How to Use the *DEA "72-Hour Emergency Rule"* for Methadone in Jails

HMA ISSUE BRIEF

Version 3 – Revised April 4, 2024

Patients may enter your facility on methadone for treatment of opioid use disorder (OUD). This brief explains how jail prescribers can use the U.S. Drug Enforcement Agency (DEA) "72-Hour Emergency Rule" to continue this essential medication without interruption while the jail establishes a longer-term plan for continuation. This is essential to maintain sobriety and prevent relapse, overdose, and death.

Jails may face challenges in timely access to methadone when a person is booked and reports receiving treatment with methadone for OUD from a community provider prior to detention. Confirming methadone treatment at the patient's opioid treatment program (OTP), also known as a narcotic treatment program (NTP), can take several days, especially if jail intake occurs over a weekend or holiday. The DEA provides physicians with emergency access to methadone for up to 72 hours in such cases to enable detainees to receive methadone without interruption while the jail establishes a longer-term plan for the remainder of incarceration. This issue brief provides important information on ***HOW*** jails can access methadone under the DEA's "72-Hour Emergency Rule."

WHY CONTINUE METHADONE DURING INCARCERATION?

Detainees who enter jails on methadone for treatment of OUD will begin to experience opioid withdrawal just 24 to 48 hours after the last dose of methadone. The withdrawal will worsen and typically peak at five to seven days and can last more than 21 days. Opioid cravings during withdrawal, driven by dopamine depletion, are extremely strong and the physical effects of withdrawal are torturous. SAMHSA's Treatment Improvement Protocol 63 *Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families,* updated in 2020, provides detailed evidence on the clinical importance of maintaining methadone treatment.

Detainees in methadone withdrawal are at extremely high risk for relapse and overdose either by obtaining illicit opioids in the jail or using immediately upon release. Various studies have demonstrated that in the first four weeks following jail release, the risk of overdose is anywhere from 13 to more than 100 times greater than the risk for the general population. [1,2] In addition, detainees who are maintained on methadone during incarceration are more than 400% more likely to return to their community

[1] Moore, K. E., Roberts, W., Reid, H. H., Smith, K. M. Z., Oberleitner, L. M. S., & McKee, S. A. (2019). Effectiveness of medication assisted treatment for opioid use in prison and jail settings: A meta-analysis and systematic review. Journal of substance abuse treatment, 99, 32–43. https://doi.org/10.1016/j.jsat.2018.12.003

[2] Binswanger, I. A., Stern, M. F., Deyo, R. A., Heagerty, P. J., Cheadle, A., Elmore, J. G., & Koepsell, T. D. (2007). Release from prison--a high risk of death for former inmates. The New England journal of medicine, 356(2), 157–165. https://doi.org/10.1056/NEJMsa064115

methadone providers after release than those who are forcibly withdrawn or tapered from methadone.[3] Many jail releases are unplanned and occur rapidly once ordered, so maintaining detainees on methadone treatment throughout their tenure in the jail is imperative to preventing relapse, overdose, and death during and following incarceration.

Finally, OUD is a condition protected by the Americans with Disabilities Act (ADA) for which there are evidence-based treatments. Providers who willingly terminate such treatment deviate from the standard of care. This creates the risk of deadly outcomes for patients and legal risk for the provider and the jail.

Rapid access to methadone is essential to sustain treatment for OUD during incarceration and mitigate adverse outcomes. The DEA's "72-Hour Emergency Rule" was created specifically for this circumstance.

METHADONE TREATMENT FOR OUD

Methadone is a Schedule II Controlled Substance. Physicians with DEA registration may prescribe methadone to treat pain. Nurse Practitioner and Physician Assistant authority to prescribe methadone to treat pain varies by state.

However, treatment of OUD with methadone for persons who are not hospitalized, may only take place through a licensed OTP/NTP as specified in CFR Title 21 §1306.07 Administering or dispensing of narcotic drugs:

> (a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:
>
> (1) The practitioner is separately registered with DEA as a narcotic treatment program.
>
> (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

Note the terms "administer" and "dispense." Federal law expressly prohibits the "prescription" of methadone for the treatment of OUD.

Many treatment requirements are imposed on OTPs/NTPs, including daily in-person methadone administration until stability is documented and sustained, take-home dosing at prescribed intervals for stable patients, random periodic urine drug screens, mandatory counseling, and more. The Office of the Federal Register is currently reviewing comments on a proposed rule to update regulations in 42 CFR Part 8 that govern assessment and treatment within OTPs/NTPs; the proposed rule updates, **if approved** and published in the Federal Register, will amend some of these requirements. Some of the proposed rules would directly affect how the jail would operate regarding methadone for OUD and are addressed below.

