

### Vehicle Specifications

#### » **What are the MNTP vehicle guidelines?**

MNTPs must follow [DEA security requirements](#). An MNTP is an NTP operating from a motor vehicle. DEA has defined "motor vehicle" as a vehicle propelled under its motive power and lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground, excluding trailers. DEA has also outlined physical security requirements that the MNTP must comply with in [21 CFR 1301.72](#). To provide flexibility, no specific vehicle make/models are required for MNTPs. The MNTP should ensure that it, at minimum, complies with requirements established by the DEA and is built out with adequate space and privacy to provide services to patients.

#### » **What are the clinic and counseling room requirements for an MNTP an MNTP to maintain confidentiality and will these requirements be verified by DHCS?**

MNTPs providing counseling services and clinical treatment must follow the guidance provided in the [Code of Federal Regulations \(CFR\) Title 42, Part 2, Health Insurance Portability and Accountability Act \(HIPAA\)](#), which provides information about patient confidentiality requirements. These requirements discuss the space's construction to ensure reasonable confidentiality and the requirements for storing patient medical records. DHCS will verify adequate space and soundproofing during the onsite inspection to ensure confidentiality during the patient visit.

#### » **What are the counseling and intake space requirements for an MNTP to maintain confidentiality, and will these requirements be verified by DHCS?**

MNTPs must follow the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which requires reasonable safeguards to protect patient privacy. Accordingly, an MNTP seeking approval from DHCS to provide any services in addition to dispensing medications for opioid use disorder (MOUD), such as counseling and/or intakes, must have a separate, soundproof area to maintain patient confidentiality with adequate space to provide the services. DHCS will verify adequate space and

soundproofing during the onsite inspection to ensure confidentiality during the patient visit.

## Medication Storage and MNTP Parking Requirements

### » What are MNTP medication storage requirements?

MNTPs are required to secure medications in accordance with the requirements outlined in [21 CFR 1301.72](#) within the registered vehicle location to decrease the risk of theft and potential diversion. It is up to the NTP to develop procedures to secure the vehicle at the registered location once the controlled substances are no longer in the vehicle. The DEA requires all controlled substances on board the MNTP to be removed from the vehicle and securely stored when the MNTP is not in use.

### » Can you provide other medications for opioid use disorder (OUD) through the MNTP (buprenorphine and naltrexone)?

Yes, MNTPs may provide medication as defined in the [California Code of Regulations \(CCR\), Title 9, Chapter 4 § 10000](#). "Medication" means any opioid agonist medications that have been approved for use in replacement narcotic therapy, including:

- A. Methadone;
- B. Buprenorphine and buprenorphine products approved by the FDA for maintenance treatment or detoxification treatment of opioid addiction; and
- C. Any other medication approved by the FDA for the purpose of narcotic replacement treatment or medication-assisted treatment of substance use disorders.

### » What are MNTP parking requirements?

When an MNTP is not operating, the vehicle shall be securely parked at the NTP (registered location) unless approval is obtained to park the vehicle at an off-site parking location that is secured and fenced in. To park a mobile NTP vehicle at a location other than the NTP, the NTP shall obtain prior, written approval from the Department and the DEA. ([See, 21 CFR § 1301.72\(e\)\(1\)](#)).

## Alternative Service Routes and Dispensing Locations

### » Can the MNTP take an alternative service route that is different than the original route submitted and approved by DHCS?

The MNTP may deviate from the route submitted and approved by DHCS if circumstances prevent them from taking the exact same route. Alternative routes are allowed under reasonable circumstances. For example, a road closure may require the MNTP to use an alternative route for a temporary period of time. DHCS approval is

required, prior to any permanent changes in servicing route for the MNTP, then the NTP operating the MNTP must send the Protocol Amendment form ([DHCS Form 1832](#)) to [dhcsntp@dhcs.ca.gov](mailto:dhcsntp@dhcs.ca.gov). As indicated in DHCS Form 1832, a permanent change to the approved standard daily route is “any permanent change to the approved standard daily route for mobile NTP to and from the service/dispensing location(s)” and requires the submission of this protocol amendment form. A permanent change to the servicing route shall not be implemented until such approval is received.

