SAMHSA ADVISORY
Substance Abuse and Mental Health Services Administration

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CLINICAL CONSIDERATIONS FOR METHADONE TREATMENT OF OPIOID USE DISORDER IN CORRECTIONAL FACILITIES

Introduction

People with opioid use disorder (OUD) are frequently encountered in jails and prisons in the United States. More than 40 percent of Americans who used heroin in the past year reported they had been recently arrested, on probation, or on parole.[1]

The risks of untreated OUD among incarcerated individuals are significant, particularly upon their return to the community following release. Studies indicate opioid-related overdose mortality rates as high as 40 to 129 times that of the general population, especially in the few weeks following reentry.[2,3,4] Medications for opioid use disorder (MOUD), specifically methadone and buprenorphine, reduce that mortality substantially.[5]

Methadone and buprenorphine reduce opioid use, promote recovery from OUD, and lower the risk of opioid-related overdose and mortality.[6] While all forms of Food and Drug Administration (FDA)-approved MOUD are effective, they are not equivalent. Recent data suggest that patients are more likely to remain in treatment when taking methadone compared to buprenorphine, and therefore have a lower risk of death and overdose.[7] Patients also may have a strong preference for one medication over the other based on prior experience, medical comorbidities, or access to an opioid treatment program (OTP) — the only outpatient setting in which methadone treatment for OUD is available in the United States.[8]

Given the significant risks of untreated OUD, it is, therefore, important that people with OUD who are incarcerated have access to methadone as a treatment option. The Department of Justice has issued guidance that correctional facilities risk violating the Americans with Disabilities Act if they deny MOUD to patients who are being treated for OUD at the time of their incarceration. Access to buprenorphine in jails and prisons has increased rapidly in the past 5 years, but progress in methadone access has been much slower.[9,10]

Methadone, along with other MOUD, should be available to incarcerated patients with OUD in every correctional facility in the United States. Offering only tapering doses of methadone to minimize withdrawal is not sufficient, as return to illicit opioid use is common following withdrawal management and is associated with risk of morbidity and mortality.[11] This *Advisory* on Clinical Considerations for Methadone Treatment of Opioid Use Disorder in Correctional Facilities seeks to guide correctional health care providers and correctional leaders on ways to expand access to methadone, taking into consideration variables such as the size of correctional facilities, average length of stay, and staffing patterns.

This *Advisory* embodies the core principles of President Trump's Make America Healthy Again (MAHA) initiative by addressing one of our nation's most devastating chronic disease epidemics—opioid use disorder—through evidence-based, transparent healthcare approaches. Nowhere is this more important than in correctional settings where mortality rates following release can be 40 to 129 times higher than the general population. By expanding access to methadone treatment in correctional facilities, this *Advisory* advances the commitment to ensuring that every American, regardless of their circumstances, has access to life-saving treatments that work. The evidence is overwhelming: methadone, as well as other MOUD reduce mortality, promote recovery, and break the cycle of addiction and incarceration that devastates families and communities across the nation.

Furthermore, this *Advisory's* recommendations help reduce institutional barriers and conflicts of interest that prevent Americans from accessing effective healthcare, a MAHA principle. The five models presented for implementing treatment of OUD with methadone, demonstrate the transparency and flexibility that MAHA champions—allowing facilities to select the option that best serves their populations and facilities while maintaining rigorous safety standards. By treating OUD as the chronic medical condition it is, and by ensuring continuity of care from incarceration through community reentry, the recommendations support fundamental health principles that prioritize healing. The clinical considerations included represent a critical step in fulfilling MAHA's promise to address the chronic disease burden affecting millions of Americans, while building a healthcare system that empowers both providers and patients to achieve lasting wellness and recovery.

Models for Providing Methadone

For incarcerated patients with OUD, methadone can be provided via a partnership with a community OTP, or it can be provided directly by healthcare staff of the correctional facility. These two options can be subdivided into a total of five potential models.

