

# *Options to Ensure Access to Methadone for Treatment of Opioid Use Disorder in Corrections Settings*

PREPARED BY  
HEALTH MANAGEMENT ASSOCIATES (HMA)

AUTHORS:  
SHANNON ROBINSON, MD  
BREN MANAUGH, LCSW  
JULIE WHITE, MSW  
KELLY WRIGHT, MA

VERSION 3 – SEPTEMBER 7, 2023

*THIS ISSUE BRIEF WAS WRITTEN UNDER THE MAT IN JAILS AND DRUG COURTS LEARNING  
COLLABORATIVE, WHICH IS FUNDED THROUGH CALIFORNIA'S DEPARTMENT OF HEALTH CARE  
SERVICES (DHCS) WITH STATE GENERAL FUNDS.*

HEALTH MANAGEMENT ASSOCIATES

## Table of Contents

Introduction.....	1
Ensuring Access to Methadone in Jails for Individuals with OUD .....	2
Guiding Principle: <i>Medication First</i> .....	2
Screening and Assessment .....	2
Withdrawal Management and Continuity of Care .....	2
Continuous Quality Improvement .....	3
Options for Ensuring Access to Methadone (Beyond 72 Hours) for Treatment of Individuals with OUD in Jails.....	3
Transport Incarcerated Individuals to an Offsite, Licensed OTP/NTP for Dosing and Treatment .....	4
Jail Transports Medication from OTP/NTP into Facility for Staff Administration .....	4
Jail Becomes a Medication Unit Attached to a Community OTP/NTP .....	5
Jail Transports Individuals to Mobile Unit Outside the Facility but on Jail Grounds.....	5
OTP/NTP Staff Transport Medication Inside Jail and Administer Medication .....	5
Jail Becomes Licensed as a Hospital or Clinic .....	5
Jail Becomes a Licensed OTP/NTP .....	6
Jail Develops an Agreement with a Licensed OTP/NTP to Provide Methadone and Related/Required Services..	8

## Introduction

Methadone was the first medication that the US Food and Drug Administration (FDA) approved to treat opioid use disorder (OUD). Research and use over the past 50 years offers extensive evidence of methadone's effectiveness, including reduced illicit opioid use and mortality. Individuals who receive methadone during incarceration are more likely to continue treatment after their release,<sup>1</sup> and its use has been associated with lower levels of criminal activity.<sup>2,3</sup>

Methadone is one of the most heavily regulated drugs in the United States. Under federal law, methadone for OUD treatment can only be obtained through an opioid treatment program (OTP), also referred to as a narcotic treatment program (NTP). The [Substance Abuse and Mental Health Services Administration \(SAMHSA\)](#), the [Drug Enforcement Administration \(DEA\)](#), and [State Opioid Treatment Authority \(SOTA\)](#) regulate OTPs/NTPs. Federal rules govern the accreditation and certification processes for OTPs/NTPs and impose treatment requirements, including mandatory behavioral health counseling.

In accordance with the Narcotic Addict Treatment Act of 1974, "A practitioner who dispenses [Schedule II](#) narcotic drugs for maintenance and/or detoxification must obtain separate registration as a narcotic treatment program."<sup>4</sup> The registration allows practitioners to administer or dispense but not prescribe Schedule II narcotic drugs that the FDA has approved for OUD treatment.

The language used in these regulations can be confusing. Under federal rules, patients with OUD who are starting treatment with methadone must undergo supervised medication administration, which generally occurs daily at the OTP/NTP. Later in treatment, guidelines indicate that patients may become eligible for take-home dosing (or self-administration), freeing them and OTPs/NTPs from the need for daily administration.

According to the National Sheriff's Association (NSA) and the National Commission of Correctional Health Care (NCCHC), jails "are in a unique position to initiate treatment in a controlled, safe environment. Pharmacotherapy (i.e., medication assisted treatment [MAT]) is a cornerstone of best practice for recovery from substance abuse."<sup>5</sup> Jails can ensure access to methadone for incarcerated individuals by working with local, licensed OTPs/NTPs or can become licensed as OTPs/NTPs. The American Society of Addiction Medicine (ASAM) in 2020 issued a "Public Policy Statement on Criminal Justice Treatment of Opioid Use Disorder in Correctional Settings", which specifies that all

### What is the difference?

**Prescribe:** To order the use of a drug or device as a remedy

**Dispense:** To prepare and package a drug or device in a container and label the container with information required by state and federal law and deliver a controlled substance to an ultimate user

**Administer:** The direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means

Source:  
<http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section802&num=0&edition=prelim>

<sup>1</sup> National Institute on Drug Addiction. Methadone Maintenance Treatment During Incarceration Has Long-Term Benefits. 2019. Available at: <https://nida.nih.gov/news-events/nida-notes/2019/04/methadone-maintenance-treatment-during-incarceration-has-long-term-benefits>.

