

**TOPIC:**

## Options to Assure Access to Methadone for Treatment of Opioid Use Disorder in Jails

Methadone is one of three medications for addiction treatment (MAT) approved by the United States Food and Drug Administration (FDA) to treat opioid use disorder (OUD). Methadone has the longest history of FDA-approved MAT and has been proven effective in reducing illicit opioid use and mortality. Methadone remains one of the most heavily regulated drugs in the United States despite extensive evidence of its effectiveness. Under federal law, methadone for OUD treatment can only be obtained at opioid treatment programs (OTPs; also known as Narcotics Treatment Programs, or NTPs), which are regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA). The regulation states “A practitioner who dispenses Schedule II narcotic drugs for maintenance and/or detoxification must obtain separate registration as a narcotic treatment program” pursuant to the Narcotic Addict Treatment Act of 1974. This registration allows a practitioner to administer or dispense, but not prescribe, Schedule II narcotic drugs that are approved by the FDA for the treatment of narcotic addiction.”<sup>1</sup> Federal rules govern the accreditation and certification processes for OTPs and impose treatment requirements, such as mandatory behavioral health counseling. Patients receiving methadone must also undergo supervised medication dosing, which generally occurs daily at the OTP. In addition to federal rules, states have supplementary regulations on establishing and licensing OTPs and the services OTPs must provide. Jails and prisons can assure access to methadone for incarcerated individuals by working with local, licensed OTPs or can become licensed as OTPs. American Society of Addiction Medicine (ASAM) National Practice Guideline revisions for criminal justice populations (2020), specify that all FDA- approved medications for OUD, which includes methadone, should be available to incarcerated individuals.<sup>2</sup> Most jails and prisons are familiar with methadone through experience assuring access for pregnant inmates with an OUD and can build on this experience to extend access to all FDA-approved MAT for all inmates with OUD.

### Decision Points for Assuring Access to Methadone for Individuals with OUD in Jails

There are three options for assuring access to methadone for the treatment of individuals with OUD in jails:

1. Transport inmates offsite from the correctional facility to a licensed OTP for dosing and treatment
2. Develop an agreement with a licensed OTP to provide methadone and related, required services within the facility, and/or
3. Become licensed as an OTP as a jail or prison facility

**“72-Hour Rule” for temporary methadone dosing:** This option assures access to methadone for an incarcerated individual with an OUD for management of acute withdrawal and for bridging until arrangements can be made with a provider for continued dosing for individuals for whom methadone is the most appropriate treatment. This “three-day rule” or “72-hour rule” (Title 21,

<sup>1</sup> [https://www.dea.gov/pubs/advisories/emerg\\_treat.htm](https://www.dea.gov/pubs/advisories/emerg_treat.htm)

<sup>2</sup> [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)

Code of Federal Regulations, Part 1306.07(b))<sup>3</sup> is intended to be an exception to OTP 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, under the following conditions:

- » Not more than one day's medication may be administered or given to a patient at one time
- » This treatment may not be carried out for more than 72 hours and;
- » This 72-hour period cannot be renewed or extended

“The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent the separate registration requirement.”<sup>4</sup> Correctional facilities should consider the applicability of the “72-hour rule” in ensuring access to MAT for individuals with OUD who are incarcerated as an option to relieve acute withdrawal.

- 1) **Transport Inmates:** Most correctional facilities (jails; prisons/prison systems) begin with provision of methadone by transporting inmates to a licensed OTP, typically beginning with pregnant inmates with an OUD. Transporting inmates to a community-based provider supports a facility's ability to make this evidence-based treatment available to inmates while they are incarcerated to minimize disruption of their established treatment regimen and recovery process. As a facility expands treatment options for all inmates, or in facilities with larger daily census, transportation of inmates offsite for treatment presents logistical challenges. This includes allocating custody staff for escort and transport as well as security concerns that arise whenever an inmate leaves the detention facility. Options for providing methadone within the facility are an attractive alternative but many sites are unsure about the regulations and logistics required to take this step.

In order for correctional facility sites to take the next step toward provision of methadone within the correctional facility sites the must explore and develop options that best align with the facility's goals and resources to determine a pathway, either establishing a relationship with a community-based provider for distribution of methadone inside the detention setting or becoming a licensed OTP.

