

DATE: March XX, 2024 **DRAFT**

Behavioral Health Information Notice No: 24-XXX

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: Medication-Assisted Treatment (MAT) also referred to as Medications for Opioid Use Disorder Treatment for Incarcerated Patients

PURPOSE: The purpose of this notice is to provide treatment options and requirements for incarcerated patients diagnosed with an opioid use disorder (OUD); including guidance on the application process for an Office Based Narcotic Treatment Network, Mobile Narcotic Treatment Program or Medication Unit

REFERENCE: California Code of Regulations (CCR), Title 9, Section [10020](#), [10030](#), [10190](#), [10425](#). 21 Code of Federal Regulations (CFR) Parts [1300](#), [1301](#), and [1304](#), [Drug Enforcement Agency MNTP Final Rule](#), [Health and Safety Code \(HSC\)11839.6.1](#), [Behavioral Health Information notice \(BHIN\) 24-005](#), and [CalAIM Justice Involved Policy and Operations Guide](#).

## BACKGROUND:

This Behavioral Health Information notice (BHIN) addresses treatment options and requirements for incarcerated patients diagnosed with an OUD.



On January 26, 2023, California became the first state in the nation approved to offer a targeted set of Medicaid services to youth and eligible adults in state prisons, county jails, and youth correctional facilities for up to 90 days prior to release. Through a federal Medicaid 1115 demonstration waiver approved by the Centers for Medicare & Medicaid Services (CMS), CalAIM justice-involved initiative<sup>1</sup> focuses on improving care transitions for incarcerated individuals and supports justice-involved individuals by providing key services pre-release, enrolling them in Medi-Cal coverage, and connecting them with behavioral health, social services, and other providers that can support their re-entry into the community.

## **POLICY:**

### **CalAIM and Justice-Involved Individuals**

Justice-involved (JI) individuals are people who are currently, or have previously spent time, in jails, youth correctional facilities, or prisons and are at higher risk for injury and death, including overdose, than the general public. The CalAIM JI Initiative seeks to address the unique health care needs of JI individuals. By providing eligible JI individuals pre-release services in the 90-day period before their release, California aims to improve health outcomes and reduce health disparities. Additional information about the CalAIM JI Initiative, including a list of the pre-release Medi-Cal services, is available ([CalAIM Justice Involved Policy and Operations Guide](#)).

### **MAT for Substance Use Disorder**

One of the pre-release services available under the CalAIM JI Initiative is Medication-Assisted Treatment, defined as Medications for Substance Use Disorder in the [CalAIM Justice Involved Policy and Operations Guide](#). This includes all medications to treat opioid use disorder (MOUD) or medications to treat alcohol use disorder (MAUD), including the important use of medication as a stand-alone treatment without the prerequisite use of psychosocial services, when clinically indicated.

The following is a treatment approach for correctional facilities that house eligible JI individuals with OUD. Not every individual will require all treatments listed below.

- Assessment of individuals who screened positive for OUD.
- Treatment planning, consistent with Medi-Cal requirements, including Cal. Code Regs. (CCR) Tit. 9, § 10305 – Patient Treatment Plans for applicable NTP services, in collaboration with the patient, if a correctional facility is operating as a licensed NTP or medication unit.
- Management of opioid withdrawal with agonist medication (i.e., either methadone or buprenorphine) using evidence-based tools and interventions.

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<sup>1</sup> CalAIM Justice Involved Initiative: <https://www.dhcs.ca.gov/CalAIM/Justice-Involved-Initiative/Pages/home.aspx>

- Timely induction of an appropriate form of MOUD based on the individual's preference for agonist or antagonist treatment.
- Timely continuation of any agonist MOUD prescribed in the community, for the duration of incarceration. Correctional facility providers must use the available legal pathways to administer these medications, including the Drug Enforcement Administration's (DEA) 72-hour emergency rule for methadone, where appropriate, and have policies and procedures to support evidence-based dosing, urine drug screening, diversion control, and patient expectations/consent.<sup>2</sup>
- Tapering or discontinuation of MOUD (determined by both the clinician and the patient and on a case-by-case basis in accordance with evidence-based practices).
- Services and placement in non-residential level of care (if available within a correctional facility) as determined by a full ASAM Criteria assessment. The ASAM Criteria assessment shall be completed for individuals who are estimated to be in the correctional facility for more than 30 days. For county correctional facilities, the ASAM Criteria assessment shall be completed within 30 days of the individual's first visit with an LPHA and/or SUD counselor.
- Examples of evidence-based practices that may be provided as part of non-residential SUD treatment include:
  - o Motivational interviewing.
  - o Cognitive behavioral therapy.
  - o Peer support services.
  - o Psychoeducation.
- Maintenance of continuity of care by transitioning to community provider (including but not limited to MOUD access through primary care and SUD treatment) through close coordination with pre- and post-release care managers.
- Providing an appropriate supply of take-home MOUD medication to meet the need between release and transition to community provider. Medications used for addiction include those that create a high risk of overdose or diversion. The quantity of take-home medications depends on the timing of the arranged follow-up visit, the particular risk for the patient, and the clinical judgment of the prescriber. For methadone, correctional facilities should reference the [Methadone Take-Home Flexibilities Extension Guidance](#).<sup>3</sup>

