

# Jails and Methadone Provision

Catching Up with COSSAP, April 2020 Edition

Jails and community providers collaborating in the Bureau of Justice Assistance's [Building Bridges Initiative](#) recently engaged representatives of the Drug Enforcement Administration (DEA) in an open conversation on the parameters of providing medication-assisted treatment (MAT) in correctional facilities, with a focus on methadone. The following Q&A on methadone basics, methadone provision in jails, and narcotic treatment program (NTP) licensing and scope summarize this informative discussion and provide valuable links for COSSAP grantees.

## Methadone Basics

### What is MAT?

As defined by the [Substance Abuse and Mental Health Services Administration](#) (SAMHSA), MAT is the use of Food and Drug Administration-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to treatment of substance use disorders.<sup>1</sup>

### What is methadone?

Methadone is a synthetic narcotic approved for short-term detoxification and ongoing maintenance treatment of opioid use disorder (OUD), as well as management of severe pain. As a long-acting full opioid agonist,<sup>2</sup> it reduces opioid craving and withdrawal in addition to blocking the effects of opioids. DEA classifies methadone as a Schedule II drug (those with a high potential for abuse, with use potentially

leading to severe psychological or physical dependence) under the Controlled Substances Act of 1970. Nonmedical use of methadone is illegal. For use in MAT, methadone can only be dispensed through programs registered as NTPs with [DEA](#); must be certified by [SAMHSA](#) and accredited by an independent, SAMHSA-approved accrediting body to dispense opioid treatment medication; and must abide by [state licensing](#) requirements.

### Who administers methadone as a component of MAT?

As stipulated under [Section 1301.74](#) of the Code of Federal Regulations (C.F.R.) Title 21:

Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

### What is the 72-hour emergency methadone dosing rule?

DEA-registered physicians have the authority to administer daily doses of methadone for up to 3 days while trying to secure patients' entry into a maintenance or detoxification

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treatment program. Qualified physicians need not be associated with an NTP, as stated in [C.F.R. 1306.07](#):

Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

No patient-specific communication associated with 72-hour dosing is required at the federal level, but states and counties may have their own requirements.

## Methadone Provision in Jails

### What options do jails have for providing methadone to individuals who are incarcerated?

Correctional facilities may accept delivery of methadone doses for incarcerated clients of an external NTP. In such a case, the correctional facility will take custody of the inmate's doses through a formal chain-of-custody process. Medication is dispensed per the order of the NTP medical director.

DEA-registered physicians may arrange to have a secured supply of methadone at the correctional facility. If a pharmacy is servicing the process, DEA's controlled substance order form ([DEA 222](#)) must be in place to show a paper trail from one registrant (the pharmacy) to another (the physician).

Alternatively, correctional facilities may choose to register as an NTP with DEA. This option also requires [the approval of and registration with SAMHSA](#) and the applicable state

methadone authority. Once cleared by all stakeholders, the medical director issues the medical orders necessary for the administration of methadone out of the stock obtained under the DEA registration.

DEA's campus registration allows larger correctional facilities with a pharmacy or medication unit to offer a dosing window and storage for methadone or opioid products in another wing of the facility. Inmates in this wing are treated at the supplemental window. Correctional facilities registered as an NTP that are interested in obtaining a campus registration may contact DEA at [DRG@dea.usdoj.gov](mailto:DRG@dea.usdoj.gov).

### What forms of methadone can be administered in correctional facilities?

Liquid concentrate is the most common form of methadone used to treat OUDs, but powder, diskettes, and tablets are also available. DEA does not dictate the types of methadone formulations allowed in correctional facilities. For liquid formulation, DEA will audit for proper machine calibration, appropriate security measures, and overall recordkeeping. Auditors recognize that bottle content volume is often slightly more than what is printed on the label.

## Narcotic Treatment Program Licensing and Scope

### What is the difference between an NTP and an OTP?

DEA monitors storage and diversion of narcotics and uses "NTP" as a registration-oriented term. DEA's [Narcotic Treatment Programs Best Practice Guideline](#) explains the Controlled Substances Act and facilitates implementation of the regulations as they apply to dosage reconciliation practices.

