - (C) Insurance certificate or rider or both for general liability;
 - (D) Directory and resume of all professional staff providing services through the mobile narcotic treatment program;
 - (E) 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 mobile narcotic treatment program, including, but not limited to, patient confidentiality and the privacy and security of patient protected information;
 - (F) The type of mobile narcotic treatment vehicle;
 - (G) The proposed schedule of the 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
 - (H) Any other information required by the department.
 - (4) Following initial review and approval of complete application materials submitted pursuant to this section, the department shall schedule and conduct an on-site

inspection at a time suitable to the proposed mobile narcotic treatment program and the department. Upon completion of a satisfactory inspection by the department, the department shall provide the inspection report to the multicare institution, and the multicare institution shall secure accreditation from DMHAS for the proposed mobile narcotic treatment program as follows:

- (A) The multicare institution shall submit the department's inspection report to DMHAS and shall submit a copy of the application for DMHAS accreditation to the department. The multicare institution shall secure DMHAS accreditation in accordance with DMHAS procedures for the proposed mobile narcotic treatment program.
 - (B) The multicare institution shall submit documentation of DMHAS accreditation to the department. The department shall issue an approval determination for the mobile narcotic treatment program after receipt of documentation of DMHAS accreditation.
- (5) Failure by the multicare institution to submit documentation of DMHAS accreditation to the department not later than forty-five days after the date the department receives a complete application for approval of the proposed mobile narcotic treatment program shall result in denial of the application.
- (6) A mobile narcotic treatment program's approval may be renewed biennially at the time of the multicare institution's biennial renewal pursuant to Section 19a-493(a) of the Connecticut General Statutes.
- (7) 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 in writing not less than thirty days prior to enacting any changes in services provided by the mobile narcotic treatment program, including, but not limited to, termination of mobile narcotic treatment program services. The multicare institution shall also notify each patient receiving services in writing not less than thirty days prior to enacting any changes in services provided by the mobile narcotic treatment program, including, but not limited to, termination of mobile narcotic treatment program services.
- (9) The commissioner may, in the commissioner's discretion, deny, suspend, or revoke any approval for, or impose a civil penalty pursuant to Section 19a-494 of the General Statutes upon, a mobile narcotic treatment program for the following reasons:
 - (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 program does not have DMHAS accreditation for the mobile narcotic treatment program;
 - (C) The failure of the mobile narcotic treatment program to comply with these regulations; or
 - (D) The submission of any false or misleading statements to the department in order to obtain an initial approval or renewal of the mobile narcotic treatment program's approval.

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

- (a) The multicare institution shall register all mobile narcotic treatment program vehicles with the 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.
- (b) The multicare institution shall ensure all mobile narcotic treatment program vehicles comply with the following requirements:
 - (1) A safe is installed in the mobile narcotic treatment program vehicle to store narcotic drugs in DEA schedules II to V, inclusive, 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;
 - (2) An alarm system is installed in the vehicle that will alert upon unauthorized entry in accordance with 21 CFR 1301.72;
 - (3) The area used for storage of any medications or treatment supplies is not accessible from the outside of the vehicle;
 - (4) The controlled substance area is only accessible to authorized healthcare providers;
 - (5) The vehicle has a bathroom facility;
 - (6) The vehicle has handwashing capacity;
 - (7) A refrigerator is installed in the vehicle;
 - (8) The vehicle has the capacity for adequate storage for both clean and utility purposes; and
 - (9) The vehicle has a door that physically separates the areas between narcotic drug dispensing and the patient waiting area. If the vehicle is not equipped with a door that physically separates the area, patients shall wait outside the vehicle.

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

- (a) A multicare institution that provides services with an approved mobile narcotic treatment program shall specify the scope of services offered, which may include, but need not be limited, to admission, counseling, induction, dispensing take-home treatment, outreach, and referrals.
- (b) 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.
- (c) If the mobile narcotic treatment program opts to offer admission services, the mobile component shall be staffed with a physician, physician assistant, or APRN.
- (d) If the multicare institution opts to offer counseling services from the mobile narcotic treatment program, 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.

- (e) 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.
- (f) The multicare institution shall issue and implement written contingency policies and protocols for the mobile narcotic treatment program, including, but not limited to, contingency policies and protocols concerning the following:
 - (1) Vehicle malfunction;
 - (2) Weather emergency;
 - (3) Medical emergency;
 - (4) Schedule changes; and
 - (5) Staff illness or absence.
- (g) 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) The mobile narcotic treatment program shall only dispense or administer medication in the form and manner as prescribed in Section 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.
- (i) 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.
- (j) All patient and controlled substance records for the mobile narcotic treatment program shall comply with the record requirements outlined in Section 19a-495-570 of the Regulations of Connecticut State Agencies and shall be stored and maintained at the licensed multicare institution in accordance with Section 19a-495-22-5 of the Regulations of Connecticut State Agencies and 21 CFR 1304.24.
- (k) The mobile narcotic treatment vehicle shall not transport patients for any purpose or cross state lines.

