Brief FAQ on Methadone Use to Treat Opioid Use Disorder (OUD) in Carceral Settings Using the Hospital/Clinic Designation

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH | Health Policy & Management

Methadone is a lifesaving medication for treating OUD.[1] It is clinical best practice to offer all FDA-approved medications for the treatment of OUD, including methadone, in all settings including carceral settings.[2] [3] Managing substance withdrawal in carceral settings is important as deaths due to unmanaged acute withdrawal are preventable. Counties, carceral administrators, and carceral staff have faced civil lawsuits seeking monetary awards and other relief for failure to provide withdrawal management services.[4] Treatment for OUD in carceral settings is also imperative as substance-related overdose is the third leading cause of death in jails, following illness and suicide.[5] [6] As described in our prior report, How the Drug Enforcement Administration Can Improve Access to Methadone in Correctional Facilities and Save Lives, provision of methadone in carceral settings for the management of acute opioid withdrawal syndrome (OWS) and long-term treatment of OUD has been challenging because of federal rules and regulations around the provision of methadone and the scarcity of opioid treatment programs (OTPs) in many geographical locations.[7]

What do the updated final rules of 42 CFR Part 8, recently published by SAMHSA, say about provision of methadone in carceral settings?

"If a correctional facility has registered as a hospital/clinic, a physician or authorized staff may administer or dispense narcotic drugs to maintain or manage withdrawal for an inmate as an incidental adjunct to medical or surgical treatment of conditions other than addiction."

Interpretation: The revised rules clearly and unequivocally state that if a carceral setting has registered as a hospital/clinic, it can treat patients with methadone under the exemption available to hospitals/clinics. Under this exemption, the clinic can dispense methadone for opioid withdrawal syndrome (OWS) and/or treatment of OUD to patients, provided that they have an additional diagnosis besides OWS and/or OUD. The guidance does not list or otherwise specify the additional diagnoses that are required to use this option, which gives some leeway to the clinician. There should be clear documentation in the medical record identifying what additional diagnoses the patient has.

How can a carceral setting register with the DEA as a hospital/clinic?

The process to register with the DEA as a hospital/clinic is straightforward. DEA form 224, which is available online, asks for information such as the address of the facility and the DEA license of the provider supervising the clinic. Some jails and prisons may already be registered with the DEA as a hospital/clinic.[8] To the extent States have licensing requirements for hospitals/clinics, the facility will need to be appropriate licensed by the State in order to obtain a DEA registration.. State regulators might include the State Opioid Treatment Authority (SOTA), the Department of Health, or other agencies that oversee controlled substances.

What is the DEA 72-Hour Emergency Rule for methadone and buprenorphine and how does it apply to carceral settings?

The DEA 72-Hour Rule or the Three Day Rule allows practitioners to dispense up to 3 days dosing to a person with OUD from a stock supply of methadone or buprenorphine at the facility. Most typically, this is done in hospital emergency departments but the rule applies to carceral settings as well. This would allow for uninterrupted treatment with methadone or buprenorphine when an individual is released from a carceral facility, particularly when done on a weekend. This is particularly significant for individuals being treated with methadone, as methadone cannot be dispensed by a pharmacy for the treatment of OUD. In contrast, buprenorphine can be dispensed by a pharmacy.[9]

It is important to check with state regulatory authorities to determine if there are additional state laws, rules, or regulations regarding the 72-hour Emergency Rule.

See more information in this Health Management Associates Brief,[10] issued March 2021.

What is the role of state regulations in ensuring access to methadone for entities regulated as hospitals/clinics? How can state policymakers be supportive of the hospital/clinic pathway?

There has been significant confusion, even in hospital/clinic settings, around utilization of methadone for acute OWS management and OUD treatment. In the absence of addiction medicine consult services in those settings, methadone often is not utilized, and individuals are not treated with clinical best practices. To ensure that the SAMHSA rules are understood clearly and applied in settings that qualify for this designation state regulators overseeing hospitals/clinics, OTPs, and carceral settings could issue clinical guidance and eliminate additional state-specific regulations.