Option 1: A community OTP can treat incarcerated patients through one of the following models:	
1	Correctional facility transports patients to an OTP
2	Correctional facility collaborates with an OTP and allows them to establish a brick-and-mortar medication unit (with a separate Drug Enforcement Administration [DEA] registration) within the facility
3	Correctional facility allows an OTP to bring a mobile unit onto the grounds of the facility
Option 2: Healthcare practitioners within the jail or prison can provide methadone without partnering with an outside entity through either of the following models:	
4	Correctional facility becomes certified as its own OTP
5	Correctional facility uses its DEA hospital/clinic registration to administer methadone to patients with OUD "to maintain or detoxify a patient as an incidental adjunct to medical or surgical treatment of conditions other than addiction." 21 CFR 13.07(c)

* Note that the DEA refers to Narcotic Treatment Programs (NTPs), for which SAMHSA refers to as OTPs.

† 21 CFR 1306.07(b) states: "Nothing in this section shall prohibit a practitioner, who is not specifically registered to conduct a narcotic treatment program, from dispensing (but not prescribing) narcotic drugs, in accordance with applicable Federal, State, and local laws relating to controlled substances, to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both). Not more than a three-day supply of such medication may be dispensed to the person or for the person's use at one time while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended."

This document will review the clinical and related administrative considerations of each of these models. Each of these models requires compliance with all relevant state and federal regulations, including SAMHSA and DEA regulations.* Of note, this *Advisory* is in reference to use of methadone for long-term treatment of OUD and is not meant to exclude use of methadone under the 3-day rule of 21 CFR 1306.07(b).† It also does not cover the use of methadone for pain management.

The clinical and administrative model best suited to each correctional facility will vary based on the type of facility (jails vs. prisons), average length of stay, proximity and capacity of community OTPs, staffing resources and their skill sets, and other considerations. There are a variety of federal funding sources that can be used to fund expansion of methadone access in correctional settings, including SAMHSA grants through State and Tribal Opioid Response programs or the Medication-Assisted Treatment – Prescription Drug and Opioid Addiction program, the Centers for Medicare & Medicaid Services' Medicaid 1115 waivers, and Department of Justice Bureau of Justice Assistance grants.

Option 1: Partnership With Community OTP Models

Any partnership with a community OTP will require memoranda of understanding or contracts to specify the expectations of both the facility staff and the external OTP staff. These documents should delineate the following:

- Staff roles at each organization pertaining to the care of patients enrolled in the OTP, including screening, diagnosis, treatment planning, medication dispensing and monitoring, toxicology testing and results interpretation, and medication discontinuation.
- Procedures for sharing of medical records and other protected health information between the OTP and other healthcare providers serving the facility.
- Specification of the extent of OTP services provided in-person or provided via telehealth and with what frequency.[12]
- Logistics of transporting patients and/or medication to and from the correctional facility (including identification of clinical spaces, medication storage and handling, requirements for OTP staff who will be entering the facility, etc.).
- Coordination of reentry planning including care coordination and case management responsibilities.
- Mutual expectation of regulatory compliance with state and federal entities.
- Mutual expectation of adherence to accreditation standards if appropriate.
- Quality assurance processes and data collection and reporting requirements specific to the partnership and progress of the shared patients.
- Policy and processes for dispute resolution.
- Financial responsibilities, including payment or billing for services.

See the Federal Guidelines for Opioid Treatment Programs (2024) or more information.