(NEW) 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 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 narcotic treatment program 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 narcotic treatment program 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 narcotic treatment program, for any timeframe selected by Department and DEA personnel during an investigation. If these summary reports are maintained in hard copy form, they shall 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 Sections 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.

(NEW) 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 as part of a mobile narcotic treatment program:
 - (1) The authorized healthcare providers shall have control over all narcotic drugs in DEA schedules II to V, inclusive, 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 DEA schedules II to V, inclusive, transferred to the mobile narcotic treatment vehicle shall be secured in the safe when not dispensing;
 - (3) The mobile narcotic treatment vehicle shall return 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 healthcare providers shall remove all narcotic drugs in DEA schedules II to V, inclusive, from the mobile narcotic treatment vehicle, secure such drugs in the facility and park the mobile narcotic treatment vehicle in a secure area; and
 - (4) Approved mobile narcotic treatment programs may apply to the DEA for a waiver of the daily return requirement for DEA approval. The mobile narcotic treatment program shall notify the department of any waiver approved by the DEA.
- (b) Authorized healthcare providers 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 vehicles 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.

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 1300.01(b), as a satellite unit of the multicare institution. These proposed regulations implement the requirements of Public Act 23-122 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 unit of licensed multicare institutions. 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.

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION

Department of Public Health

Proposed Regulation Concerning

Mobile Narcotic Treatment Programs

eRegulations System Tracking Number PR2023-010

I hereby certify the following:

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities: **Conn. Gen. Stat. 19a-493(d)(4)**

For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.

(2) As permitted by Section 4-168(h) of the *Connecticut General Statutes*, the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on _____.

For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)

(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on **March 3, 2023**. The public comment period was opened on September 1, 2023 and closed on October 2, 2023.

(4) (Complete one) ☒ No public hearing held or was required to be held.

(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on **December 13, 2023**.

(6) (Complete one) ☒ No comments were received.

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **January 19, 2024**.

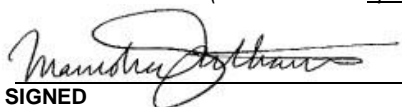
(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, **the final regulation shall be effective**

(Check one and complete as applicable)

☒ X When posted to the eRegulations System website by the Secretary of the State.

OR ☐ On _____

(Date must be a specific calendar date not less than 11 days after submission to the Secretary of the State)



SIGNED

(Head of Board, Agency or Commission,
or duly authorized deputy)

Commissioner

OFFICIAL TITLE

5-23-2024

DATE

OFFICE OF THE ATTORNEY GENERAL REGULATION CERTIFICATION

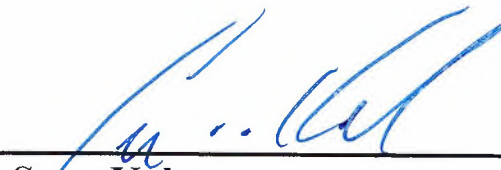
Agency: Department of Public Health

REGULATION NUMBER: PR2023-010

This Regulation is hereby **APPROVED** by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: 6/17/2024

Signed:



Sean Kehoe

Associate Attorney General

Chief of the Division of Government Affairs

Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator John Kissel
Senate Chair



Representative Lucy Dathan
House Chair

Official Record of Committee Action

July 23, 2024

Agency:	Department of Public Health
Description:	Mobile Narcotic Treatment Programs
LRRC Regulation Number:	2024-009A
eRegulation Tracking Number:	PR2023-010

The above-referenced regulation has been

Approved with Technical Corrections

by the Legislative Regulation Review Committee in accordance
with CGS Section 4-170.

Catherine M. Thomas
Committee Administrator



State of Connecticut
Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Public Health concerning Mobile Narcotic
Treatment Programs
eRegulations System Tracking Number PR2023-010
Legislative Regulation Review Committee Docket Number 2024-009A

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4-172 on July 31, 2024.

Said regulation is assigned Secretary of the State File Number 6414.

The effective date of this regulation is August 1, 2024.

A handwritten signature in blue ink, appearing to read "Stephanie Thomas".

Stephanie Thomas
Secretary of the State
August 1, 2024

By:

/s/ Christopher R. Drake
Christopher R. Drake
Director, Business Services
Division