» **Can you operate anywhere in the county?**

Yes, however, the MNTP cannot cross state lines and must operate within California.

» **How can an MNTP add a dispensing location?**

Adding a dispensing location must be reported to DHCS as it is considered a permanent change to the MNTP operating protocol. The NTP operating the MNTP must send the Protocol Amendment form ([DHCS Form 1832](#)) to [dhcsntp@dhcs.ca.gov](mailto:dhcsntp@dhcs.ca.gov) when adding a dispensing location.

## Staffing Requirements

» **What are MNTP staffing guidelines?**

Regarding the dispensing of controlled substances: Staff members are individuals employed by the NTP. Since the MNTP operates under the license of the primary NTP and distributes controlled substances, these staff members are subject to DEA guidelines regarding eligibility to handle controlled substances. Please review the [DEA's Practitioners Manual Section III Registration Requirements](#) to determine which staff members are eligible to handle controlled substances.

Regarding other staffing needs: The services provided by the MNTP will determine the staff required to offer these services. Staff hired for specific services areas may only operate in their scope of work as defined by HSC 11844 and appropriate [Business and Professional Codes](#). Staff members can include but are not limited to registered, certified, exempt counselors pursuant to [HSC 11833](#), licensed behavioral health clinicians, peer support specialists, nurses, case managers, or other administrative staff.

» **Does a counselor have to travel with the MNTP and be on site?**

The counselors may provide counseling services on the MTNP or may provide counseling services remotely via telehealth.

## Reporting MNTP Incidents to DHCS

» **Are MNTPs required to submit incident reports? What kind of incidences need to be reported to DHCS?**

Any incidents that affect the operation of the MNTP or prevent services from being rendered must be reported to DHCS. MNTPs are required to submit written standard operating procedures, and policies and procedures that will be followed in the event of an unforeseen circumstance, emergency, or disaster, including:

- Theft or loss of controlled substances from an MNTP;
- Mechanical breakdown of the MNTP vehicle;
- Compromised safety of MNTP staff;
- Compromised safety of MNTP patients; and
- Other unforeseen emergencies involving the MNTP.

## The County's Role

### » What is the county's role for required certifications?

A county certification is not required to operate an MNTP as an affiliated facility to the primary NTP and operating under the primary NTP's license. In alignment with [Title 9 10040 of the California Code Regulations \(CCR\)](#), a completed, original protocol shall be filed with the County Alcohol and Drug Program Administrator as the narcotic treatment program's application for original licensure. Patients served by an MNTP are considered to be the same patients served by the primary NTP under which the MNTP is operated.

### » What is the county's role in protocol amendments?

When an NTP submits an amendment via the MNTP Protocol Amendment Form ([DHCS Form 1832](#)), DHCS will include the Alcohol or Other Drugs (AOD) county administrator in the correspondence when DHCS approves the form. Any changes to an approved DHCS Form 1832 will require DHCS approval via submission of an updated DHCS Form 1832.

### » What circumstances require the submission of an amendment?

Section A on the [DHCS 1832 Mobile Narcotic Treatment Program Application](#) outlines which circumstances require submission of an amendment. They include:

- Relocation of where the mobile NTP is parked overnight;
- Permanent change in the standard daily route to and from the service/dispensing location(s);
- Addition, reduction, or termination of service(s);
- Modification of mobile NTP vehicle, including expansions or modifications of; dispensing stations
- Replacement of the mobile NTP vehicle; and
- Other.

# MNTP Federal Approvals, Licensing, and Registration Requirements

## » Is DHCS licensing required in addition to obtaining federal approvals?

Yes, DHCS licensing is required along with DEA and SAMHSA approvals. BHIN 24-005 states that, "After receiving preliminary approval from the Department, the NTP shall obtain approval from the DEA and SAMHSA in accordance with the applicable federal requirements." Please reference [BHIN 24-005 Mobile Narcotic Treatment Programs](#) for complete details about the full licensing process and all required applications.