Model 1: Transport Patients to a Community OTP

The jail or prison can transport patients to an outside OTP for some or all of the OTP services, including medical evaluations, medication dosing, toxicology testing, addiction counseling, and other recovery support services. Given the logistical challenge of transporting patients daily for directly observed therapy, there are mechanisms available for medication to be brought to the facility. Staff employed by the correctional facility may take custody from the OTP/Narcotic

Treatment Program (NTP) of a locked container that holds patient-specific medication. Facilities should consult section 12.2 of the DEA Narcotic Treatment Program Manual for further details about this option. Some OTPs may be able to provide addiction counseling via telehealth, and urine toxicology may be able to be collected by correctional facility health staff, reducing travel needs.[13] SAMHSA's revised 42 CFR Part 8, released in February 2024, facilitates more OTP services being delivered remotely, including the provision to initiate methadone via audio-visual telehealth platforms. See the Federal Guidelines for Opioid Treatment Programs (2024) for more information.

A benefit of transporting patients to a community OTP is that neither the community OTP nor the correctional facility has to navigate regulatory requirements that may be new to them. It may not require significant investments in infrastructure or medical staff inside the facility but will require understanding of federal and state regulations regarding medication storage procedures and medication administration for days when the OTP is closed. Admittedly, in some cases it is costly to have sufficient correctional staff to supervise transportation out of the facility, and transportation may convey additional security risks. It requires protocols for timely transportation to the OTP, including models for dedicated times for the OTP to provide services. This model may be best for facilities that have a very small number of patients with OUD at any one time. Other factors that are important to consider include distance from a community OTP, its hours of operation, and who at the correctional facility can transport the methadone under chain-of-custody record.

Model 2: Brick-and-Mortar Medication Unit Within the Correctional Facility

SAMHSA defines a medication unit as an entity that is part of, but geographically separate from, a community OTP located in the same state. A brick-and-mortar medication unit is located within a fixed location in a different facility from the home OTP. Such medication units require separate DEA NTP registration, as stated in the DEA NTP Manual Section 2.9. At that unit, OTP staff can administer methadone (and buprenorphine) and provide other services, including new patient evaluations, although most brick-and-mortar locations in practicality function to primarily dispense methadone. Required services that are not available in the medication unit are generally offered by the affiliated OTP. See the Federal Guidelines for Opioid Treatment Programs (2024) page 23, for more information.

Model 3: Mobile OTP Medication Unit on the Grounds of the Correctional Facility

Medication and other services can also be delivered to patients via a mobile unit (such as a van) that travels onto the grounds of the correctional facility. Notably, OTP nursing staff working on a mobile unit must administer or dispense medication to patients from the mobile unit; they cannot go into the correctional building to administer medication. Mobile units are required to return to their registered location (their affiliated OTP) after completing their clinical operations each day because controlled medications cannot remain in the mobile unit for security purposes. The mobile NTP may only operate in the same state in which the existing NTP is registered.[‡]

Considerations for Determining Type of Medication Unit

Establishing a medication unit, whether brick-and-mortar or mobile, requires more institutional planning than transporting patients or having corrections staff take custody of the patient-specific medication from the OTP.[§] However, this model minimizes the need to transport patients out of the facility, while still relying on the clinical staff of the OTP. The size and layout of the correctional facility will help determine whether a fixed medication unit or a mobile unit is more practical for the respective facility.

[‡] See section 12 of the DEA Narcotic Treatment Program Manual. DEA's final rule regarding Registration Requirements for Narcotic Treatment Programs With Mobile Components is available from the *Federal Register*. Mobile NTP regulations can be found at 21 CFR 1301.13(e)(4) and 1301.72(e)(1)13.

[§] See Model 1 above.

For facilities with limited space availability, it may not be reasonable to establish a brick-and-mortar medication unit; a mobile unit offers more flexibility if the facility has an appropriate outdoor location to accommodate medication dispensing. Consideration should be given to which OTP services will be provided in person at the medication unit and which will be provided via telehealth. All medication units, whether brick-and-mortar or mobile, require SAMHSA and DEA approval and compliance with federal, state and local laws and regulations. Correctional facilities and OTPs can obtain more information

about state regulations by consulting with their respective state's State Opioid Treatment Authority (SOTA). This is a state-level administrator who oversees state and federal requirements related to the provision of OTP services. For more information, see SAMHSA's Federal Guidelines for Opioid Treatment Programs (2024) and DEA's Narcotic Treatment Program Manual, Section 2.9.

