



DATE: January 4, 2024

Behavioral Health Information Notice No: 24-005

TO: California Alliance of Child and Family Services
California Association for Alcohol/Drug Educators
California Association of Alcohol & Drug Program Executives, Inc.
California Association of DUI Treatment Programs
California Association of Social Rehabilitation Agencies
California Consortium of Addiction Programs and Professionals
California Council of Community Behavioral Health Agencies
California Hospital Association
California Opioid Maintenance Providers
California State Association of Counties
Coalition of Alcohol and Drug Associations
County Behavioral Health Directors
County Behavioral Health Directors Association of California
County Drug & Alcohol Administrators

SUBJECT: Mobile Narcotic Treatment Programs

PURPOSE: To provide guidance regarding mobile Narcotic Treatment Programs (NTP) applications, implementation, and operation.

REFERENCE: 21 Code of Federal Regulations (CFR) Parts 1300, 1301, and 1304; Health and Safety Code (HSC) Section 11839.6.1

BACKGROUND

Effective July 28, 2021, the Drug Enforcement Administration (DEA) authorized NTPs to operate mobile NTPs under the existing DEA registration of a NTP, so long as all applicable federal, State, tribal, and local requirements have been met. Pursuant to 21 CFR § 1300.01, operating a mobile NTP is a coincident activity of an existing NTP. Therefore, the DEA determined that NTPs seeking to add a mobile component to dispense narcotic drugs in schedules II–V at remote location(s) for the purpose of maintenance or detoxification treatment do not need to obtain a separate DEA registration for the mobile component. (See, 21 CFR. § 1301.13.)

HSC Section 11839.6.1 authorizes the Department of Health Care Services (the Department) to regulate and establish a program for the operation of mobile NTPs. This BHIN sets forth the minimum requirements that a mobile NTP shall comply with to lawfully operate in California.



SECTION 1: GENERAL REQUIREMENTS

A mobile NTP established pursuant to HSC Section 11839.6.1 shall:

- (1) Operate under the license of only one NTP with which it is affiliated and associated;
- (2) Comply with all applicable State, federal, tribal, and local requirements, including the requirements set forth in this BHIN; and
- (3) Receive all necessary approvals from the Department, DEA, and the Substance Abuse and Mental Health Services Administration (SAMHSA) prior to operating a mobile NTP.

SECTION 2: APPLICATION PROCESS

A. Initial Mobile NTP Application

A NTP seeking to operate a mobile NTP shall submit to the Department the Mobile NTP Initial Application Form [DHCS 1830](#) and a written protocol, which shall serve as an application for the operation of a mobile NTP to obtain preliminary approval. The written protocol shall include the following information and documents related to the operation of a mobile NTP:

- (1) A written statement explaining the geographical areas to be served, including the specific address(es), or description of, of the dispensing location(s);
- (2) A written statement explaining the population of the area(s) to be served;
- (3) A resume for every mobile NTP staff member;
- (4) A list of names and job titles of the mobile NTP staff members and NTP staff members, if any, who have access to the safe that stores medication;
- (5) A description of the method used to transfer medications from the NTP to the mobile NTP;
- (6) A schedule identifying the days and hours of operation for dispensing medications. The mobile NTP may have different hours of operation for dispensing medications than the NTP.
- (7) A diagram showing dimensions of the mobile NTP, including the measurements of the safe for storing controlled substances, and an accompanying narrative that, at minimum, describes patient flow, applicable waiting areas, and the parking location of the mobile NTP when not in operation.
- (8) An approximate number of patients to be served and a description of how patients utilizing services provided by the mobile NTP will participate in regular treatment provided by the NTP;
- (9) A written statement explaining how the NTP will track and account for all controlled substances on the mobile NTP;

- (10) A copy of the vehicle registration of the mobile NTP;
- (11) Proof of auto insurance for the mobile NTP;
- (12) A written statement describing the mobile NTP safe's alarm system and its direct connection to a central protection company or a local or State police agency;
- (13) A written statement and map describing the mobile NTP's standard route(s) to and from dispensing location(s); and
- (14) Written policies and procedures to be followed in the event of an unforeseen circumstance, emergency or disaster, including the standard operating procedure:
 - a. To ensure that all controlled substances on a mobile NTP are accounted for, removed from the mobile NTP, and secured at the registered location;
 - b. To notify all NTP patients regarding the mobile NTP's delay or inability to provide services and the instructions for how NTP patients may obtain their daily dosing.

Each page of the protocol, including any index, shall be numbered beginning with page one. NTPs shall not break the numerical order of the protocol when changing headings. Failure to number pages properly may delay processing the mobile NTP application.