<sup>2</sup> Bukten A, Skurtveit S, Gossop M, Waal H, Stangeland P, Havnes I, Clausen T. Engagement with Opioid Maintenance Treatment and Reductions in Crime: A Longitudinal National Cohort Study. *Addiction*. 2012;107(2):393–399.

<sup>3</sup> Schwartz RP, Jaffe JH, O'Grady KE, Kinlock TW, Gordon MS, Kelly SM, Wilson ME, Ahmed A. Interim Methadone Treatment: Impact on Arrests. *Drug and Alcohol Dependency*. 2009;103(3):148–154.

<sup>4</sup> Narcotic Addict Treatment Act, S.1115, 93rd Cong. 1974. Available at: <https://www.congress.gov/bills/93rd-congress/senate-bill/1115>.

<sup>5</sup> National Sheriffs Association and National Commission on Correctional Health Care. Jail-Based MAT: Promising Practices, Guidelines and Resources. 2018. Available at: <https://www.sheriffs.org/jail-based-mat>.

FDA-approved medications for OUD, including methadone, should be available to incarcerated individuals.<sup>6</sup> Most jails are familiar with methadone treatment for pregnant detainees with an OUD and can build on this experience to extend access to all FDA-approved MAT for all incarcerated individuals who have OUD.

## Ensuring Access to Methadone in Jails for Individuals with OUD



### Guiding Principle: *Medication First*

Though federal guidance for OTPs/NTPs stipulates a requirement for delivery of behavioral health counseling, ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder states that a "patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay treatment with methadone." The Bureau of Justice Assistance (BJA) and National Institute of Corrections (NIC) emphasized this point in their *Guidelines for Managing Substance Withdrawal in Jails: A Tool for Local Government Officials, Jail Administrators, Correctional Officers and Health Care Professionals*.<sup>7,8</sup> As with all medications for opioid use disorder (MOUD), treatment planning with each individual should prioritize medical stabilization of any withdrawal symptoms or other health conditions, followed by determination of the best medication for the patient based on the prescriber's clinical judgment, the patient's choice, access to the medication, and the patient's ability to benefit from medication and psychosocial interventions.<sup>9</sup>

### Screening and Assessment

Best practices for MOUD programs in correctional settings include OUD screening of all people entering the system (universal screening) using a validated screening tool. This screening should be followed by a psychosocial assessment that includes evaluation for co-occurring behavioral health conditions and needs for social supports to inform release planning. Incorporation of these tools and practices improves access to appropriate mental health and substance use disorder (SUD) treatment and ensures MOUD treatment continues upon community reentry in coordination with community-based treatment providers.



### Withdrawal Management and Continuity of Care

The **72-hour rule** for temporary methadone dosing ensures access to methadone for an individual with an OUD to manage acute withdrawal and to arrange continued dosing of individuals for whom methadone is the most appropriate treatment. This three-day rule<sup>10,11</sup> is intended to be an exception to OTP/NTP licensure requirements to allow "a practitioner who is not separately registered as a narcotic [opioid]

<sup>6</sup> American Society of Addiction Medicine. Public Policy Statement on Treatment of Opioid Use Disorder in Correctional Settings. 2022. Available at: [https://www.asam.org/docs/default-source/public-policy-statements/2020-statement-on-treatment-of-oud-in-correctional-settings.pdf?sfvrsn=ff156c2\\_2](https://www.asam.org/docs/default-source/public-policy-statements/2020-statement-on-treatment-of-oud-in-correctional-settings.pdf?sfvrsn=ff156c2_2).

<sup>7</sup> American Society of Addiction Medicine. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. Available at: <https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline>.

<sup>8</sup> Bureau of Justice Assistance and National Institute of Corrections. Guidelines for Managing Substance Withdrawal in Jails A Tool for Local Government Officials, Jail Administrators, Correctional Officers and Health Care Professionals. 2023. Available at: <https://www.cossapresources.org/Tools/JailResources/Guidelines>.