Option 2: Methadone Treatment by Correctional Facility Healthcare Practitioners

Model 4: OTP Certification

To operate an OTP, a correctional facility must be certified by SAMHSA, registered with DEA as a NTP and licensed by the state in which it operates. After 1 year of operation, they then obtain accreditation from one of the SAMHSA-approved accreditation entities (see Approved Accreditation Bodies). The National Commission on Correctional Health Care (NCCHC) is the primary accreditation body for jails and prisons, and can provide consultation on implementation and ongoing service delivery. Programs applying for accreditation, certification and registration must also comply with the applicable laws and regulations in their states. Each state's SOTA is a valuable resource throughout this process. For detailed guidance on the process of becoming certified as an OTP, consult SAMHSA's Certification of Opioid Treatment Programs website.

Having an OTP as part of a correctional institution facilitates close collaboration between the OTP, the correctional facility's other health services (including infectious disease screening and treatment and mental health services), and correctional officers. It also allows the facility to dispense take-home medication at the time of release to facilitate reentry. For prisons and jail facilities with larger populations and longer lengths of stay, this may be a model that provides comprehensive whole-person care at a scale that can be administratively and financially supported. Facilities that become licensed OTPs will still need to establish relationships with community OTPs for coordination of reentry services.

SAMHSA's 42 CFR Part 8 requires OTPs to offer adequate counseling and other services either directly or by referral, in addition to medication and medical evaluations. They are required to provide drug testing and counseling on the prevention of HIV and other communicable disease. These services are particularly valuable for incarcerated individuals, so incorporating them into the rehabilitative operations at the correctional facility may be in line with other institutional goals and efforts. To help OTPs achieve regulatory compliance, SAMHSA developed the Federal Guidelines for Opioid Treatment Programs (2024).

Model 5: Hospital/Clinic Registration

Some correctional facilities may be registered with DEA as a hospital/clinic, following state recognition as such. DEA regulations provide that "a physician or authorized hospital staff may administer or dispense methadone in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction" (21 CFR 1306.07(c)). The primary diagnosis for care cannot be addiction. While correctional facilities using this regulatory provision are not registered with DEA as Narcotic Treatment Programs and are not required by SAMHSA to offer the full suite of services that OTPs provide as delineated in SAMHSA's 42 CFR Part 8, clinical best practices

indicate that patients should be able to access counseling services (either provided by an addiction counselor or a licensed behavioral health provider), harm reduction services, and recovery support services.

Methadone treatment under the hospital/clinic registration may be advantageous for smaller facilities or facilities with high turnover. Hospital/clinic registration does not entail the up-front costs of creating an in-house OTP, nor does it require the staff time that transportation to an outside OTP would require. In practice, facilities currently providing methadone under the hospital/clinic registration report that the majority of patients with OUD have other medical conditions that require treatment. However, it is still important for correctional facilities that provide methadone via their hospital/clinic registration to partner with a community OTP to ensure availability of methadone for patients with OUD who present without a primary condition. Developing connections with community OTPs is also necessary to facilitate continuity of treatment upon reentry.

Other Considerations for Implementation of Methadone Treatment in Correctional Facilities

Built Environment and Medication Storage

In preparation for implementing methadone treatment for OUD, correctional settings should consider the built environment and layout of the campus. For example, consideration should be given to whether medical evaluations, medication dispensing, and other clinical services will occur in a single building or at each building in the facility. What space is needed for medication administration in an efficient and compassionate manner? Correctional facilities that store methadone on-site must install equipment and establish policy and procedures to safeguard against theft and diversion, as described in 21 CFR 1301.71-1301.76. Planners may seek input from front-line staff, DEA regional offices and state regulators on how to use available space or modify the physical plant to manage patient flow and diversion risks during medication hours.