SAMHSA certifies [opioid treatment programs](#) (OTPs) to prescribe and administer medication. "OTP" is a medically-oriented term. SAMHSA's expectations for opioid treatment

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standards are described in its [Federal Guidelines for Opioid Treatment Programs](#).

## Where would a county jail start when seeking to establish an NTP?

Jail administrators should be well versed in both county and state requirements surrounding controlled substances before submitting applications to SAMHSA and DEA. Upon completion of the state's and SAMHSA's respective licensing processes, DEA will proceed with its registration process, which includes an onsite inspection. Timeframes for approval depend on the extent of local DEA resources, the speed of the state's and SAMHSA's information verification, the accuracy of the application, and adequate security. To facilitate the process, jails are encouraged to seek assistance from their local DEA office before applying. Federal, state, and county entities may be eligible for a registration fee waiver.

## How do security requirements for NTPs in correctional facilities differ from those in the community?

All NTP applicants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances. Before an entity registers, the local DEA field office will examine layers of security, as dictated by C.F.R. [Section 1301.71](#). DEA exercises discretion on the degree of security required based on the size of the program (number of enrolled patients, physicians, and staff members) and layers of security. Standards for physical security controls and operating procedures also depend on the quantity of product stored. For example, in larger facilities, the required [GSA Class V container](#) for storage of small quantities of Schedule II controlled substances may be augmented by an alarm system. Schedule III-V controlled substances may be stored in the safe along with Schedule II controlled substances as per 21 C.F.R. Section 1301.72(b)(8)(i).

DEA conducts both preregistration inspections of new applicants and random unannounced inspections of

established NTPs for recordkeeping, security, and dosing counts.

## May a community NTP open a medication unit in a local jail?

If allowed by the state opioid treatment authority and the regulatory boards of the state, current DEA-registered NTPs seeking to open a medication unit in a local jail must apply for a new registration as an NTP within a jail setting, even if the in-facility service serves as a medication unit of the community NTP.

## In urban areas with multiple NTPs, the provider to the jail often provides methadone dosing for clients of other NTPs. What guidance does DEA provide for this practice?

DEA oversight for so-called "courtesy dosing" is limited to the record of drugs received, the record of persons who dosed or dispensed treatment, and alignment of those two records. All other matters related to courtesy dosing are under the purview of the state opioid treatment authority and/or SAMHSA.

## How can jails assist persons exiting incarceration transition from the NTP-type service of daily dosing to a prescription in the community?

To continue a prescription of methadone for someone who is exiting incarceration into the community, a referral should be made to a community-based NTP.

Alternatively, individuals seeking a prescription, rather than daily dosing, for MAT may consider switching from methadone to buprenorphine. A Drug Addiction Treatment Act (DATA) waiver (sometimes referred to as the "X waiver") from [SAMHSA](#) authorizes qualified physicians to conduct maintenance and detoxification treatment using specifically approved Schedule III, IV, or V narcotic medications, such as buprenorphine, independent of a registered NTP.

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Prescriptions fall under a physician's personal DEA registration/tax number and will be counted against that practitioner's patient cap (30 patients for the first year and up to 100 thereafter).

## How might telemedicine be used by an NTP?

DEA regulations do not prohibit the use of telemedicine in treating substance use disorders; new regulations are expected to clarify its use. Currently, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires an initial in-person exam to take place in the presence of a DEA-registered practitioner (e.g., physician assistant, nurse practitioner) or at a DEA-registered hospital clinic before controlled substances can be prescribed. (Many correctional facilities are associated with DEA-registered hospital clinics.) As proof of compliance, DEA may ask to see the telemedicine equipment used or the name of the DEA-registered practitioner who was physically present at the time of the in-person exam and their DEA registration numbers.

## Does the DEA allow mobile units to dispense methadone?

In 2014, DEA placed a moratorium on new treatment vans until compliance regulations are updated. In February 2020, DEA posted to the *Federal Register* a [proposed rule](#) on registration requirements for NTPs with mobile components. Comments can be submitted electronically or by mail until April 27, 2020.

## Endnotes

1 Substance Abuse and Mental Health Services Administration. (2019, September 9). Medication-assisted Treatment. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. <https://www.samhsa.gov/medication-assisted-treatment>.

2 An agonist is a drug that activates certain receptors in the brain.