[3] Moore, K. E., Oberleitner, L., Smith, K. M. Z., Maurer, K., & McKee, S. A. (2018). Feasibility and Effectiveness of Continuing Methadone Maintenance Treatment During Incarceration Compared with Forced Withdrawal. Journal of addiction medicine, 12(2), 156–162. https://doi.org/10.1097/ADM.0000000000000381

"THE 72-HOUR EMERGENCY RULE"

CFR Title 21 §1306.07 (b) sets forth the conditions for *emergency administration of methadone outside of an OTP/NTP*, known as the "72-Hour Emergency Rule" or the Three-Day Rule:

> (b) 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.

DEA Form 222 can be ordered online by the physician registrant at https://apps.deadiversion.usdoj.gov/webforms2/spring/orderFormsLogin?execution=e1s1

Of note:

- Only **physicians** may use this provision; midlevel providers are excluded.[4]
- One dose per day is allowed and for not more than three days.
- The emergency period cannot be renewed or extended during the withdrawal period (but the provision applies separately to each instance of incarceration).
- No more than one day's medication may be administered or given to a patient at one time.
- Legislative efforts to ease these requirements were unsuccessful in 2020 but may be revisited in the future.

USING THE "72-HOUR EMERGENCY RULE" IN A JAIL

Accessing Stock Methadone

Because methadone cannot be *prescribed* for treating OUD, patient-specific doses are prohibited when using the "72-Hour Emergency Rule". Instead, a jail physician must have access to *stock* methadone under one of the following options:

1. If the jail has a licensed pharmacy on site, the pharmacy can stock methadone and manage the inventory, expiration dates, wastage, and related requirements. State pharmacy board requirements apply.
2. If the jail does not have a licensed pharmacy but has a relationship with a pharmaceutical vendor, the vendor may be able to provide stock methadone. State pharmacy board requirements apply.
3. If the jail has a relationship with a pharmacy that is not on site, that pharmacy can provide methadone in an emergency box owned by a pharmacy and transferred to the facility under the pharmacy's license. This option is widely used in nursing facilities and rarely in jails.
4. A "physician office" can be established in the jail under the physician's license for dispensing/administering methadone under that license. This is the most common scenario seen in jails across the country, and it comports with the DEA rules for 72-hour emergency use of

[4] Midlevel providers would no longer be excluded from this provision under the proposed changes.

methadone. The methadone is obtained from a local retail or hospital pharmacy using a DEA Form 222. State pharmacy board requirements may also apply to this option.

USING DEA FORM 222 TO PROCURE METHADONE

Obtain Form 222

Physicians who are registered with the DEA may obtain Form 222 from the DEA. It serves as a "prescription pad for Schedule I or II Controlled Substances." The physician's unique DEA registration number is required. DEA 222 forms must be kept on record for two years.

Plan with a Local Pharmacy

If the jail has never obtained methadone from a pharmacy, the physician or health services administrator should confer with the pharmacy to discuss the jail's intent and the pharmacy's processes. Most pharmacists should be familiar with the DEA Form 222 though they may wish to confer with the state pharmacy board. Also, local pharmacies may not have methadone in house and may need time to procure a supply. Because the need for methadone will be very time sensitive, this conversation and an initial stock order should take place *before* a case presents.

Decide on Quantity

Stock quantities should be sufficient to address emergent needs at the jail for 30 to 60 days. DEA may consider frequent Form 222 requests as evidence that the process supports treatment beyond emergent use. The jail should also confer with the pharmacy about shelf life/expiration dates in determining stock quantities.

Safeguarding Methadone at the Jail

Stock methadone must be safeguarded as any other controlled substance inside a jail. In accordance with DEA and state rules and regulations for safeguarding controlled substances, they must be stored properly, including being logged into the medication area by two parties, double-signed, and stored in a separate locked device. Patient-specific data is recorded for each dose administered, and the count is verified and double-signed by nursing or pharmacy techs at the end of each shift. Wasting methadone for any reason must be witnessed and documented as with other controlled substances.

Administering Methadone

The physician acting under the "72-Hour Emergency Rule" may delegate the administration of the methadone to nursing staff with proper documentation. The nurse should document the dosage in the Medication Administration Record.