<sup>9</sup> US Food and Drug Administration and Substance Abuse and Mental Health Services Administration. Dear Colleague Letter. May 9, 2023. Available at: <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-fda-samhsa.pdf>.

<sup>10</sup> National Archives. Code of Federal Regulations. Title 21, CFR, § 1306.07 (b). Last amended August 9, 2023. Available at: <https://www.ecfr.gov/current/title-21/chapter-II/part-1306/subject-group-ECFR1eb5bb3a23fddd0/section-1306.07>.

<sup>11</sup> US Department of Justice Drug Enforcement Agency. Instructions to Request for Exception to Limitations of Dispensing for Opioid Use Disorder. [https://www.deadiversion.usdoj.gov/drugreg/instructions-to-request-exception-to-21-CFR%201306.07\(b\)-3-day-rule-\(EO-DEA248R1\).pdf](https://www.deadiversion.usdoj.gov/drugreg/instructions-to-request-exception-to-21-CFR%201306.07(b)-3-day-rule-(EO-DEA248R1).pdf).

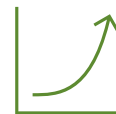
treatment program to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving **acute withdrawal** symptoms while arranging for the patient's referral for treatment," with the following stipulations:

- The 72-hour rule applies to physicians only. Other DEA-registered prescribers (e.g., nurse practitioners, physician assistants) are prohibited from exercising this prescribing authority.
- This treatment may not be conducted for more than 72 hours.
- This 72-hour period cannot be renewed or extended.
- Only a single day's dosage of medication may be administered or given to a patient at a time.
  - Congress directed the DEA to allow a three-day supply of medication at a time under specific exception provisions. Guidance on the 72-hour rule can be found in the [DEA's January 12, 2023 letter](#), which states, "In accordance with 21 CFR 1307.03, a DEA-registered practitioner working in a hospital, clinic, or emergency room, or any DEA-registered hospital/clinic that allows practitioners to operate under their registration number as per [21 CFR 1301.22\(c\)](#), may request an exception to the one-day supply limitation currently imposed pursuant to [21 CFR 1306.07\(b\)](#). Consistent with Pub. L. 116-215, DEA will grant such requests to allow a practitioner to administer or dispense (but not prescribe) up to a three-day supply of the medication under the circumstances described in subsection 1306.07(b).

**Correctional facilities may consider the applicability of the 72-hour rule in ensuring access to MAT for incarcerated individuals with OUD as an option to relieve acute withdrawal.**

### Continuous Quality Improvement

Jails should incorporate the OTP/NTP and methadone maintenance treatment into ongoing comprehensive healthcare service delivery and continuous quality improvement (CQI) efforts (i.e., medical advisory committee meetings, CQI workgroup sessions, and quality assurance projects).<sup>12</sup>



### Options for Ensuring Access to Methadone (Beyond 72 Hours) for Treatment of Individuals with OUD in Jails

Jails have the option of collaborating with an offsite OTP/NTP to provide methadone and related required services or may provide these services independently.

Collaboration with an offsite OTP/NTP through one of the following mechanisms*	Jail managing OTP/NTP services without local OTP collaboration
<ul style="list-style-type: none"> <li>• Jail transports individuals who are incarcerated to licensed OTP/NTP for dosing and treatment</li> <li>• Jail transports medication from OTP/NTP into facility for administration by staff</li> <li>• Jail transports individuals to mobile unit outside the facility but on jail grounds</li> <li>• Jail becomes a medication unit attached to a licensed OTP/NTP</li> <li>• OTP/NTP staff transport medication inside jail and administer medication</li> </ul>	<ul style="list-style-type: none"> <li>• Jail becomes licensed as a hospital/ clinic (this does not take care of all patients in need of treatment - see below for more details)</li> <li>• Jail becomes licensed as an OTP/NTP</li> </ul>

<sup>12</sup> Health Management Associates. Using Data to Understand and Evaluate MOUD in Jails. September 10, 2023. Available at: <https://vimeo.com/477175681/4423ab9598>.