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<sup>2</sup> Methadone may be dispensed under the DEA 72-hour emergency rule (21 CFR 1306.07(b)). The 72-hour rule allows a practitioner to dispense (but not prescribe) not more than a three-day supply of narcotic drugs, including methadone, to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's treatment.

<sup>3</sup> On May 11, 2023, upon the expiration of the federal COVID-19 PHE, SAMHSA implemented new Methadone Take-Home Flexibilities Extension [Guidance](#) that will remain in effect for the period of one year from the end of the COVID-19 PHE, or until such time that the U.S. Department of Health and Human Services publishes final rules revising 42 C.F.R. Part 8 entitled '[Medications for the Treatment of Opioid Use Disorder](#)' (87 FR 77330), whichever occurs sooner. These take-home flexibilities were granted to ensure continuity of care until SAMHSA finalizes updating the take-home medication requirements and guidance due to the positive outcomes in treatment.

## MOUD for Incarcerated Patients

MOUD provided under the CalAIM JI Initiative in the carceral setting must be done in a manner consistent with federal and state regulations. Buprenorphine and methadone are approved by the FDA for treatment of OUD. Practitioners who have a current DEA registration may prescribe buprenorphine. Methadone is typically dispensed at licensed NTPs in California. There are, however, options available for delivering methadone to incarcerated patients in correctional facilities when clinically indicated.

## Options for Correctional Facilities to Provide Methadone to Incarcerated Patients

Option 1: Correctional facilities may provide methadone as an incidental adjunct to medical or surgical conditions other than opioid dependency in a state and DEA registered hospital or clinic. (21 CFR 1306.07(c).)<sup>4</sup>

Administration of methadone under this circumstance is for maintaining or detoxifying a person as an incidental adjunct treatment to conditions other than addiction. The following are required to be able to deliver methadone under this regulation:

- I. Registration with the State as a Clinic: A correctional facility's "Exempt from Licensure Clinic Medi-Cal" enrollment path is considered a state registered clinic under this regulation; and
- II. Registration with the DEA: A correctional facility clinic must be registered with the DEA as a hospital/clinic. Correctional facility clinics may register with the DEA through the [DEA website](#) under the hospital/clinic registration using form 224.

Methadone provided under this regulation must be done as an incidental adjunct treatment while the individual is receiving treatment for a medical or surgical condition other than OUD. The only limitation for providing medication as an incidental adjunct treatment is the length of treatment for the individuals primary medical or surgical condition.

If an individual is being treated for another condition by the correctional facility clinic (e.g., pregnancy, hypertension, depression), they qualify for methadone under this pathway if clinically appropriate. If an individual only has OUD without any other co-occurring illnesses, they cannot receive methadone under 21 CFR 1306.07(c).

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<sup>4</sup> See also "[Providing Methadone in Jails and Prisons: An explanation of DEA regulations to increase access to methadone in carceral settings.](https://opioidprinciples.jhsph.edu/wp-content/uploads/2023/05/Methadone-Fact-Sheet.pdf)" John's Hopkins Bloomberg School of Health, available at <https://opioidprinciples.jhsph.edu/wp-content/uploads/2023/05/Methadone-Fact-Sheet.pdf>.

Option 2: Correctional facilities may provide methadone under the DEA 72-hour emergency rule (21 CFR 1306.07(b)).

The 72-hour rule allows a practitioner to dispense (but not prescribe) not more than a three-day supply of narcotic drugs, including methadone, to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's treatment.

### **Options for NTPs to Provide MOUD, Including Methadone, to Incarcerated Patients**

NTPs play a critical role in ensuring that incarcerated patients have access to MOUD. Below are various options for NTPs to provide MOUD (including buprenorphine and methadone) to, or coordinate the provision of MOUD for, to incarcerated patients.

#### Option 1: Provision of MOUD via a Medication Unit (MU) or Mobile Narcotic Treatment Program (MNTP)

A NTP may add a MU or MNTP to its license to expand services to additional locations, including correctional facilities. Please refer to "State Guidance for MUs and MNTPs" below for additional information regarding licensure.