ARRANGEMENTS WITH OTP/NTP FOR METHADONE THROUGHOUT INCARCERATION

During the 72-hour emergency period, the jail must make arrangements with the patient's OTP/NTP to provide the methadone during the remainder of incarceration. This is usually done through take-home dosing. There are many options for take home dosing and payment for methadone during incarceration, and these topics are beyond the scope of this document. Note the following:

- The DEA expects OTPs/NTPs to make meaningful efforts to serve incarcerated patients but does not provide rules or guidance as to how this may occur.

- State OTP/NTP licensing rules address take-home dosing and expectations of OTPs/NTPs to serve their clients during incarceration.
- Tapering methadone during incarceration is not evidence-based care and places the patient at extreme risk for relapse, overdose, and death.
- One OTP/NTP may provide methadone to a patient of another OTP/NTP under "courtesy dosing" rules. For jails in communities with more than one OTP/NTP, this allows a contract with a single OTP/NTP that can serve any incarcerated methadone patient.

For more information on arrangements, please review *Options to Ensure Access to Methadone for Treatment of Opioid Use Disorder in Correctional Facilities*.

AUTHORS

Shannon Robinson MD, FASAM
Principal, HMA
srobinson@healthmanagement.com

Scott Haga MPAS, PA-C

Donna Strugar-Fritsch BSN, MPA, CCHP

RESOURCES

Binswanger, I. A., Blatchford, P. J., Mueller, S. R., & Stern, M. F. (2013). Mortality after prison release: opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. Annals of internal medicine, 159(9), 592–600. https://doi.org/10.7326/0003-4819-159-9-201311050-00005

Binswanger, I. A., Stern, M. F., Deyo, R. A., Heagerty, P. J., Cheadle, A., Elmore, J. G., & Koepsell, T. D. (2007). Release from prison--a high risk of death for former inmates. The New England journal of medicine, 356(2), 157–165. https://doi.org/10.1056/NEJMsa064115

Federal Register Notice for Single Sheet Form 222
https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-21021.pdf

Krinsky, C. S., Lathrop, S. L., Brown, P., & Nolte, K. B. (2009). Drugs, detention, and death: a study of the mortality of recently released prisoners. The American journal of forensic medicine and pathology, 30(1), 6–9. https://doi.org/10.1097/PAF.0b013e3181873784

Møller, L. F., Matic, S., van den Bergh, B. J., Moloney, K., Hayton, P., & Gatherer, A. (2010). Acute drug-related mortality of people recently released from prisons. Public health, 124(11), 637–639. https://doi.org/10.1016/j.puhe.2010.08.012

Moore, K. E., Oberleitner, L., Smith, K. M. Z., Maurer, K., & McKee, S. A. (2018). Feasibility and Effectiveness of Continuing Methadone Maintenance Treatment During Incarceration Compared with Forced Withdrawal. Journal of addiction medicine, 12(2), 156–162. https://doi.org/10.1097/ADM.0000000000000381

Moore, K. E., Roberts, W., Reid, H. H., Smith, K. M. Z., Oberleitner, L. M. S., & McKee, S. A. (2019). Effectiveness of medication assisted treatment for opioid use in prison and jail settings: A meta-analysis and systematic review. Journal of substance abuse treatment, 99, 32–43. https://doi.org/10.1016/j.jsat.2018.12.003

U.S. Department of Justice Drug Enforcement Administration. DEA Form 222 Order Request
https://apps.deadiversion.usdoj.gov/webforms2/spring/orderFormsLogin?execution=e1s1

U.S. Department of Justice Drug Enforcement Administration. DEA Form 222 Q&A
https://www.deadiversion.usdoj.gov/faq/form_222_faq.htm

U.S. Department of Justice Drug Enforcement Administration. Summary of New Rule for of Single Sheet Form 222
https://www.fderalregister.gov/documents/2019/09/30/2019-21021/new-single-sheet-format-for-us-official-order-form-for-schedule-i-and-ii-controlled-substances-dea

U.S. Department of Justice Drug Enforcement Administration, Diversion Control Division
Title 21 Code of Federal Regulations §1306.07 – Administering or Dispensing of Narcotic Drugs
https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_07.htm

Waddell, E. N., Baker, R., Hartung, D. M., Hildebran, C. J., Nguyen, T., Collins, D. M., Larsen, J. E., Stack, E., & ROAR Protocol Development Team (2020). Reducing overdose after release from incarceration (ROAR): study protocol for an intervention to reduce risk of fatal and non-fatal opioid overdose among women after release from prison. Health & justice, 8(1), 18. https://doi.org/10.1186/s40352-020-00113-7