**Collaboration with an offsite OTP/NTP through one of the following mechanisms\*****Jail managing OTP/NTP services without local OTP collaboration**

*\*Collaborative options require development of an MOU, described in more detail at the end of the document, after all options are reviewed.*

## Transport Incarcerated Individuals to an Offsite, Licensed OTP/NTP for Dosing and Treatment

Jails can provide access to methadone by transporting detainees to a licensed OTP/NTP. Transporting detainees to a community-based provider supports facilities' ability to make this evidence-based treatment available to detainees while they are incarcerated to minimize the disruption of their established treatment regimen and

It is unlikely that all people who need MOUD will already be affiliated with an offsite OTP/NTP or enrolled in the jail's OTP/NTP (if the jail has an OTP/NTP license). Therefore, regardless of which option for providing methadone is chosen, staff will need familiarity with guest dosing.

**Guest medication dosing** provides a mechanism for patients who are ineligible for take-home medication to travel from their home clinic for business, pleasure, or family emergencies. It also provides an option for patients who need to travel for a period that exceeds the amount of eligible take-home doses.

recovery process. The OTP/NTP may file an *exception request for take-home dosing* to allow less frequent transport of the individual to the OTP/NTP when medication jail staff could administer the MAT in a controlled environment. Set times for detainees to receive services should be established regardless of the frequency of transport to the OTP/NTP. Furthermore, according to the DEA's *Narcotic Treatment Program Manual*, any individual who transports or dispenses the medication should be made an agent of the OTP/NTP through a formal written agreement.<sup>13</sup>

Transportation of detainees offsite for treatment presents logistical challenges. Allocating custody staff for escort and transport strains the workforce, contributes to staff overtime expenses, and heightened safety and security concerns that arise whenever a detainee leaves the facility. Options for providing methadone within or closer to the facility are attractive alternatives, but many sites are unfamiliar with the regulations and logistics required to take this step.

## Jail Transports Medication from OTP/NTP into Facility for Staff Administration

SAMHSA provided exceptions to increase allowable take-home doses of methadone in response to the COVID-19 public health emergency and has extended the take-home flexibilities for one year beyond the declaration of the end of the pandemic, during which time the proposed rule may be finalized.<sup>14,15</sup> Not all SOTA OTPs/NTPs are granted this exception, so HMA advises that jails contact their local SOTA to verify applicability in their state. Jails that select this option should ensure that all individuals who transport or dispense the medication are made agents of the OTP/NTP and ensure use of chain of custody documents. [SAMHSA's Federal Guidelines for Opioid Treatment Programs](#) includes specific reference for the "Provision of Medication to Patients Who Are Incarcerated, in

<sup>13</sup> US Department of Justice Drug Enforcement Agency. *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations*. Available at: [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-056\)\(EO-DEA169\)\\_NTP\\_manual\\_Final.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-056)(EO-DEA169)_NTP_manual_Final.pdf).

<sup>14</sup> Substance Abuse and Mental Health Services Administration. *Methadone Take-Home Flexibilities Extension Guidance*. Updated August 4, 2023. Available at: <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance>.

<sup>15</sup> Substance Abuse and Mental Health Services Administration. *Medications for the Treatment of Opioid Use Disorder Notice of Proposed Rulemaking*. Released December 16, 2022. Available at <https://public-inspection.federalregister.gov/2022-27193.pdf>.

Residential Treatment, Medically Compromised, or Homebound” including an “Example of Medication Chain-Of-Custody Record” as well as “Program Responsibilities.”<sup>16</sup>

### **Jail Becomes a Medication Unit Attached to a Community OTP/NTP**

A medication unit is an entity that dispenses methadone at a separate location but in affiliation with an OTP/NTP. Medication units’ DEA registration, records, and inventories must be separate from the affiliated OTP/NTP. As with any other expansion of services, the affiliated OTP/NTP should contact SAMHSA and its SOTA as the medication unit cannot exist without a sponsoring OTP/NTP.<sup>17</sup> The sponsoring OTP/NTP for a medication unit can be in a different county but must be in the same state. Additional requirements include:

- Admission of patients by the OTP/NTP and not the medication unit.
- A medication unit can be used for dosing, including guest dosing, of patients already enrolled in an OTP/NTP.
- Medication units can collect and analyze toxicology tests.
- Patients must still participate in treatment at the OTP/NTP for services not available at the medication unit.

