Options to Ensure Access to Methadone for Treatment of Opioid Use Disorder in Correctional Facilities

PREPARED BY
HEALTH MANAGEMENT ASSOCIATES (HMA)

AUTHORS:
SHANNON ROBINSON, MD
BREN MANAUGH, LCSW
JULIE WHITE, MSW
KELLY WRIGHT, MA
DEBBI WITHAM, LMSW, JD

VERSION 4 – MARCH 25, 2024

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.

Table of Contents

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 offer extensive evidence of methadone's effectiveness, including reduced illicit opioid use and mortality.[1,2] Individuals who receive methadone during incarceration are more likely to continue treatment after their release, and its use has been associated with lower levels of criminal activity. [3,4,5,6]

Methadone is one of the most heavily regulated medications 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) in each state regulate OTPs/NTPs. Federal rules govern the accreditation and certification processes for OTPs/NTPs

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: 21 USC 802

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."[7] The registration allows practitioners to administer or dispense but not prescribe Schedule II narcotic drugs that the FDA has approved for OUD treatment.

Federal rules require that patients with OUD being initiated on, and in the early stages of treatment with, methadone receive frequently supervised dispensing until the patient has stabilized on the dosage of methadone and has decreased or eliminated other opioid use. Current rules now allow for up to seven days of take-home doses from the first day of administration when clinically indicated for patients in all settings. This initial treatment stage generally occurs at the OTP/NTP. When patients are considered by their provider and treatment team to be eligible for take-home dosing (or self-administration), this frees them and OTPs/NTPs from the need for daily administration of methadone.[8]

SAMHSA published a frequently asked question (FAQ) webpage to accompany 42 CFR Part 8 Final Rule that was published in 2024.

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

[1] Mattick RP, Breen C, Kimber J, Davoli M. Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence. *Cochrane Database of Systematic Reviews*. 2009(3):CD002209.
[2] Sordo L, Barrio G, Bravo MJ, Indave BI, Degenhardt L, Wiessing L, Ferri M, Pastor-Barriuso R. Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies. British Medical Journal. 2017; 26(357):j1550.
[3] 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.
[4] 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.
[5] 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.
[6] Centers for Disease Control and Prevention. Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices. 2022. Available at: https://www.cdc.gov/drugoverdose/pdf/pubs/linkage-to-care_edited-pdf_508-3-15-2022.pdf
[7] Narcotic Addict Treatment Act, S.1115, 93rd Cong. 1974. Available at: https://www.congress.gov/bill/93rd-congress/senate-bill/1115.
[8] GOVREGS. Code of Federal Regulations. Title 42 § 8. – Medications Assisted Treatment for Opioid Use Disorder. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8

recovery from substance abuse."[9] Correctional facilities 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) issued guidance in 2020 which specifies that all FDA-approved medications for OUD, including methadone, should be available to incarcerated individuals.[10] The US Centers for Disease Control (CDC) also recommends that incarcerated individuals with OUD receive medications for opioid use disorder (MOUD) to ensure correctional facilities are aligned with current medical standards for treating OUD and to reduce overdose and other adverse outcomes.[11] The Bureau of Justice Assistance (BJA) and National Institute of Corrections (NIC) also state that methadone and buprenorphine are considered first line for opioid withdrawal and OUD.[12] Most correctional facilities are familiar with methadone treatment for pregnant detainees with an OUD and can build on this experience to extend access to all FDA-approved MOUD for all incarcerated individuals with OUD.