The NTP shall submit completed copies of all forms developed for a mobile NTP to the Department with the protocol. If an electronic service will be utilized to maintain electronic health records, sample pages of the electronic system including intake documents, dosing sheet, and treatment plan shall be submitted with the protocol.

B. Preliminary Approval

The Department shall notify the NTP, in writing, within 60 calendar days of receipt of a mobile NTP application whether the application is:

- (1) Complete, including all required documents, and accepted for review; or
- (2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The NTP shall have 60 calendar days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the application if the NTP does not provide the required information or documentation within 60 calendar days. Upon termination of review, the incomplete application shall be returned to the NTP. The NTP may reapply by submitting a new application to the Department in accordance with this BHIN.

The Department shall either grant preliminary approval of, or deny, in writing, a complete application for the operation of a mobile NTP within 60 calendar days after the application is accepted for review. If the Department denies the preliminary application, the Department shall send a written notice of denial to the NTP by certified mail that:

- (1) Explains the reason(s) for denial;
- (2) Informs the NTP that they may reapply by submitting a new application and required fees to the Department in accordance with this BHIN;
- (3) Informs the NTP that denial of an application for the operation of a mobile NTP does not affect the NTP's existing license; and
- (4) Informs the NTP of their right to an administrative review in accordance with this BHIN.

The Department may grant preliminary approval to the NTP upon determining that the:

- (1) NTP submitted all applicable fees; and
- (2) Application demonstrates that the NTP is able to operate a mobile NTP in compliance with all applicable State, federal, tribal and local requirements.

C. Federal Approval

After receiving preliminary approval from the Department, the NTP shall obtain approval from the DEA and SAMHSA in accordance with the applicable federal requirements. The NTP shall notify the local DEA office, in writing, of its intent to operate a mobile NTP and receive all necessary approvals from the DEA.

In instances when the mobile NTP staff will transport medication inside a facility to administer directly to patients, (e.g., in a correctional facility, residential facility) the NTP must clearly outline the process to DEA and DHCS for approval. The NTP shall also submit the 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.

D. On-site Inspection

After providing preliminary approval, and before issuing a written notice of final approval, the Department shall conduct an on-site inspection of the mobile NTP and the parking location of the mobile NTP to ensure compliance with applicable State and federal requirements. The on-site inspection may be conducted prior to the NTP receiving DEA and SAMHSA's approval.

E. Final Approval

The NTP shall, within 30 calendar days of the date of the DEA or SAMHSA's letter of approval, whichever occurs later, provide to the Department a copy of the DEA and SAMHSA's written approvals of the NTP's operation of a mobile NTP.

Within 30 calendar days of receipt of the NTP's DEA and SAMHSA written approvals, the Department shall provide the NTP with a written notice of final approval that authorizes the NTP to begin operating a mobile NTP. Upon receiving a written notice of final approval from the Department, the NTP may begin operating a mobile NTP.

A mobile NTP shall become operational within six (6) months from the date of the written notice of final approval from the Department. A NTP that fails to meet this time requirement shall submit a detailed letter of explanation to the Department describing the reason(s) contributing to the delay and the proposed date the mobile NTP will become operational.

Within 30 calendar days of receipt of the letter of explanation, the Department shall notify the NTP, in writing, whether:

- (1) The Department approves the letter of explanation and the proposed date the mobile NTP will become operational. A mobile NTP that fails to become operational by the proposed date shall submit a new application in accordance with this BHIN; or
- (2) The Department disapproves the letter of explanation and the proposed date the mobile NTP will become operational. The NTP shall submit a new application for the operation of a mobile NTP in accordance with this BHIN.

SECTION 3: LICENSE AND CAPACITY

A mobile NTP shall post the NTP license under which it is operating in a conspicuous place where it can be seen by anyone receiving services from the mobile NTP.

The licensed patient capacity of the NTP and any of its mobile NTP(s), medication unit(s), and/or Office-Based Narcotic Treatment Network shall not exceed the total patient capacity set forth on the NTP license.

SECTION 4: AMENDMENTS TO PROTOCOL

The following changes to a NTP protocol require prior approval of the Department. A NTP shall submit the Mobile NTP Protocol Amendment Form [DHCS 1832](#) and supplemental protocol to the Department for approval of the following changes:

- (1) Any relocation of where the mobile NTP is parked overnight;
- (2) Any permanent change in the approved standard route(s) to and from the service/dispensing location(s)
- (3) Any change to the physical structure or floor plan of the mobile NTP, including expansions or modifications to dispensing stations;
- (4) Any replacement of the mobile NTP vehicle; or
- (5) Any addition, reduction or termination of service(s).