### **Jail Transports Individuals to Mobile Unit Outside the Facility but on Jail Grounds**

As of 2021, the process for opening a mobile unit no longer requires obtaining a separate DEA registration from the affiliated OTP/NTP. The unit must operate in the same state as the OTP/NTP with which it is affiliated. A benefit of a mobile unit over a medication unit is that both new and existing patients can be treated, and records remain with the affiliated OTP/NTP. Approval from the local DEA and SOTA must be obtained. For additional information, please visit the following webpages:

- <https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components>

### **OTP/NTP Staff Transport Medication Inside Jail and Administer Medication**

If OTP/NTP staff transport medication inside the jail, the MOU between the jail and OTP/NTP should include expectations and requirements for staff providing services within the facility, including:

- Background checks
- Security protocols
- Behavior and conduct requirements
- Orientation to correctional settings versus community settings
- MAT program policies, procedures, and processes

### **Jail Becomes Licensed as a Hospital or Clinic**

Individuals receiving in-hospital medical or surgical care for a condition other than addiction may be administered or dispensed narcotic medications for treatment maintenance or detoxification (withdrawal management) purposes under longstanding regulations.<sup>18</sup> For example, pregnancy is a recognized medical condition, and

---

<sup>16</sup> Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs*. Washington, DC; US Department of Health and Human Services. March 2015. Available at: <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>.

<sup>17</sup> US Department of Justice Drug Enforcement Agency. *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations*. June 25, 2022. Available at: [https://www.deadiversion.usdoj.gov/GDP/DEA-DC-056\(EO-DEA169\)\\_NTP\\_manual\\_Final.pdf](https://www.deadiversion.usdoj.gov/GDP/DEA-DC-056(EO-DEA169)_NTP_manual_Final.pdf).

<sup>18</sup> National Archives. Code of Federal Regulations. Title 21 C.F.R. § 2.1306 - Prescriptions. Amended August 9, 2023. Available at: <https://www.ecfr.gov/current/title-21/chapter-II/part-1306>.



methadone treatment for pregnant individuals in hospital units has been in place for decades; however, this option only covers individuals who have other medical and surgical conditions and, therefore, does not apply to individuals who are experiencing opioid withdrawal and OUD without comorbidities. Consequently, some individuals who may need in-patient treatment for SUD/OUD may receive inadequate care. The federal government has been encouraged by SUD providers and other stakeholders to expand this provision in the future.

## Jail Becomes a Licensed OTP/NTP

The program must have SAMHSA certification, a state license, and DEA registration to qualify for a license to establish an OTP/NTP within a carceral setting. The [SAMHSA Federal Guidelines for Opioid Treatment Programs](#) is a helpful resource to become familiar with regulatory requirements, and the OTP/NTP application process workflow provided within the Toolkit provides a broad overview. This process can take long time to complete. Project management tools can help facilities stay on track during the licensure process. Facilities pursuing this option should consider engaging their local DEA office early on to review regulations that may affect policies and procedures.

Recommended steps for pursuing OTP/NTP licensure and certification include:

- Understand state licensure requirements
  - Contact the state opioid authority to confirm accurate understanding of state licensure requirements.
- Review overall OTP/NTP requirements
  - The Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8, governs the use of MAT for OUD in OTPs.<sup>19</sup>
  - OTPs must provide counseling and other behavioral therapies that ensure a whole-person approach to treatment. Federal regulations stipulate access to behavioral healthcare and wraparound services as part of the treatment that OTP/NTPs or affiliated providers offer; however, national practice guidelines clearly emphasize a medication-first approach.
  - OTPs must provide urine drug testing.
  - OTPs must provide counseling on the prevention of HIV.
  - To help OTPs/NTPs achieve regulatory compliance for both certification and accreditation, SAMHSA developed *Federal Guidelines for Opioid Treatment Programs – 201*, and DEA's *Narcotic Treatment Program Manual: A Guide to Narcotic Treatment Program Regulations* was updated in 2022.<sup>20,21</sup>

### **OTPs must be:**

**Licensed:** OTPs/NTPs must be licensed by the state in which they operate.

**Accredited:** Peer-review process that evaluates OTP/NTP against SAMSHA's opioid treatment standards and the accreditation standards of SAMSHA-approved accrediting bodies (NCCHC or The Joint Commission).

**Certified:** OTPs/NTPs must be licensed and accredited before they become certified. This process confirms the OTP/NTP complies with federal regulations governing SUD treatment.

**Registered:** OTPs/NTPs must register with the DEA through the local office.

<sup>19</sup> GOVREGS. Code of Federal Regulations. Title 42 § 8.11 - Opioid treatment program certification. 2023. Available at: [https://www.govregs.com/regulations/expand/title42\\_chapterI\\_part8\\_subpartC\\_section8.12](https://www.govregs.com/regulations/expand/title42_chapterI_part8_subpartC_section8.12).