Ensuring Access to Methadone in Correctional Facilities for Individuals with OUD

Guiding Principle: *Medication First*

Though federal guidance for OTPs/NTPs has historically stipulated a requirement for delivery of non-pharmacological cognitive and behavioral health interventions - referred to as behavioral health services - in conjunction with methadone treatment, Title 42, Code of Federal Regulations (CFR), part 8, section (f)(5) now explicitly states "patient refusal of counseling shall not preclude them from receiving MOUD."[13] ASAM 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."[14] The CDC's published guidance on the issue of behavioral services to treat OUD in conjunction with MOUD states "compared to other forms of treatment based solely on counseling, psychotherapy, social support, or behavioral therapy, buprenorphine and methadone stand out consistently as effective treatments for OUD and for preventing overdose." The CDC further states "treatment programs that adopt a medication-first, low-barrier approach (i.e., placing low expectations on persons wishing to begin treatment) are crucial for helping persons access and initiate MOUD treatment."[15]

The BJA and NIC emphasize 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.*[16] With all 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

[9] 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.
[10] 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.
[11] Centers for Disease Control and Prevention. Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices. 2022. Available at: https://www.cdc.gov/drugoverdose/pdf/pubs/linkage-to-care_edited-pdf_508-3-15-2022.pdf
[12] 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.
[13] GOVREGS. Code of Federal Regulations. Title 42 § 8.12(f)(5) – Federal Opioid Treatment Standards. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12
[14] 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.
[15] Centers for Disease Control and Prevention. Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices. 2022. Available at: https://www.cdc.gov/drugoverdose/pdf/pubs/linkage-to-care_edited-pdf_508-3-15-2022.pdf
[16] 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.

prescriber's clinical judgment, the patient's choice, access to the medication, and the patient's ability to benefit from medication and psychosocial interventions.[17]

Screening and Assessment

Best practices for MOUD programs in correctional facilities includes OUD screening of all people entering the system (i.e., universal screening) using a validated screening tool.[18] 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 informs MOUD treatment 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.[19,20] This three-day rule is intended to be an exception to OTP/NTP licensure requirements to allow "a practitioner who is not separately registered as a narcotic [opioid] 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 providers (e.g., nurse practitioners, physician assistants) are not eligible.
- 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 methadone for incarcerated individuals with OUD as an option to relieve acute withdrawal.

[17] 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.
[18] Centers for Disease Control and Prevention. Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices. 2022. Available at: https://www.cdc.gov/drugoverdose/pdf/pubs/linkage-to-care_edited-pdf_508-3-15-2022.pdf
[19] 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.
[20] 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 .

Continuous Quality Improvement

Correctional facilities should incorporate the OTP/NTP and methadone maintenance treatment into ongoing comprehensive healthcare service delivery and continuous quality improvement (CQI) efforts (e.g., medical advisory committee meetings, CQI workgroup sessions, and quality assurance projects).[21]

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

Correctional facilities 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*	• Correctional facility transports individuals who are incarcerated to licensed OTP/NTP for dosing and treatment. • Correctional facility transports medication from OTP/NTP into facility for administration by correctional staff. • Correctional facility transports individuals to mobile unit outside the facility but on correctional facility grounds. • Correctional facility becomes a medication unit attached to a licensed OTP/NTP. • OTP/NTP staff transport medication inside correctional facility and administer medication. • Use of telehealth between OTP/NTP and correctional facility supporting required physician evaluation for initiation of methadone treatment for OUD.
Correctional facility managing OTP/NTP services without local OTP/NTP collaboration	• Correctional facility becomes licensed as an OTP/NTP.
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

Correctional facilities 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 recovery process. The OTP/NTP may file an *exception request for take-home dosing* by submitting the SMA-168 exception request to obtain approval from the SOTA to allow less frequent transport of the individual to the OTP/NTP when healthcare staff could administer the MOUD in a controlled environment.[22] Detainees should receive services on an established schedule 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.[23]

[21] Health Management Associates. Using Data to Understand and Evaluate MOUD in Jails. September 10, 2020. Available at: https://vimeo.com/477175681/4423ab9598.
[22] Substance Abuse and Mental Health Services Administration. *Submit an Opioid Treatment Exception Request*. Available at: https://www.samhsa.gov/medications-substance-use-disorders/otp-resources/submit-exception-request
[23] 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.