#### Option 2: Provision of MOUD via Courtesy Dosing

A NTP may provide MOUD to a patient of another NTP on a short-term basis (less than 30 days) in accordance with 9 CCR, Section 10295. Courtesy dosing may be an option if an NTP's existing patient is placed in a correctional facility that is geographically closer to another NTP. The medical director or program physician of the originating NTP must provide prior approval for an existing patient to receive services on a temporary basis from another NTP (9 CCR, Section 10295). The approval must be noted in the patient's record and shall include the following documentation:

- The patient's signed and dated consent for disclosing identifying information to the NTP that will provide services on a temporary basis;
- A medication change order by the referring medical director or program physician permitting the patient to receive services on a temporary basis from another NTP for a length of time not to exceed 30 days; and
- Evidence that the medical director or program physician for the NTP contacted to provide services on a temporary basis has accepted responsibility to treat the visiting patient, concurs with their dosage schedule, and supervises the administration of the medication, subject to 9 CCR, Section 10210(d).

If an incarcerated patient needs courtesy dosing for more than 30 days, a NTP must request an exception from DHCS and SAMHSA by submitting a written request through the Center for Substance Abuse Treatment exception portal.

If a NTP contracts with a county or another NTP to provide treatment for incarcerated patients, the contracted medical director or program physician must coordinate with the home NTP's medical director or program physician on dosing levels if the contracted NTP identifies a need to change the dosing level.

### Option 3: Provision of MOUD by Authorized Correctional Facility Staff

A NTP may coordinate with the correctional facility to deliver take-home medication doses to incarcerated patients enrolled in the NTP. This option is not limited to individuals who were existing NTP patients prior to incarceration; this option permits NTPs to enroll new patients who are currently incarcerated. Under this option, authorized correctional facility staff may take possession of methadone and/or buprenorphine at the NTP and deliver it to the correctional facility for administration. Only the following correctional facility staff may dispense or directly administer medication on behalf of an NTP to incarcerated patients (21 CFR 1301.74(i)):

- (1) a licensed practitioner,
- (2) a registered nurse under the direction of the licensed practitioner,
- (3) a licensed practical nurse under the direction of the licensed practitioner,
- (4) a pharmacist under the direction of the licensed practitioner.

Any correctional facility staff who transports or administers medication must be made agents of the NTP through a formal writing that specifies the scope of their authority and duties.

Correctional facility staff who are not licensed to administer medication (21 CFR 1301.74(i)) may take transport medications from a NTP in a locked container. The authorized correctional facility staff transporting take-home medications cannot have a key to the locked container. The locked container must be given directly to the correctional facility nursing staff.

Incarcerated patients enrolled in a NTP may receive take-home medication for the duration of incarceration.

### Chain of Custody Requirements

A NTP that coordinates with a correctional facility to deliver take-home medication to incarcerated patients enrolled in the NTP must develop a standard process to document chain-of-custody. The chain-of-custody documentation must include:

- Name and address of treatment program;
- Medication to be delivered;
- Name of authorized staff transporting the take-home medication;
- Date take-home medication is picked up;
- Date take-home medication is delivered;

- Patient ID information (name, date of birth, ID #, admit date, dosage, amount of take-home medication being delivered, date incarcerated, date of potential release);
- Signature of authorized staff transporting the take-home medication;
- Signature of authorized staff receiving the take-home medication;
- Incarcerated patient must date and initial each day they are administered a dose from the correctional facility nursing staff.

A NTP must verify the identification of the authorized correctional facility staff before releasing take-home medication.

### **Counseling and Testing Requirements**

Counseling may be provided to incarcerated patients via telehealth or the correctional facility may transport patients to a NTP to receive counseling and complete required testing including laboratory tests to screen for illicit drug use and evidence of methadone and buprenorphine metabolites. Alternatively, a NTP may enter into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide counseling and testing services to incarcerated patients enrolled in the NTP pursuant to 42 CFR 8.12 (f)(1). The formal documented agreement must be submitted to DHCS along with a [DHCS 5135 Application for Protocol Amendment](#).

Counseling and testing requirements may be temporarily waived for the duration of incarceration. To obtain a waiver, a NTP must submit an electronic exception by using the Center for Substance Abuse and Treatment exception portal. An exception must be submitted for each incarceration patient needing an exception.

### **Federal Guidance**

#### **MUs**

42 CFR 8.11(i) provides that NTPs certified by the SAMHSA may establish MUs (as defined under 42 CFR 8.2) that are authorized to dispense opioid agonist treatment medications. Federal regulations under 42 CFR 8.12(b) require that NTP facilities “shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations.” Consistent with this requirement, SAMHSA issued guidance “[Letter to OTP Directors, SOTAs and State Directors on Mobile Component](#)” by clarifying the range of services that can be provided in MUs and MNTPs.