Any other changes to a NTP protocol directly affecting the operations of a mobile NTP shall be reported to the Department within 30 calendar days after the date such change becomes effective.

After a NTP submits the Mobile NTP Protocol Amendment Form DHCS 1832 and supplemental protocol the Department shall notify the NTP, in writing, within 60 calendar days of receipt of the form, whether the Mobile NTP Protocol Amendment Form DHCS 1832 and supplemental protocol is:

- (1) Complete and accepted for review; or
- (2) Incomplete, and the Department shall specify the missing or incomplete information or documentation. The NTP shall have 30 calendar days from the date of the notification to provide the missing information or documentation. The Department shall terminate review of the protocol amendment if the NTP does not provide all required information or documentation within 30 calendar days. Upon termination of review, the incomplete protocol amendment shall be returned to the NTP. The NTP may reapply by submitting a new Mobile NTP Protocol Amendment Form DHCS 1832 to the Department.

The Department shall either approve or deny, in writing, the complete Mobile NTP Protocol Amendment Form DHCS 1832 and supplemental protocol within 60 calendar days after the amendment is accepted for review. If the Department denies the protocol amendment, the Department shall send a written notice of denial to the NTP by certified mail that:

- (1) Explains the reason(s) for denial;
- (2) Informs the NTP that they may resubmit a new protocol amendment, required fees if applicable, information, and forms to the Department in accordance with this BHIN;
- (3) Informs the NTP that denial of a protocol amendment does not affect the NTP's existing license; and
- (4) Informs the NTP of their right to an administrative review in accordance with this BHIN.

SECTION 5: RENEWAL

As part of the annual license renewal, a NTP with a mobile component shall submit to the Department by March 31st of each year the Mobile NTP Renewal Form [DHCS 1831](#) together with the required information and documentation described under 9 California Code of Regulations (CCR) Section 10055. The Mobile NTP Renewal Form DHCS 1831 shall be reviewed by the Department in accordance with 9 CCR Section 10055(c). The Department shall either approve or deny the Mobile NTP Renewal Form DHCS 1831 in accordance with 9 CCR Section 10055(d).

Each mobile NTP may be subject to an on-site inspection prior to the renewal of the NTP license.

SECTION 6: APPLICATION SUBMISSION

Any forms referenced in this BHIN shall be completed, as needed, by the NTP and submitted either electronically to DHCSNTP@dhcs.ca.gov or to the following address:

Licensing and Certification Division
P.O. Box 997413, MS 2603
Sacramento, CA 95899-7413

SECTION 7: APPLICATION FEES

The Department shall assess a license fee to cover the cost of licensing a mobile NTP. License fees shall be calculated in accordance with 9 CCR 10056. A license fee for a mobile NTP includes:

- (1) A fee for initial application of a mobile NTP licensure; and
- (2) An annual license fee, which includes a base annual license fee.

NTPs should refer to the Department's website, [NTP Applications and Fees](#), for current fees as well as any changes to applicable fees.

The initial application licensing fee shall be submitted to the following address:

Licensing and Certification Division
P.O. Box 997413, MS 2603
Sacramento, CA 95899-7413

The mobile NTP base annual renewal fee shall be submitted to the following address:

Department of Health Care Services
ACCOUNTING SERVICES
P.O. Box 997415, MS 1101
Sacramento, CA 95899-7415

SECTION 8: ADMINISTRATIVE REVIEW

For purposes of this BHIN, licensing action means any administrative action taken by the Department that would adversely affect the license of a NTP, including:

- (1) Denial of an application to operate a mobile NTP; or
- (2) Denial of a protocol amendment.

A licensee may appeal a licensing action by complying with the requirements in 9 CCR Section 10057. The Department shall follow the administrative review process for licensing actions as set forth in 9 CCR Section 10057.

SECTION 9: UNANNOUNCED INSPECTIONS

After a NTP commences operation of a mobile NTP, any authorized employee or agent of the Department may inspect the mobile NTP at any reasonable time, upon presentation of proper identification, with or without advance notice, to determine compliance with all applicable State and federal requirements, including the requirements set forth in this BHIN.

SECTION 10: VEHICLE SPECIFICATIONS

A mobile NTP shall operate from a motor vehicle that is propelled under its own motive power and lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground. A trailer shall not be used to operate a mobile NTP. A mobile NTP shall not be modified in any manner to operate or function as a hospital, long-term care facility, emergency medical service vehicle, or patient transport.