<sup>20</sup> Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs*. US Department of Health and Human Services. March 2015. Available at: <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>.

<sup>21</sup> US Department of Justice Drug Enforcement Agency. *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations*. June 25, 2022. [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-056\)\(EO-DEA169\)\\_NTP\\_manual\\_Final.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-056)(EO-DEA169)_NTP_manual_Final.pdf)



- The Division of Pharmacologic Therapies (DPT), part of [SAMHSA's Center for Substance Abuse Treatment \(CSAT\)](#), manages the day-to-day oversight activities necessary to implement federal regulations on the use of SUD medications, including methadone.
- [SAMHSA's OTP/NTP Compliance Officers](#) process new and renewal certifications for OTPs. In addition, SAMHSA's OTP/NTP Compliance Officers provide OTPs/NTPs with ongoing guidance and support.
- Review SAMHSA OTP/NTP **application** requirements at: <https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program>.
  - Provisional certification application: <https://dpt2.samhsa.gov/sma162/>.
  - Certification must be renewed annually.
- The application must include:
  - A description of the organizational structure of the program, with a chart indicating the position and title of key OTP/NTP personnel. The description should include the name and complete address of any central administration or larger organizational structure that runs the OTP/NTP is responsible.
  - A diagram and description of the facilities that the program intends to use, which demonstrate whether the facilities are adequate for drug dispensing and for individual and group counseling. The description shall specify how the OTP/NTP will provide adequate medical, counseling, vocational, educational, and assessment services at the primary facility, unless the program sponsor has entered into a formal agreement with another entity for such services.
  - The name, address, and description of each hospital, institution, clinical laboratory, or other facility the OTP/NTP uses to provide the necessary medical and rehabilitative services.
  - The name and address of any facility other than the primary dispensing site where methadone will be dispensed either regularly or on weekends and as a service to the treatment program.
  - A copy of the medical director's DEA registration, state medical license, and curriculum vitae. If the medical director also serves in this role at another treatment program, enclose a written justification for the feasibility of such an arrangement. This statement should explain the portion of the medical director's time spent treating unrelated patients and membership on boards and committees that compete for time allocated to the treatment programs.
  - The name and state license number of all OTP/NTP personnel (other than program physicians) who are legally permitted to dispense narcotic drugs even if they have no responsibility for administering or dispensing methadone at the program. These individuals would include pharmacists, registered nurses, and licensed practical nurses.
  - A tentative schedule of dispensing hours, counseling hours, and hours when physicians, nurses, and counselors are working. Any work to be performed away from the primary dispensing site also should be stated. The program must be open for dispensing at least six days per week. **In a correctional facility**, provisions need to be made for dispensing and administration 7 days per week, and a description of how the dispensing hours are adequate and will ensure quality of patient care per 42 CFR 8.12 (b) is required.
  - A list of the program's funding sources, including the name and address of each government agency that provides funds.
  - A description of the number of patients whom the program will treat when operating at capacity.
  - An affirmative statement that the treatment program will use containers that have safety closures for all take-home medication dispensed to outpatients.
  - Acknowledgement (and registration) that the medical director and/or program physician must register for an account on the SAMHSA OTP/NTP extranet website to submit federal patient exception requests (Form SMA168) online. After the request is verified, the applicant will receive an email with a username and password.

- **Accreditation:** A copy of the application to the appropriate accrediting body. The document should indicate the date on which the program applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to occur, and the anticipated schedule for completing the accreditation process.
  - [NCCHC](#) (National Commission on Correctional Health Care) accredits OTPs.
  - [The Joint Commission](#) accredits OTPs/NTPs.
- **DEA Licensure:** OTPs/NTPs must apply for a federal DEA license, as well as any required state licensure (confirmation required on DEA federal license application).<sup>22</sup>
- Ensure the facility meets DEA security/diversion requirements. This may require purchase of a medication safe, video recording equipment, or augmented medication security procedures.<sup>23</sup>
- Once SAMHSA has approved an application, the DEA and any subsequent state site inspections must be completed. DEA site inspection will include review of:
  - State and SAMHSA licenses
  - Names and titles of OTP/NTP administrators
  - Hours of operation/dispensing times
  - Whether a correctional officer is present during dispensing times and where the officer will be located
  - Identification of methadone supplier and **reverse distributor**
  - Medication forms (powder, tablets, liquid form for methadone). The "DEA does not dictate the types of methadone formulations allowed in correctional facilities."<sup>24</sup>
  - Name, Social Security number (SSN), date of birth (DOB), and home address of all dosing nurses
  - Name, SSN, and DOB of all staff who will have the combination and/or access to secured methadone
  - Name, address, point of contact of the security company responsible for the installation and maintenance of security systems. *Note:* In a correctional facility, information regarding the facilities' security measures will need to be provided (i.e., access to medication rooms, key control, lock boxes)
  - Identification of responsible party for record keeping