SAMHSA's Federal Guidelines for Opioid Treatment Programs (2015) include specific reference for the “Provision of Medication to Patients Who Are **Incarcerated**, in Residential Treatment, Medically Compromised, or Homebound” (emphasis added); including an “Example of

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<sup>3</sup> [https://www.deadiversion.usdoj.gov/pubs/advisories/emerg\\_treat.htm](https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm)

<sup>4</sup> [https://www.deadiversion.usdoj.gov/pubs/advisories/emerg\\_treat.htm](https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm)

Medication Chain-Of-Custody Record” as well as “Program Responsibilities.”<sup>5</sup> Review of the guidelines and requirements help the correctional facility determine the responsibilities and requirements for an OTP in providing treatment to patients who are incarcerated and determining whether it is feasible and desirable for the facility to obtain an OTP license. Whether a correctional facility seeks to become an OTP or to develop relationships with an established OTP, several specific operational steps are recommended. Following are recommendations and resources for sites seeking to establish a relationship with a community-based OTP for provision of methadone within their correctional facility:

## 2) Provision of methadone inside the correctional facility by an OTP:

- » **Develop or expand a relationship with a licensed OTP. See OTP Application Process workflow provided within the Toolkit.**
- » **Identify local OTP/potential partner for provision of methadone for OUD**
  - <https://dpt2.samhsa.gov/treatment/directory.aspx>
- » **Conduct outreach/determine willingness/availability of local partner**
- » **Engage local drug and alcohol authority in collaborative planning**
- » **Negotiate agreement with local OTP which should be a memorandum of understanding (MOU) or other clear, written formal agreement that clearly delineates roles, responsibilities and timelines for the treatment partners: the OTP and the Correctional Facility**
- » **Ensure agreement addresses:**
  - Timely process for confirming patient enrollment and dosage with OTP (exchange of information)
  - Method of medication transportation/delivery to the facility (including Chain of Custody documentation if needed)
  - Payment for medication and required counseling while incarcerated
  - Method (in person or telehealth), location and frequency of required counseling (NOTE: In Pennsylvania the licensed OTP must provide counseling component per DDAP requirements – see HMA webinar “Collaboration Opportunities for County Jails and Opioid Treatment Programs to Support and Expand MOUD services” for more information)
  - Expectations regarding coordinated/integrated care planning with other jail general health, behavioral health and other programming (including peer supports if available); including integrated care for co-occurring healthcare needs
  - Expectations and requirements for staff providing services within the facility, including:
    - Background checks
    - Security protocols
    - Behavior and conduct requirements
    - Orientation to correctional settings versus the community setting
    - MAT program policies, procedures and processes

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<sup>5</sup> <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP> is helpful to inform the site’s approach.

- Understanding of “guest dosing”<sup>6 7</sup> for inmates who are not/were not enrolled with partner OTP but are receiving methadone from other OTP. For example, if an individual is enrolled in one OTP (OTP A) and is incarcerated in another county with an agreement with another OTP to provide methadone (OTP B), OTP B may provide methadone for the individual in the jail. This would be considered “guest dosing” and would require an exception request for the “take home” medication. This would require coordination between the correctional facility, OTP B and OTP A. This was confirmed with DDAP, see HMA webinar “Collaboration Opportunities for County Jails and Opioid Treatment Programs to Support and Expand MOUD services” for more information.
  - Plan for communication regarding, and management of, diversion of methadone doses, missing doses and returned doses. (See Implementation Toolkit Topic: Medication Administration with Diversion Considerations)
  - Re-entry planning and coordination
  - Data/outcome collection and reporting expectations
  - Process for remediation/dispute resolution
  - Term of the agreement
    - NOTE: Many of these areas also apply when the facility is transporting the individual to the OTP for treatment and should be addressed via formal, written agreement.
- » **Incorporate OTP coordination and methadone maintenance treatment into ongoing planning and quality improvement efforts.**
- This includes monitoring pandemic related regulatory flexibilities and changes in same.
  - For reference, see HMA webinar “Using Data to Understand and Evaluate MOUD in Jails” within Additional Resources list.
- » **Several jails and prisons have attained licensure as an OTP by working through the process, outlined in an example workflow. See OTP Application Process workflow provided within the Toolkit and outlined below:**
- » **Understand state licensure requirements:**  
Contact Pennsylvania Department of Drug and Alcohol Programs (PA DDAP) to assure current, accurate understanding of PA licensure requirements:  
[https://www.ddap.pa.gov/Licensing/Pages/Licensing\\_Drug\\_and\\_Alcohol\\_Facilities.aspx](https://www.ddap.pa.gov/Licensing/Pages/Licensing_Drug_and_Alcohol_Facilities.aspx)
- » **Review overall OTP requirements:**
- The use of MAT for OUD in OTPs is governed by the Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8.<sup>8</sup>
  - OTPs must be:
    - Certified and Accredited;
    - Licensed by the state in which they operate; and
    - Registered with the DEA, through their local DEA office
  - To help OTPs achieve regulatory compliance for both certification and accreditation, SAMHSA developed Federal Guidelines for Opioid Treatment Programs – 2015.<sup>9</sup>
  - OTPs must provide counseling and other behavioral therapies to provide patients with a whole-person approach.

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<sup>6</sup> <http://www.aatod.org/advocacy/policy-statements/aatod-guidelines-for-guest-medication/>

<sup>7</sup> <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>

<sup>8</sup> [https://www.govregs.com/regulations/expand/title42\\_chapter1\\_part8\\_subpartC\\_section8.12](https://www.govregs.com/regulations/expand/title42_chapter1_part8_subpartC_section8.12)

<sup>9</sup> <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>

- OTPs must also provide counseling on the prevention of human autoimmune virus (HIV). SAMHSA recommends OTPS also screen and educate high-risk patients on other infectious diseases.