SECTION 11: SECURITY AND CONFIDENTIALITY

NTP staff members shall maintain adequate security at all times over any controlled substances stored in a mobile NTP.

NTP staff members shall require individuals receiving services from a mobile NTP to wait in an area that is physically separated from the controlled substance storage and dispensing area by a physical entrance such as a door or other entryway. Individuals shall wait outside a mobile NTP if the mobile NTP does not have seating, or a reception area separated from the controlled substance storage and dispensing area.

A mobile NTP is responsible for maintaining patient confidentiality and shall adhere to the requirements of 42 CFR Part 2.

SECTION 12: GENERAL SAFEGUARDS

A mobile NTP shall comply with the following minimum requirements to protect against theft and diversion:

- (1) Install a safe in the mobile NTP that meets the requirements specified under 21 CFR Section 1301.72(a)(1) to store and secure any controlled substances in the mobile NTP; and
- (2) Equip the mobile NTP with an alarm system that meets the requirements specified under 21 CFR Section 1301.72(a)(1)(iii).

SECTION 13: STORAGE AREA

The storage area for controlled substances in a mobile NTP shall not be accessible from outside the mobile NTP. The safe, as described in [21 CFR 1301.72\(a\)\(1\)](#), shall be accessible only to NTP staff members who are licensed to dispense narcotic medication and authorized to administer such medication in accordance with HSC Section 11215. If any individual needs to be present in, or pass through, the storage area containing controlled substances, there shall be adequate observation of the area by an authorized NTP staff member.

SECTION 14: TRANSPORTATION OF CONTROLLED SUBSTANCES

NTP staff members transporting controlled substances in a mobile NTP shall retain control over all controlled substances when transferring them between the NTP and the mobile NTP, while en route to and from the dispensing location(s), and at the dispensing location(s). At all other times during transportation, all controlled substances shall be properly secured in a mobile NTP's safe.

A mobile NTP shall also not reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location. A mobile NTP shall only obtain controlled substances from the

NTP under which it is licensed. A NTP staff member permitted to dispense controlled substances from a mobile NTP shall not:

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

On days the mobile NTP is operating, NTP staff members shall maintain accurate records reflecting:

- (1) The date of operation;
- (2) The starting quantity of each controlled substance that was transferred from the NTP to the mobile NTP's safe prior to traveling to the first approved dispensing location; and
- (3) The remaining quantity of each controlled substance that is secured within the NTP at the end of each day of operation.

These records shall be retained for a period of 3 years.

SECTION 15: DURING OPERATION

While in operation, in the event the mobile NTP needs to make a stop at any location other than an approved dispensing location(s), at least one NTP staff member shall remain in the mobile NTP at all times to maintain adequate security over any controlled substances stored in the mobile NTP.

SECTION 16: AFTER OPERATION

A mobile NTP shall return to the NTP at the end of each day of operation. Upon return, all remaining controlled substances in a mobile NTP shall be secured within the NTP-by-NTP staff members.

When a mobile NTP is not operating, it shall be securely parked at the NTP (registered location) unless approval is obtained to park the mobile NTP at an off-site parking location that is secured and fenced in. To park a mobile NTP 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).)

For DEA approval, the NTP shall submit an application in accordance with 21 CFR § 1307.03. To obtain Departmental approval, the NTP shall submit a completed Mobile

NTP Protocol Amendment Form DHCS 1832 together with evidence of approval from the DEA.

SECTION 17: DISPOSAL

Any controlled substances being transported for disposal from the dispensing location of a mobile NTP shall be secured and disposed of in compliance with 21 CFR § 1317, and all other applicable federal, State, tribal, and local laws and regulations.

SECTION 18: EMERGENCIES, UNFORSEEN CIRCUMSTANCES, AND PLANNED MAINTENANCE

If a mobile NTP becomes inoperable for any reason, the mobile NTP shall comply with the NTP's written policies and procedures described in the protocol, which includes:

- (1) Ensuring that all controlled substances on a mobile NTP are accounted for, removed from the mobile NTP, and secured at the NTP, and
- (2) Notifying all impacted patients regarding the mobile NTP's delay or inability to provide services at the dispensing location(s) and the instructions for NTP patients to obtain their daily dosing.

The NTP shall notify the Department, in writing at DHCSNTP@dhcs.ca.gov, by completing the Mobile NTP Protocol Amendment Form DHCS 1832 within one working day after the mobile NTP becomes inoperable and dispensing services are temporarily discontinued. At minimum, the notice shall include the following information:

- (1) The date, time and location when the mobile NTP became inoperable impacting dispensing services;
- (2) Assurance that the NTP has complied with all applicable policies and procedures described in the protocol;
- (3) The proposed plan to make the mobile NTP operational; and
- (4) The expected date when the mobile NTP will resume operations.