*What is a reverse distributor?*

A **reverse distributor** is a person registered with the DEA to acquire and accept controlled substance from another registrant or destroy the unused substance.

## Jail Develops an Agreement with a Licensed OTP/NTP to Provide Methadone and Related/Required Services

Several operational steps are recommended for jails to develop relationships with established OTPs, beginning with the following:

- Identify [certified OTP](#)/potential partner for provision of methadone for OUD.
- Conduct outreach/determine willingness/availability of local partner.
- Engage local drug and alcohol authority in collaborative planning.
- Negotiate an MOU with the local OTP/NTP. The MOU or another clear, written formal agreement must clearly delineate roles, responsibilities, and timelines for the treatment partners—the OTP/NTP and the correctional facility. Exemplars from other jails can often be accessed to facilitate development of a site's new MOU for this purpose.
- The agreement should address:

<sup>22</sup> US Department of Justice Drug Enforcement Agency. Form 363. Available at: <https://www.deadiversion.usdoj.gov/>.

<sup>23</sup> National Archives. Code of Federal Regulations. 21 CFR 1301.72. Amended August 8, 2023. Available at: <https://www.ecfr.gov/current/title-21/chapter-II/part-1301>.

<sup>24</sup> Bureau of Justice Assistance Comprehensive Opioid, Stimulant, And Substance Abuse Program. Jails and Methadone Provision. April 2022. Available at: [https://www.cossapresources.org/Content/Documents/Articles/Jails\\_and\\_Methadone\\_Provision.pdf](https://www.cossapresources.org/Content/Documents/Articles/Jails_and_Methadone_Provision.pdf).

- A timely process for confirming patient enrollment and dosage with OTP/NTP (exchange of information), hours of operation, and emergency contacts.
- Method of payment and/or billing for medication, counseling, and other required services during incarceration.
- Method (in person or via telehealth), location, and frequency of required counseling and toxicology. Health Management Associates' (HMA) [Collaboration Opportunities for County Jails and Opioid Treatment Programs to Support and Expand MOUD Services](#) provides more information. Check state requirements.
- Method of medication transportation/delivery to the facility, including chain of custody documentation. Consider staff job descriptions, labor agreements, and payment for transportation. Locked containers for transporting the actual methadone, with keys made available only to the individual dispensing the medication at OTP/NTP and the designated jail staff receiving the lockbox.
- Expectations regarding coordinated/integrated care planning with other jail general health, behavioral health, and other programming (i.e., peer support)
- Expectations regarding documentation in a paper record or an electronic health record (EHR)
- Understanding of "guest dosing"<sup>25,26</sup> for detainees who are not or were not enrolled with a partner OTP/NTP but are receiving methadone from another OTP/NTP. For example, if an individual is enrolled in one OTP/NTP (OTP A) and is incarcerated in another county that has an agreement with another OTP/NTP to provide methadone (OTP B), OTP/NTP B may provide methadone for the individual in the jail. This arrangement would be considered guest dosing.
- Plan for communication regarding and management of diversion of methadone doses, missing doses, and returned doses. (See HMA's [Implementation Toolkit Topic: Medication Administration with Diversion Considerations](#).)
- Re-entry planning and coordination
- Data/outcome collection and reporting expectations
- Process for remediation/dispute resolution
- Terms of the agreement

---

<sup>25</sup> American Association for Treatment of Opioid Dependence, Inc. AATOD Guidelines for Guest Medication. <http://www.aatod.org/advocacy/policy-statements/aatod-guidelines-for-guest-medication/>

<sup>26</sup> Substance Abuse and Mental Health Service Administration. *Federal Guidelines for Opioid Treatment Programs*. March 2015. Available at: <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>.