What are some factors that county jails and state prisons should consider for utilization of methadone?

Methadone is a long-acting, full agonist at the mu opioid receptor, which is very efficacious for the treatment of OUD. In fact, evidence indicates that methadone reduces overdose mortality, reduces all-cause mortality, and reduces recidivism. Due to variability in how methadone is metabolized, and its long-half life, the administration of methadone requires clinical expertise and clinical oversight.[11] Clinicians unfamiliar with methadone should seek support from clinicians with training and expertise in addiction medicine before starting patients on treatment. Clinicians should also consult methadone's labeling, including instructions for use and warnings.

As a Schedule II medication, methadone carries requirements for registration, storage, inventory, and records under the Controlled Substances Act.

Correctional facilities should check with state regulators about other rules related to methadone that may apply.

What should my carceral setting have in place to make the hospital/clinic approach work?

As a recommended practice, carceral facilities that are interested in the hospital/clinic designation approach to treat persons with OUD with methadone should establish and maintain:

a) Written policies and procedures outlining which conditions would qualify as a "primary condition" that would make an individual with OUD eligible for methadone treatment;

b) Protocols and work flows for initiation and adjustment of the methadone dose;

c) A protocol and work flow for communicating with patients' community-based opioid treatment program (if applicable), especially during intake at the carceral setting (for dose verification) and before release;

d) A protocol and work flow for re-entry planning for persons initiated onto methadone while incarcerated (i.e., the patient has no prior relationship with a community-based opioid treatment program and needs this care established before leaving the carceral setting); the DEA 72-Hour Emergency Rule should be utilized to dispense a 72-hour (3-day) supply to patients leaving the carceral setting to ensure there is no gap in medication access until the patient presents to the opioid treatment program;

e) A relationship with an addiction medicine provider to discuss any challenging cases;

f) A plan to review periodically how well the program is working and how it can be improved;[12]

g) Written policies and procedures for DEA regulatory compliance and a protocol for the procurement, documentation, and safe storage of methadone.

Created by Kelly S. Ramsey, *MD, MPH, MA, FACP, DFASAM* [kellysueramsey@gmail.com],
Addiction Medicine Public Health Consultant, updated March 27, 2024

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Endnotes

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2 SAMHSA, TIP 63: Medications for Opioid Use Disorder For Healthcare and Addiction Professionals, Policymakers, Patients, and Families, updated 2021. Available at: TIP 63: Medications for Opioid Use Disorder (samhsa.gov).

3 ASAM, The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder, 2020 Focused Update. Available at: The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder – 2020 Focused Update.

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5 5NCCHC. Position Statement: Naloxone in Correctional Facilities for the Prevention of Opioid Overdose Deaths, adopted 10/2021. Available at: Naloxone in Correctional Facilities (ncchc.org)

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7 Joudrey PJ, Edelman EJ, Wang EA. Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States. JAMA. 2019;322(13):1310–1312. doi:10.1001/jama.2019.12562J

8 Johns Hopkins University Bloomberg School of Public Health. Providing Methadone in Jails and Prisons: An explanation of a new approach to increase access to methadone in carceral settings FAQ, issued 5/2023. Available at: Methadone-Fact-Sheet.pdf (jhsph.edu)

9 DEA. Dispensing of Narcotic Drugs To Relieve Acute Withdrawal Symptoms of Opioid Use Disorder, issued 8/8/23. Available at: National Archives Federal Register: Federal Register :: Dispensing of Narcotic Drugs To Relieve Acute Withdrawal Symptoms of Opioid Use Disorder

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11 SAMHSA. TIP 63: Medications for Opioid Use Disorder For Healthcare and Addiction Professionals, Policymakers, Patients, and Families, updated 2021. Available at: TIP 63: Medications for Opioid Use Disorder (samhsa.gov).

12 Johns Hopkins University Bloomberg School of Public Health. Providing Methadone in Jails and Prisons: An explanation of a new approach to increase access to methadone in carceral settings FAQ, issued 5/2023. Available at: Methadone-Fact-Sheet.pdf (jhsph.edu)