Medication Administration Procedures

Medication administration procedures require interdisciplinary planning and continuous process improvement to ensure that patients receive their medication in a timely and compassionate manner. Correctional facilities must "provide effective controls and procedures to guard against theft and diversion of controlled substances" (21 CFR 1301.71(a)). It is also important that clinical and correctional staff involved with medication administration do not make patients accessing methadone treatment feel stigmatized. Trauma-informed approaches can support recovery even within the carceral environment. See SAMHSA's Practical Guide for Implementing a Trauma-Informed Approach for more information. Medication can be administered in a centralized location or in a decentralized manner provided that a control plan is in place to minimize the risks of medication theft or diversion (42 CFR 8.12(c)(2)).

Correctional Staff Engagement

Correctional staff play a critical role in clinical care in jails and prisons, and addiction treatment programs' success will depend on whether they have obtained support from front-line officers and senior correctional leadership. Facilities implementing methadone treatment should seek to engage and educate all correctional officers to avoid the stigmatization of people with addiction or medications for OUD.[14] People in recovery who take methadone, or correctional leadership from other facilities who have seen the benefits of MOUD, are often effective ambassadors when front-line officers are skeptical about methadone treatment. Staff trainings should be multidisciplinary, involving not only medical staff but also correctional officers and administrative personnel. Training should cover the benefits of MOUD, common myths and misconceptions, diversion prevention, regulatory compliance and strategies for supporting people with OUD in the facility.[15]

Additional Services

OTPs must offer adequate medical, counseling, vocational, and educational services, either onsite or by referral to an outside entity or practitioner. These services are particularly valuable to patients with OUD who will be incarcerated for extended periods of time and can either be provided by employees (or contractors) of the correctional facility by an outside entity, such as a community OTP. If the providers of these services are not employees of the correctional facility or an OTP, the correctional facility should encourage their participation in staff trainings as well. In particular, the implementation team should ensure that other service providers are not exposing patients or their families to messaging that further stigmatizes against methadone or buprenorphine.

Peer support specialists who share their lived experience with correctional staff and incarcerated people can reduce stigma regarding discussion of drug use and addiction treatment and can provide other valuable recovery support services. Correctional facilities' policies may unintentionally prevent peers from working in their jail or prison by requiring extensive background checks, drug testing, and excluding people with any history of incarceration or drug use. It is important that the correctional facilities develop policies and practices that enable peer specialists to work with their residents.

Continuity of Care

Disruptions in access to methadone or buprenorphine can lead to uncomfortable, and sometimes life-threatening, withdrawal. Interruption in any MOUD puts patients at risk of return to use or overdose. Therefore, continuity of MOUD should be a priority in all correctional settings. There are three key transition points where gaps in treatment can occur:

Intake

Because some people with OUD may be taking methadone prior to arrest and because many people who have OUD experience withdrawal once they are incarcerated, quality care requires timely screening and diagnosis. Starting at intake, there should be universal screening using a validated tool, such as the NIDA Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS) Tool, to identify patients with SUDs, including OUD. Those who screen positive will need follow-up assessments to make the diagnosis of OUD and to evaluate for any co-occurring health conditions and psychosocial factors that will inform treatment and reentry planning.[16,17] The intake process should, in a timely manner, identify patients who are already receiving methadone in the community or who are transferring from another jurisdiction, as well as patients who may benefit from methadone initiation. The facility will then be able to communicate with the OTP or prior jurisdiction to determine dosage and to arrange for continued medication, recognizing that the dosing interval for methadone is 24 hours with a half-life of the medication of between 24 and 36 hours.