Before a mobile NTP can be towed, repaired, or maintained by any third party or business entity, all controlled substances, patient records, dispensing logs, and any other identifying patient information shall be removed from the vehicle. A mobile NTP may be subject to an on-site inspection by the Department prior to resuming operations.

SECTION 19: RECORD KEEPING

A mobile NTP shall maintain dispensing records with the following information for each narcotic controlled substance:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date dispensed;
- (5) Identification of patient (consumer);
- (6) Amount consumed;
- (7) Amount and dosage form taken home by patient;
- (8) Dispenser's initials; and
- (9) Batch code marks of the medication

The above records shall be maintained in a dispensing log at the registered site of the NTP and shall be in compliance with all applicable recordkeeping requirements.

Alternatively, the mobile NTP may use an automated/computerized data processing system for the storage and retrieval of the dispensing records, if the following conditions are met:

- (1) The automated system maintains the information required above;
- (2) The automated system has the capability of producing a hard copy printout of the dispensing records;
- (3) The NTP or its mobile component prints a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the patients;
- (4) The automated system is approved by DEA;
- (5) The mobile NTP maintains an off-site back-up of all computer-generated information; and
- (6) The automated system is capable of producing accurate summary reports for both the NTP and any mobile component, for any timeframe selected by 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 NTP.

The NTP shall retain all records for the NTP as well as any mobile component three years from the date of execution. (9 CCR § 10255; 21 CFR § 1304.04(a)).

Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of the NTP shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by 21 CFR Part 310 and 42 CFR Part 2.

SECTION 20: SERVICES PROVIDED BY THE MOBILE NTP

In addition to dispensing medications for opioid use disorder treatment, a mobile NTP may provide any of the following additional services, if approved by the Department:

- (1) Collecting samples for drug testing or analysis ([9 CCR § 10315](#));
- (2) Dispensing take-home medications ([9 CCR, Division 4, Chapter 4, Subchapter 5, Article 4](#));
- (3) Admission ([9 CCR § 10270](#));
- (4) Medical evaluation ([9 CCR § 10270](#)); and/or
- (5) Counseling ([9 CCR § 10345](#)).

A mobile NTP seeking approval from the Department to provide any additional services shall, at a minimum, have a separate, soundproof area to maintain patient confidentiality with adequate space to provide the requested services.

The NTP shall be responsible for ensuring that mobile NTP patients have access to any treatment services not provided by a mobile NTP.

A mobile NTP shall operate a minimum of five (5) days per week and may travel any distance from the NTP to dispense controlled substances at approved dispensing location(s). However, a mobile NTP shall, upon completion of their operation, return to the NTP each day and safely transfer all remaining controlled substances from the mobile NTP to the NTP. Methadone shall be available seven (7) days a week at the NTP.

A mobile NTP shall not operate or function as a hospital, long-term care facility, emergency medical service vehicle, or patient transportation vehicle.

SECTION 21: MOBILE NTP CLOSURE

A NTP shall notify the Department, in writing, by completing the Mobile NTP Protocol Amendment Form DHCS 1832 at least 30 days prior to the closure of a mobile NTP. In the event that a mobile NTP ceases to dispense medications to enrolled patients, the NTP shall be responsible for notifying those patients and informing them how they may receive their dosage after the closure of the mobile NTP.

SECTION 22: VIOLATIONS/TERMINATION

Pursuant to HSC Section 11839.6.1(c), the NTP shall be subject to action under Section 11839.9 for any violation by its mobile NTP. The Department may terminate the

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operation of a mobile NTP for failing to comply with this BHIN or any applicable State or federal requirements. A mobile NTP shall immediately cease the provision of services in the event the license of the NTP is suspended or revoked.

The Department's approval to operate a mobile NTP shall automatically terminate if SAMHSA withdraws or revokes its approval of the NTP or its mobile NTP, or if the DEA revokes the NTP's registration or approval of its mobile NTP.

CONTACTS

To speak with the Diversion Field Office, please call (800) 882-9539 or email DEA.Registration.Help@usdoj.gov.

To speak to a SAMHSA Compliance Officer, please call (240) 276-2700 or email DPT@samhsa.hhs.gov.

If you have questions regarding this BHIN, please contact DHCSNTP@dhcs.ca.gov or contact (916) 322-6682.

Sincerely,

Original signed by

Janelle Ito-Orille, Chief
Licensing and Certification Division