Transportation of detainees offsite for treatment presents logistical challenges. Allocating custody staff for escort and transport strains the workforce, as well as 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, and new rules allowing for seven days of take-home doses presents a new option, but many sites are unfamiliar with the regulations and logistics required to take this step. Alternatives are described below.

It is unlikely that all people who need MOUD will already be affiliated with an offsite OTP/NTP or enrolled in the correctional facility's OTP/NTP (if it 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.

Correctional Facility 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 made these flexibilities permanent in the updates to the 42 CFR Part 8.[24] States that choose to implement the new take-home flexibilities may need to do so through their own rule-making process, thus correctional facilities should verify take-home medication regulation applicability in their state. Correctional facilities 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 processes and documents. SAMHSA's Federal Guidelines for Opioid Treatment Programs includes specific reference for the "Provision of Medication to Patients Who Are Incarcerated, in Residential Treatment, Medically Compromised, or Homebound" including an "Example of Medication Chain-Of-Custody Record" as well as "Program Responsibilities."[25] While the document cited has not been updated to incorporate the final rule published in February 2024 (and will go into effect in October 2024), the chain of custody guidance provided would not be impacted by these changes.

Correctional Facility 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 the SOTA to clearly understand the federal, state, and local rules to open a medication unit.[26] 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.

[24] GOVREGS. Code of Federal Regulations. Title 42 § 8. – Medications Assisted Treatment for Opioid Use Disorder. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8

[25] 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.

[26] 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.

Patients must still participate in treatment at the OTP/NTP for services not available at the medication unit; however, updated regulations allow for medication units to provide all services provided in an OTP/NTP, provided there are appropriate provisions for privacy and adequate space.[27]

Correctional Facility Transports Individuals to Mobile Unit Outside Facility but on 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 review the DEA Rule on Registration Requirements for Narcotic Treatment Programs With Mobile Components.

OTP/NTP Staff Transport Medication Inside Correctional Facility and Administer Medication

If OTP/NTP staff transport medication inside the correctional facility, the MOU between the correctional facility 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.

Correctional Facility Becomes Licensed as a Hospital or Clinic

While the final rule clarifies that correctional facilities do not require certification as an OTP/NTP for initiation or continuation of medication treatment or withdrawal management, it does not address the rule language that the use of methadone for the treatment of OUD must be secondary to another condition, as it is out of the scope of rulemaking.[28] It will be beneficial for correctional facilities to continue to monitor the development of this rule and potential federal guidance.

Correctional Facility 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 SAMHSA guidelines provides a broad overview.[29] 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 SOTA to confirm accurate understanding of state licensure requirements.
- Review overall OTP/NTP requirements:

[27] GOVREGS. Code of Federal Regulations. Title 42 § 8.11(h) - Opioid treatment program certification. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.11

[28] GOVREGS. Code of Federal Regulations. Title 42 § 8 - Opioid treatment program certification. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8?toc=1

[29] 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.

- The Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8, governs the use of MOUD in OTPs/NTPs.[30]
- OTPs/NTPs are required to have a medical director and program sponsor.[31]
- OTPs/NTPs must provide:
  - Counseling and other behavioral therapies as clinically necessary. The updated regulations explicitly state that patient lack of participation in counseling *shall not* preclude treatment with MOUD.
  - Initial and periodic physical and behavioral health assessments.
  - Initial medical examinations.
  - Drug testing.
  - Special services to pregnant persons, including education.
  - Counseling on the prevention of HIV.[32]
- OTPs/NTPs must arrange for appropriate record-keeping and confidentiality.
- 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.[33,34]

OTPs/NTPs must be:

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

Accredited: Peer-review process that evaluates OTP/NTP against SAMHSA's opioid treatment standards and the accreditation standards of SAMHSA-approved accrediting bodies (National Commission on Correctional Health Care [NCCHC], Commission on Accreditation of Rehabilitation Facilities [CARF], Council on Accreditation [COA] or The Joint Commission [TJC]).

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.