Guest dosing is a mechanism that allows patients to be administered methadone by a different OTP when they must travel away from their home clinic, if the home OTP has not provided a sufficient supply of take-home methadone doses for the time the patient will be away. Incarceration is an example of an emergency where guest dosing is appropriate, and guest dosing can be a useful tool for ensuring there are no interruptions in methadone treatment. For example, correctional facilities who partner with a local community OTP should develop a shared understanding of their partner OTP's guest dosing policies. When people receiving methadone from a different OTP become incarcerated, the correctional facility's partner OTP can coordinate guest dosing with the person's home OTP to confirm their dose and ensure the patient receives medication promptly. Guest dosing does not require an evaluation by a provider at the partner OTP. If the patient is going to remain incarcerated for a prolonged period, the partner OTP can perform its own admission and enroll the patient for ongoing treatment.

Transfers Between Jurisdictions or Facilities

Correctional facilities in different jurisdictions may not offer methadone or may offer methadone through differing models. Jails and prisons that offer methadone should perform an assessment of the facilities in the area where they frequently transfer residents, to see if and how they offer methadone treatment. Patients may elect not to start methadone if they are uncertain whether they will have access to medication because of a potential transfer. Some gaps in treatment can be avoided by creating procedures for closed-loop communication between the transferring and the receiving correctional facility.

For instances in which continued methadone maintenance cannot be arranged, the Bureau of Justice Assistance provides *Guidelines for Managing Substance Withdrawal in Jails*, including management of opioid withdrawal. Per 21 CFR 1306.07, methadone may be dispensed by a practitioner for up to three days for detoxification treatment: "Up to a three day supply of methadone may be dispensed by a practitioner to one person or for one person's use for the purpose of initiating maintenance treatment or detoxification treatment (or both) while models are being made for referral for treatment. Such emergency treatment may not be renewed or extended."

Reentry

Robust reentry programs should ensure continuous access to methadone treatment. Elements of transitions of care may include:

- Warm handoffs to community OTPs.
- Take-home doses of medication on release as needed to ensure no interruption in medication continuity.
- Case management, including facilitating access to:
  - insurance
  - state identification
  - transportation
  - housing
- Peer navigation services.
- Harm reduction education and provision of opioid overdose reversal medications.

Staff from community OTPs may engage patients while they are still incarcerated (sometimes called *in-reach*) to establish relationships prior to their release.[18] In jails where people are often incarcerated for brief periods, starting reentry planning on intake can help avoid challenges at the time of release. See the National Reentry Resource Center's Implementing Evidence-Based Strategies to Reduce Overdose Risk During Reentry: A Primer for Reentry Professionals.

Conclusion

SAMHSA strongly encourages jails and prisons to facilitate access to methadone treatment for all incarcerated individuals with OUD, while ensuring adherence to all applicable federal and state regulations. Recent research has suggested that methadone provision in correctional facilities produces significant costs-savings for society as a whole[19] and may even save money for the correctional system.[20] Tools are available to assist in budget planning.[21] Through collaboration with community organizations and state and federal partners, correctional facilities can provide life-saving medication for individuals with OUD.

Resources

SAMHSA

- Federal Guidelines for Opioid Treatment Programs (2024)
- Resources on 42 CFR Part 8
- List of State Opioid Treatment Authorities (SOTAs)
- Practical Guide for Implementing a Trauma-Informed Approach
- Guidelines for Implementing Medication for Opioid Use Disorder Treatment in State Prisons
- SAMHSA's GAINS Center for Behavioral Health and Justice Transformation

DEA

- DEA Diversion Control Division Service Center
- Narcotic Treatment Program Manual
- Referenced Controlled Substance Act Regulations: 21 CFR 1301.71, 21 CFR 1306.07

Department of Justice Bureau of Justice Assistance

- Guidelines for Managing Substance Withdrawal in Jails

National Commission on Correctional Health Care

- Accreditation for Correctional Facilities

National Reentry Resource Center

- Implementing Evidence-Based Strategies to Reduce Overdose Risk During Reentry: A Primer for Reentry Professionals

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