## **MNTPs**

The DEA added provisions to [21 CFR 1301.13\(e\)\(4\)](#) to clarify that NTPs may operate MNTPs at correctional facilities where otherwise permitted by law. “A mobile NTP may operate at correctional facilities within the same State as its registered location so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws, and regulations, and so long as the local DEA office, when notified pursuant to this section, does not otherwise direct.” 21 CFR 1301.13(e)(4)(iii).

For additional information, please see the complete [final rule](#) on registration requirements for NTPs with MNTPs.

## **State Guidance for MUs and MNTPs**

Existing NTPs seeking to add a MU to their NTP license to provide MAT at a correctional facility must submit a [DHCS 5014 Narcotic Treatment Program Initial Application form](#). Existing NTPs seeking to add a MNTP to their license to provide MAT at a correctional facility must submit a [Mobile NTP Initial Application Form DHCS 1830 \(BHIN 24-005\)](#). The program sponsor of the primary NTP shall be responsible for submitting the required [DHCS forms](#) and supplemental written protocols. The primary NTP is responsible for ensuring that patients have access to all other treatment services not provided at the MU or MNTP.

### **I. MU**

A MU is a facility established as part of, but geographically separate from, a narcotic treatment program, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis. Although [SAMHSA guidance](#) permits MUs to provide a wide range of services, including counseling, California regulations are more restrictive. Treatment services at a MU are limited to the administering and dispensing of medications and/or the collection of patient body specimens for testing or analysis of samples for illicit drug use. (9 CCR § 10020(m)).

### **II. MNTP**

Treatment services at an MNTP include administering and dispensing medications for OUD treatment, collecting samples for drug testing or analysis, dispensing of take-home medications, intake/initial psychosocial and appropriate medical assessments, initiating methadone or buprenorphine after an appropriate medical assessment has been performed, counseling may be provided directly or when permissible through use of telehealth services. All MNTP services must comply with all state and federal regulations and be provided with appropriate privacy and adequate space.

### III. Applications and Forms

To apply for an MNTP or MU, the primary NTP must submit an Initial Application package with a complete supplemental protocol and application fee. Please see the [DHCS NTP](#) website under [NTP Applications, Forms and Fees](#).

#### **Additional Guidance**

DHCS oversees NTPs in conjunction with SAMSHA, Center for Substance Abuse Treatment (CSAT) and the DEA. Approval must be received from the DEA and the SAMHSA before obtaining NTP licensure from DHCS and program operations can commence.

#### SAMHSA

- SAMHSA determines whether an NTP, MU, and MNTP is qualified to carry out treatment for substance use disorders under [Certification of Opioid Treatment Programs, 42 Code of Federal Regulations \(CFR\) 8](#) and [42 CFR Part 2](#).
- For SAMHSA approval of a new NTP, MU, and MNTP form SMA-162 and supporting documents must be submitted. Click [here](#) to start the process.
- To speak to a Compliance Officer, please call (240) 276-2700 or email [DPT@samhsa.hhs.gov](mailto:DPT@samhsa.hhs.gov).

#### SAMHSA NTP Accrediting Bodies

- Federal regulations require programs to become accredited by an approved accrediting body. Form SM-163 and supporting documents must be submitted. Click [here](#) to start the process.
- SAMHSA approved the following accreditation bodies to conduct accreditation surveys for Opioid Treatment Programs
  - Commission on Accreditation of Rehabilitation Facilities (CARF)
  - Council on Accreditation (COA)
  - The Joint Commission (JCAHO)

#### DEA

- Federal registration by DEA is required in accordance with [Title 21, CFR, Chapter 2](#).
- New NTPs and MUs need to be registered with the DEA, form 363 and supporting documents must be submitted. Click [here](#) to start the process.
- To speak with the Diversion Field Office, please call (800) 882-9539 or email [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov).

## **Contacts**

To speak with the DEA Diversion Field Office, please call (800) 882-9539 or email [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov). To speak to a SAMHSA Compliance Officer, please call (240) 276-2700 or email [DPT@samhsa.hhs.gov](mailto:DPT@samhsa.hhs.gov).

If you have questions regarding this BHIN, please contact [DHCSNTP@dhcs.ca.gov](mailto:DHCSNTP@dhcs.ca.gov) or contact (916) 322-6682. For questions regarding the CalAIM Justice Involved Initiative please contact [CalAIMJusticeAdvisoryGroup@dhcs.ca.gov](mailto:CalAIMJusticeAdvisoryGroup@dhcs.ca.gov).

Sincerely,

Janelle Ito-Orille, Division Chief  
Licensing and Certification Division