## » Does the MNTP have its own SAMHSA certification separate from the primary NTP?

No, the MNTP will have the same SAMHSA certification number, however the MTNP must obtain SAMHSA's approval by completing an [on-line SMA-162 form](#) to the [SAMHSA/CSAT Opioid Treatment Program Extranet webpage](#) and comply with all other requirements set forth by SAMHSA for the operation of a mobile NTP.

## » What licenses and registrations are required for an MNTP to be operational?

The DEA registration for NTPs is for the facility, not the individual clinician. Under this registration, DEA allows for the NTP to operate an MNTP under the same registration as a coincident activity. DEA does not limit the distance an MNTP can travel but has concluded that the MNTP must return to its registered location upon completion of operations each day. However, the DEA will not authorize an MNTP to cross state lines. A MNTP may only operate in the same state in which its brick-and-mortar NTP is registered with the DEA to dispense controlled substances. More information about these DEA rules can be found in the [Federal Register](#).

## » How long is the licensure application timeline from the letter of intent?

The letter of intent only informs DHCS that the NTP intends to operate an MNTP. The NTP must submit to DHCS the MNTP protocols and all required [MNTP Application Forms and Fee](#) to apply for MTNP licensure. The timeline to review the MNTP application is specified under [BHIN 24-005 Mobile Narcotic Treatment Programs Sections B-E](#). The licensure application process typically takes 8-10 months. However, timing remains contingent on when the application is complete and federal approvals are received.

## » Is a Clinical Laboratory Improvement Amendments (CLIA) license required for a MNTP For?

No, a CLIA lab license is not required to obtain MNTP licensure.

» **What are the logistics of providing cross-county care to patients and Drug Medi-Cal Organized Delivery System (DMC-ODS) requirements?**

Each [DMC-ODS](#) county shall ensure that members receiving Narcotic Treatment Program (NTP) services and working in or traveling to another county (including a county that does not opt into the DMC-ODS program) do not experience a disruption of NTP services; this includes MNTP services. In accordance with [42 CFR 438.206](#), if the DMC-ODS county's provider network is unable to provide necessary services to a particular member (e.g., when a member travels out of the county and requires daily NTP dosing), the DMC-ODS county shall adequately and timely cover these services out-of-network for the member, for as long as the DMC-ODS county's provider network is unable to provide them. In these cases, the DMC-ODS county shall coordinate and cover the member's out-of-network MNTP services. If a member working in or traveling to another county is not able to receive medically necessary DMC-ODS services, including MNTP services, without paying "out of pocket," the DMC-ODS county of responsibility has failed to comply with the requirements contained in 42 CFR 438.206.

If a member moves to a new county and initiates an inter-county transfer, the new county is immediately responsible for DMC-ODS treatment services and can claim reimbursement from DHCS through the Short Doyle Medi-Cal System, as of the date of the inter-county transfer initiation. Please see [BHIN 24-008](#) for policy clarifications on DMC-ODS County of Responsibility.

» **Is a MNTP required to separately enroll with the Provider Enrollment Division for Drug Medi-Cal (DMC) certification?**

No, MTNPs do not need to be DMC certified, similar to Medication Units (MU). The primary NTP must apply for DMC certification for its affiliated locations (i.e., MNTP, MU, Office Based Narcotic Treatment Networks) to serve DMC patients.

## Additional Resources

- » [Behavioral Health Information Notice 24-005 Mobile Narcotic Treatment Programs](#)
- » [Behavioral Health Information Notice No: 24-008 County of Responsibility and Reimbursement for Specialty Mental Health Services \(SMHS\), Drug Medi-Cal \(DMC\), and Drug Medi-Cal Organized Delivery System \(DMC-ODS\)](#)
- » [Federal Register :: Medications for the Treatment of Opioid Use Disorder](#)
- » [Federal Register :: Registration Requirements for Narcotic Treatment Programs with Mobile Components](#)
- » [2022 DEA Narcotic Treatment Program Manual](#)
  - Serves as a guide to DEA Narcotic Treatment Program regulations.
  - Has information such as NTP registration, recordkeeping, security, and inventory requirements.
  - Section 12.1 has information for mobile narcotic treatment vans.
- » [SAMHSA | Certification of Opioid Treatment Programs \(OTPs\)](#)
- » [Local DEA Office Locator](#)