- 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/NTPs. 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: [35]

[30] GOVREGS. Code of Federal Regulations. Title 42 § 8.11 - Opioid treatment program certification. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.11

[31] GOVREGS. Code of Federal Regulations. Title 42 § 8.12(b) - Federal opioid treatment standards. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12

[32] GOVREGS. Code of Federal Regulations. Title 42 § 8.12(f) - Federal opioid treatment standards. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12

[33] 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.

[34] US Department of Justice Drug Enforcement Agency. *Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations*. 2022. Available at: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-056)(EO-DEA169)_NTP_manual_Final.pdf

[35] GOVREGS. Code of Federal Regulations. Title 42 § 8.11(b) - Opioid treatment program certification. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.11

  - Current accreditation status.
  - A description of the organizational structure of the program, including the names of the person responsible for the OTP/NTP.
  - The addresses of the OTP/NTP (and any associated medication units or other facility under the OTP/NTP).
  - The source of funding for the OTP/NTP and the name and address of each governmental entity that provides funding.
  - A statement the OTP/NTP will comply with the conditions of certification.
  - Must be signed by the program sponsor, certifying the information is true and correct.
- **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, CARF, COA, and TJC accredit 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).[36]
- Ensure the facility meets DEA security/diversion requirements. This may require purchase of a medication safe, video recording equipment, or augmented medication security procedures.[37]
- 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."[38]
  - 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, and 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 (e.g., access to medication rooms, key control, lock boxes).
  - Identification of responsible party for record keeping.

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

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

Several operational steps are recommended for correctional facilities to develop relationships with established OTP/NTPs, beginning with the following:

- Identify certified OTP/NTP or potential partner for provision of methadone for OUD.

[36] US Department of Justice Drug Enforcement Agency. Form 363. Available at: https://www.deadiversion.usdoj.gov/.
[37] 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.
[38] 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.

- 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 correctional facilities can often be accessed to facilitate development of a site's new MOU for this purpose.
- The agreement should incorporate state/SOTA-specific requirements and include:
    - A timely process for confirming patient enrollment and dosage with OTP/NTP (exchange of patient 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.
    - 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 correctional facility staff receiving the lockbox.
    - Understanding of "guest dosing" 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/NTP **A**) and is incarcerated in another county that has an agreement with another OTP/NTP to provide methadone (OTP/NTP **B**), OTP/NTP **B** may provide methadone for the individual in the correctional facility. This arrangement would be considered guest dosing. [39,40]
    - Understanding of telehealth, 72-hour rule, and take-home regulations and practices. Previous regulations required an in-person physical which created challenges for correctional facilities in partnering with an OTP/NTP for the initiation of methadone. Regulations now allow for the completion of the initial medical examination via audio/visual telehealth, reducing the requirement to transport the individual to the OTP/NTP for the initial medical examination. The 72-hour rule can be used as a bridge to ensure access to medication while awaiting admission to the partnering OTP/NTP. In partnership with the OTP/NTP, the correctional facility medical staff could administer methadone while the OTP/NTP conducts the admission physical via telehealth. Once admitted the OTP/NTP medical director may then file an *exception request for take-home dosing* by submitting the SMA-168 exception request to obtain approval from the SOTA reducing the need to transport the detainee to the OTP/NTP.
    - Expectations regarding coordinated/integrated care planning with other general health, behavioral health, and other programming (e.g., peer support).
    - Expectations regarding documentation in a paper record or an electronic health record (EHR).
    - Plan for communication regarding and management of diversion of methadone doses, missing doses, and returned doses.
    - Reentry planning and coordination.
    - Data/outcome collection and reporting expectations.
    - Process for remediation/dispute resolution.
    - Terms of the agreement.[41]

[39] American Association for Treatment of Opioid Dependence, Inc. AATOD Guidelines for Guest Medication. Available at: http://www.aatod.org/advocacy/policy-statements/aatod-guidelines-for-guest-medication/

[40] 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.

[41] GOVREGS. Code of Federal Regulations. Title 42 § 8.12(f)(2)(B)(v) - Federal opioid treatment standards. 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12