» **Review SAMHSA OTP application requirements:**

<https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program>, Provisional Certification Application: <https://dpt2.samhsa.gov/sma162/>

» **Accreditation: A copy of the application to the accrediting body to which the program has applied must be included with the federal application. 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 take place, and the expected schedule for completing the accreditation process.**<sup>10</sup>

The National Commission On Correctional Health Care (NCCHC) offers accreditation for OTPs: <https://www.ncchc.org/opioidtreatmentprogramsaccreditation>

» **Application: Applications must include:**

- A description of the organizational structure of the program with a chart indicating the position and title of key OTP personnel. The description should include the name and complete address of any central administration or larger organizational structure to which the OTP is responsible.
- A diagram and description of the facilities to be used by this program demonstrating how the facilities are adequate for drug dispensing and for individual and group counseling. The description shall specify how the OTP will provide adequate medical, counseling, vocational, educational, and assessment services at the primary facility, unless the program sponsor has entered into a formal documented agreement with another entity.
- The name, address, and description of each hospital, institution, clinical laboratory, or other facility used by the OTP 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 on a regular basis or on weekends, and as a service to the treatment program. NOTE: This is likely a simple requirement for most correctional facilities.
- A copy of the medical director's DEA registration, state license, and curriculum vitae. If the medical director is also the medical director for another treatment program, enclose a written justification for the feasibility of such an
- arrangement. This feasibility shall address the portion of the medical director's time spent in the treatment of unrelated medical patients and memberships on boards and committees that compete for time allocated to the treatment programs.
- The name and state license number of all OTP personnel (other than program physicians) licensed by law to dispense narcotic drugs even if they are not, at present, responsible for administering or dispensing methadone at the program. These would include pharmacists, registered nurses, and licensed practical nurses.
- A tentative schedule showing dispensing hours, counseling hours, and hours to be worked by physicians, nurses, and counselors. Any work to be performed away from the primary dispensing site should also be stated. The program must be open for dispensing at least six days per week. Also, describe how the dispensing hours are adequate and will ensure quality of patient care per 42 CFR 8.12 (b).
- A list of the program's funding sources, including the name and address of each governmental agency providing funds.

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<sup>10</sup> [https://www.thenationalcouncil.org/wp-content/uploads/2020/01/MA-Franklin-County\\_Becoming-a-Methadone-Clinic-OTP-at-a-Correctional-Facility-1.pdf?daf=375ateTbd56](https://www.thenationalcouncil.org/wp-content/uploads/2020/01/MA-Franklin-County_Becoming-a-Methadone-Clinic-OTP-at-a-Correctional-Facility-1.pdf?daf=375ateTbd56)

- A description of the number of patients that will be treated by the program when it is operating at capacity.
  - An affirmative statement that the treatment program will use containers having safety closures for all take-home medication dispensed to outpatients. NOTE: Potential to be a non-issue for correctional facilities.
  - Acknowledgement that the medical director and/or program physician must register for an account on the SAMHSA OTP Extranet website to submit federal patient exception requests (Form SMA168) online. Applicants may register for an extranet account at the SAMHSA OTP Extranet website. After the request is verified, the applicant will receive an email with a username and password for use of the website.
- » **DEA Licensure: OTPs must apply to the DEA for a federal DEA license, as well as any required state licensure (confirmation required on DEA federal license application).**<sup>11</sup>
- » **Assure facility meets DEA security/diversion requirements. This may require purchase of a safe or augmenting medication security procedures.**<sup>12</sup>
- » **Once SAMHSA communicate approval of application to DEA, complete DEA and any subsequent state site inspections. DEA site inspection will include review of:**
- State and SAMHSA licenses.
  - Names and titles of Narcotic Treatment Program (NTP) Administrators
  - Hours of operation/dispensing times
  - Whether a Correctional Officer present during dispensing times and where they will be located
  - Identification of Methadone supplier and Reverse Distributor.
  - Medication forms (powder, tablets, liquid form for Methadone)
  - Name, SSN, DOB, and home address of all dosing nurses.
  - Name, SSN, 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.
  - Identification of responsible party for record keeping.

**NOTE:** All approaches presume the facility has evidence-based screening, assessment, treatment planning, drug screening, and medication administration procedures in place.

For more information and resources as part of the MOUD Implementation Toolkit, please visit [www.healthmanagement.com/pajailmoud](http://www.healthmanagement.com/pajailmoud) or contact **Mary Kate Brousseau**, TA Program Manager, at [mbrousseau@healthmanagement.com](mailto:mbrousseau@healthmanagement.com)

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<sup>11</sup> [https://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/363/363\\_instruct.htm#4](https://www.deadiversion.usdoj.gov/drugreg/reg_apps/363/363_instruct.htm#4)

<sup>12</sup> [https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301\\_72.htm](https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm)