How the Drug Enforcement Administration Can Improve Access to Methadone in Correctional Facilities and Save Lives

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Executive Summary

More than 70,000 people died of opioid-related overdoses in the United States in 2021. In the setting of this national challenge, this white paper discusses how the Drug Enforcement Administration (DEA) can expand access to life-saving treatment with methadone in jails and prisons.

The potential for DEA action to save lives is based on the outsized role that the criminal justice system plays in the opioid overdose crisis. Specifically:

- *People with opioid use disorder often experience incarceration.* More than 40% of people who used heroin and almost 20% of people with a prescription opioid use disorder have had recent contact with the criminal legal system.

- *Recent incarceration is a major risk factor for dying from an overdose*. People released from a correctional facility are 40 times more likely to die of an overdose than the general population during the two weeks after discharge.

- *Treating people for addiction in jails and prisons saves lives — and reduces recidivism.* Numerous studies from the United States and other countries have shown that treating people with medications — including methadone — while they are incarcerated reduces overdose deaths and recidivism. For example, overdose deaths in Rhode Island dropped 60% after the state began offering medication treatment in its facilities. One model estimated that close to 2,000 overdose deaths could be prevented annually by the provision of medications in jails and prisons.

Based on this evidence, the National Commission on Correctional Health Care, the National Governors Association, the National Academy of Medicine, and the American Society for Addiction Medicine all support the use of medications to treat people in jail and prison. Additionally, recent court decisions have found that correctional facilities have an obligation to use evidence-based care, including medications, to treat people with an opioid use disorder.

Methadone is one of three medications for opioid use disorder, alongside buprenorphine and naltrexone; all three should be available in correctional facilities. This paper focuses exclusively on methadone, because this medication is highly effective in preventing overdose, because the regulatory barriers to its use are far greater than the other medications, and because the vast majority of prisons and jails do not offer treatment with methadone.

According to a review conducted by the Jail & Prison Opioid Project in July 2021, just 632 of the approximately 5,000 correctional facilities (12%) offer any medication to treat opioid use disorder. The number that offer methadone is likely to be substantially less. Specific reasons for DEA to seek to increase access to methadone treatment in jails and prisons include:

- *Methadone has the most evidence supporting its effectiveness in treating opioid use disorder.* Methadone was approved to treat opioid use disorder in 1973. Starting methadone while incarcerated reduces overdose deaths and recidivism; evidence suggests that it is associated with better retention in treatment than other medications.

- *Methadone is often chosen by people with opioid use disorder.* In Rhode Island correctional facilities, more than half of the people offered all three medications decided to use methadone.

- *Requiring people to discontinue methadone treatment while incarcerated results in more overdoses and less engagement in care after discharge.* Switching patients on methadone to another medication can be clinically challenging and is not recommended.

Under existing law, correctional facilities have four options to provide methadone to individuals with opioid use disorder.

- The first option is to become a narcotic treatment program (the term that the DEA uses for what the Substance Abuse and Mental Health Services Administration refers to as an opioid treatment program), which is a complex and difficult process involving many regulations that were not designed for the correctional context.

- The second option is to contract with a community-based narcotic treatment program to provide care. This could be done by transporting patients to the narcotic treatment program or by bringing the methadone to the correctional facility. This approach, however, can be expensive, logistically prohibitive, and does not always meet patient needs.

- The third option is for a community-based narcotic treatment program to establish a mobile methadone program with the correctional facility. This step may also be expensive and complex and is only feasible if there is a community-based program willing and able to establish a mobile site.

- The fourth option is for correctional facilities registered with the DEA as a "hospital / clinic" to provide methadone to people with an opioid use disorder if the condition is "an incidental adjunct to medical or surgical treatment of conditions other than addiction."[1] This option does not require the correctional facility to become or contract with a narcotic treatment program.

Some correctional facilities may be interested in pursuing an alternative approach to these existing options. This alternative approach would permit treatment of all individuals in custody with an opioid use disorder who would benefit from methadone, without becoming a narcotic treatment program. This option would require DEA to either grant exceptions to the current regulations or to revise its regulations.

Recommendations for DEA

The DEA should support the principle that all people in correctional facilities with opioid use disorder should have access to methadone treatment, because of its proven ability to prevent fatal overdoses and treat opioid use disorder. The DEA should recognize that the regulatory framework for community-based narcotic treatment programs does not apply well to correctional facilities, which are institutional settings that need to start treatment quickly to prevent people from going through withdrawal. To address current gaps, DEA should provide an alternative

pathway that permit treatment of all who can benefit from methadone without requiring correctional facilities to become or contract with narcotic treatment programs. Specifically:

1) *DEA should grant exceptions to current regulations to allow correctional facilities that are registered as a "hospital / clinic" to treat all individuals in need of methadone treatment.*

   In 21 C.F.R. § 1307.03, facilities are permitted to request exceptions to regulatory provisions under the Controlled Substances Act. DEA should be willing to consider requests and grant exceptions to 21 C.F.R. § 1306.07(c), which prohibits the use of methadone in institutional settings unless people are also receiving medical or surgical treatment for a condition other than addiction. Facilities granted this exception would be able to treat all individuals in need of methadone for opioid use disorder without becoming or contracting with a narcotic treatment program.

2) *DEA should use information gained from granting exceptions to revise its regulations and permit correctional facilities to treat people with methadone.*

   DEA should use the experiences of correctional facilities that have received an exception to define a new regulatory provision that permits all correctional facilities to treat all of those who can benefit.

In addition to helping many more correctional facilities provide methadone to patients with opioid use disorder, DEA can better support the limited number of correctional facilities that are narcotic treatment programs or contract with community-based providers (Appendix A).

None of the recommended steps above require action by Congress. All of them would expand access to life-saving treatment with methadone using approaches that already exist in the law and that work for other controlled medications, including opioid analgesics and other controlled substances. The result would be many lives saved in the opioid epidemic.

Background

People with opioid use disorder often experience incarceration.

Incarceration rates are high among people with an opioid use disorder. More than 40% of people who used heroin and almost 20% of people with a prescription opioid use disorder have had contact with the criminal legal system in the past year.[2,3]

Additionally, a significant percentage of people in jail and prison have an opioid use disorder. One study found that close to 20% of people in jails and prisons reported regular use of heroin or opioids before they were incarcerated.[4]

There are important efforts underway to prevent the unnecessary incarceration of individuals with substance use disorders. Even with these efforts, however, many people will be incarcerated who can benefit from addiction treatment.

Recent estimates suggest that there are approximately 2 million people in correctional facilities across the country at any point in time; more than 10 million people cycle through jails each year.[5] Accordingly, offering treatment in jails and prisons could reach hundreds of thousands of people each year.

Incarceration is a major risk factor for dying from an overdose.

While incarcerated, people who had previously been using opioids go through withdrawal and lose their tolerance, which is the physical adaptation that permits their bodies to consume high doses of opioids. As a result, when these individuals return to using same amount of drug that they used previously, the risk for fatal overdose is high.

In fact, a drug overdose is the leading cause of death after release from jail or prison; between 2013–2014, 40% of deaths in Massachusetts among people released from jail or prison were due to an opioid overdose.[6] The risk is especially high in the immediate weeks after release;[7,8] one review found that people released from a correctional facility are 40 times more likely to die of an overdose in the weeks after their release than the general population.[9]

In addition to overdose, people with an opioid use disorder are at high risk for other adverse outcomes after discharge. According to the Substance Abuse & Mental Health Services Administration (SAMHSA):

> *"Within 3 months of release from custody, 75 percent of formerly incarcerated individuals with an [opioid use disorder] relapse to opioid use, and approximately 40 to 50 percent are arrested for a new crime within the first year."*[10]

The lack of treatment in correctional settings contributes to other health risks (including the contraction of infectious diseases). In pregnancy, lack of access to methadone during incarceration undermines the health of the pregnant parent and increases risks to the health and life of the child.

Treating people for addiction in jails and prisons saves lives and reduces recidivism.

Medication treatment is highly effective. Methadone is a long-acting medication that reduces opioid craving and withdrawal and blunts or blocks the effects of opioids by occupying the opioid receptor sites. Studies have shown that people with opioid use disorder taking methadone have a much lower chance of overdosing and dying, with reductions as high as 60 to 80%.[11, 12, 13, 14, 15]

These benefits are lifesaving for people who are incarcerated. Studies from Scotland[16], Australia[17], Rhode Island,[18,19] and England[20] have all shown that treating people with medication for their opioid use disorder while incarcerated results in reductions in overdose deaths after release. One model estimated the effect of providing medications in jails and prisons and concluded that close to 2,000 overdose deaths could be prevented annually.[21] Other studies have found that treating incarcerated individuals also reduces recidivism rates.[22,23]

According to the federal National Drug Control Strategy,

> *"Medication for opioid use disorder (MOUD) programs in criminal justice settings, when administered properly by trained professionals, dramatically reduce mortality post-release and increase the likelihood that an individual will stay in treatment, rejoin their communities successfully, and reduce their risk of recidivism—all of which enhance individual and community public health and public safety outcomes."*[24]

Studies, including randomized trials, have also demonstrated that referring people to treatment upon their release is not as effective as starting treatment while they are incarcerated.[25] Given the high risk of death in the weeks immediately after discharge, care should be initiated in correctional facilities rather than waiting until after people are discharged.

Correctional facilities should offer all three medications approved to treat an opioid use disorder: methadone, buprenorphine, and naltrexone.

The three medications approved to treat opioid use disorder all have distinct mechanisms of action. In addition to methadone, buprenorphine is a partial opioid agonist that operates at the same opioid receptor sites but does not fully occupy the receptors. Naltrexone is an opioid antagonist, meaning that it works by blocking opioids from occupying the receptor sites. Because naltrexone is not an opioid it is not subject to controlled substances regulations and is favored by staff in many correctional facilities. However, naltrexone can only be initiated for patients who have been fully withdrawn from opioids (at least seven days since their last use of opioids); it is also associated with shorter duration of use.[26]

Based on the evidence supporting their use, numerous organizations — the National Commission on Correctional Health Care,[27] the National Governors Association,[28] the National Academy of Medicine, and the American Society for Addiction Medicine[29]—have endorsed availability of all three medications as the standard of care in correctional settings.

Expanding access to treatment in correctional settings is also a priority for the Biden-Harris Administration, as laid out in the March 2022 National Drug Control Strategy. One action item in the Strategy is: "*Simplify the regulation of methadone and buprenorphine to create the necessary flexibility for jails and prisons to offer [these medications].*"

Recent legal decisions have found that correctional facilities have an obligation to provide medications to people with an opioid use disorder.[30] In addition, the Department of Justice recently released guidance that not allowing people with an opioid use disorder to continue their treatment while incarcerated is a violation of the Americans with Disabilities Act.[31] Accordingly, expanding access to medications in correctional facilities would facilitate compliance with federal antidiscrimination laws.

This white paper focuses on expanding access to methadone because the regulatory barriers to its use are the greatest.

Need for Greater Access to Methadone

Currently, few jails and prisons are able to start treatment with methadone.

According to a review conducted by the Jail & Prison Opioid Project in July 2021, just 632 of the approximately 5,000 correctional facilities (12%) offer any medication to treat opioid use disorder.[32] The few facilities that do offer medication often limit availability to a subset of people, such as those who are pregnant or those who are already in treatment in the community.

This poor access to care has two major adverse consequences:

1. **Disrupting treatment**. People who enter correctional facilities already receiving methadone treatment are forced to go through withdrawal or abruptly switch to buprenorphine unless the facility offers methadone. Numerous studies have found that people who are able to continue on methadone while incarcerated have fewer overdoses and are more likely to continue care after discharge than those who are forced to go through withdrawal.[33,34,35]

   > The National Commission on Correctional Health Care concluded that, "*Incarcerated people with [an opioid use disorder] should not be forced to undergo withdrawal…forced withdrawal discourages engagement in community treatment, increases the risk for substance use during incarceration, and increases the risk of death after discharge.*"

2. **Missed opportunity to start care**. Correctional facilities are a critical setting to initiate voluntary treatment for people with an opioid use disorder who are not currently receiving any treatment. Methadone can be started while patients are in withdrawal. Naltrexone, in contrast, requires patients to be fully abstinent from all opioids for a minimum of seven days.

> Research from Rhode Island, which has pioneered the use of medications to treat opioid use disorder in correctional settings, showed that more than half of the program participants selected methadone when offered all three medications, indicating significant support for this treatment option.[36]

Although very few jails and prisons currently treat people with methadone, these facilities do have substantial experience handling other controlled substances. Many maintain stock of medications such as opioid pain relievers and benzodiazepines, and they comply with DEA oversight requirements for these medications. Additionally, these facilities employ heightened security measures that restrict the movement of residents and staff and routinely include locked spaces and surveillance cameras. In fact, the security standards used by jails and prisons are typically even higher than those used by hospitals, which routinely handle methadone.

The Drug Enforcement Administration now provides four options for correctional institutions to provide methadone treatment for opioid use disorder.

The first option is to become a narcotic treatment program. This requires the facilities to adhere to an extensive list of requirements that apply to all community-based treatment programs. The second option is to contract with a narcotic treatment program to provide care within the facility, which either involves bring the patients to the narcotic treatment program or transporting the methadone to the correctional facility. This approach, however, can be expensive, logistically prohibitive, and does not always meet patient needs.

The third option is for a community-based program to operate a mobile methadone site at the correctional facility, as outlined in 21 CFR 1301.13(e)(4)(iii). In this case, individuals who are incarcerated would receive treatment at the mobile site. This effort may also be costly, complex logistically, and is only feasible if there is a community-based program able to set up the mobile effort.

The fourth option is for correctional facilities registered as a “hospital / clinic” to provide methadone to people with an opioid use disorder if the condition is “an incidental adjunct to medical or surgical treatment of conditions other than addiction.” This option does not require the correctional facility to become or contract with a narcotic treatment program.

21 C.F.R. § 1306.07(c) permits hospitals to treat people with methadone without restriction if the patient is receiving medical or surgical treatment for a condition other than addiction. Hospitals must still handle methadone as they do other controlled substances, with specific requirements including registration with the DEA, security procedures, and record-keeping. There is no limit on how long hospitals may treat a hospitalized patient with methadone.

In its 2000 guide for Narcotic Treatment Programs[37], DEA indicated that correctional facilities (and other institutional settings) also can treat people who were pregnant or had another medical condition:

> ***Q: May a Department of Corrections medical staff administer methadone to incarcerated pregnant opioid dependent women during the course of their pregnancy without a separate registration as an NTP?***
>
> *A: Methadone may be administered in such circumstances when the following conditions are met. A practitioner or authorized hospital staff may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Pregnancy is recognized as a medical condition by both DEA and FDA and, therefore, this would be considered medical treatment of a condition other than addiction.*
>
> *Such medical treatment is allowed "in a hospital"* ***or institutional setting****. However, the Department of Corrections must be licensed by both the state and DEA as a clinic, a hospital, or a hospital / clinic. [21 CFR 1306.07(c).]*
>
> (Emphasis added.)

DEA also indicated in the 2022 update to this manual[38] that correctional facilities that are registered with DEA as a "hospital / clinic" may use methadone as hospitals do. This text indicates that a registered correctional facility may provide methadone to someone who is incarcerated and receiving medical or surgical treatment for a condition other than addiction. The facility would need to comply with requirements for controlled substances, but not all of the regulations governing community-based narcotic treatment programs.

This approach demonstrates that DEA recognizes the value in permitting ongoing access to methadone outside of narcotic treatment programs in institutional settings.*

The current regulatory system prevents many jails and prisons from offering methadone to all patients who can benefit.

To better understand the current challenges that correctional facilities face in providing methadone, we interviewed legal policy experts and providers delivering care in correctional settings. Among the interviewees were clinicians in both jail and prison settings and medical leadership roles in large private correctional health care vendors. These interviews build off the findings of *Medications for Opioid Use Disorder in Jails and Prisons: Moving Toward Universal Access*, a report released by the Johns Hopkins Bloomberg School of Public Health in July 2021.[39]

* DEA has discussed the applicability of the exception in 1306.07(c) to "institutional practitioners" as far back as its 1974 Final Rule.

Our interviewees described significant barriers for correctional facilities to become a narcotic treatment program or to work with community-based narcotic treatment programs. These barriers include:

- The regulations clinical and programmatic requirements are not all appropriate for correctional settings;
- State narcotic treatment authorities do not take into account the differences and needs of correctional settings; and
- Working with community-based narcotic treatment programs make it difficult for correctional facilities to have stock methadone on hand, which is necessary to treat people quickly and prevent them from going through withdrawal.

Providers who do overcome these barriers to become or work with narcotic treatment programs find that there are still unnecessary and inappropriate delays in initiating or continuing methadone treatment. When facilities can overcome these operational barriers, it is at significant financial cost and investment of staff time (and sometimes facility space). Our findings are consistent with other research that has documented that becoming or contracting with a narcotic treatment program is a significant barrier to the use of methadone in correctional facilities.[40,41]

Recommendations

Given the urgency of the opioid overdose crisis, DEA should support correctional facilities in providing methadone to all who can benefit by putting forward an alternative pathway for these facilities. This can be done in two ways.

I. DEA should grant an exception to correctional facilities to provide methadone to all patients who can benefit.

Facilities are permitted to request exceptions to regulatory provisions of the Controlled Substances Act. In the short-term, DEA should grant correctional facilities exceptions under its authority in 21 C.F.R. § 1307.03. The exception would be to the part of 21 C.F.R. § 1306.07(c) that prevents the use of methadone in institutional settings unless it is an "incidental adjunct" to the medical or surgical treatment of another condition.

This exception would permit correctional facilities to treat anyone with an opioid use disorder with methadone during their incarceration without becoming a narcotic treatment program or contracting with a community-based narcotic treatment program. Correctional facilities would still be required to handle methadone as they do other controlled substances (or as they would handle methadone as a treatment for pain). Additionally, they would still be required to register with DEA as a "hospital / clinic."

DEA could set reasonable criteria for granting an exception. For example, DEA could require that facilities that receive an exception participate in data collection and have a plan for transitioning people to a community-based methadone provider following release. DEA could also do this as part of a pilot program with a limited number of facilities.

II. Relying on experience from correctional institutions with an exception, DEA should change its regulations to provide a specific pathway for the treatment of all who can benefit from methadone.

Over time, DEA can also incorporate this exception into regulations. Proceeding with the exception first would allow DEA to learn from the experiences of correctional facilities that have used the exception before putting it into regulation. Ultimately, putting this pathway into regulation would provide correctional facilities with additional clarity and confidence in the permanence of this approach and allow more facilities to use it.

To do this, DEA can revise 21 C.F.R. § 1306.07(c) to permit correctional facilities to use methadone to treat anyone with an opioid use disorder, not just those who are also receiving treatment for another medical or surgical condition.

In setting up the regulatory change, SAMHSA might consider whether some of the clinical requirements that apply to patients seen at narcotic treatment programs should apply to patients treated for longer periods of time at correctional facilities. For example, SAMHSA requires narcotic treatment programs to provide counseling services to their patients. While providing counseling services is impractical and of limited benefit for patients with a short stay in a jail,

there may utility for a prison to provide counseling to people receiving methadone who are incarcerated for months or years.

Overall, this approach — allowing correctional facilities to receive an exception to the current regulations and then updating the regulations based on the experience with the exception — would dramatically increase access to methadone and save lives.

Appendix A: Provide clarity on existing options

For the limited number of correctional facilities that are narcotic treatment program or work with community-based narcotic treatment programs, DEA can provide guidance under existing statute and regulations to substantially improve their ability to provide care.

As part of this process, DEA should coordinate with the Substance Abuse & Mental Health Services Administration (SAMHSA).

A. DEA can provide clear guidance to state opioid treatment authorities on working with correctional facilities to reduce inconsistencies and misunderstanding about federal regulations.

We heard in our conversations that some state opioid treatment authorities serve as barriers to correctional facilities treating people with methadone. In particular, some opioid treatment authorities apply the same regulations to community-based narcotic treatment programs as they do to correctional facilities, despite the inherent differences between these types of institutions. One authority insisted on reviewing a correctional facility's fire escape plan, a document that for security reasons should never be publicly released. It took several months to overcome the state authority's desire to see this high-security document.

DEA Action: DEA can collaborate with SAMHSA to encourage state opioid treatment authorities to develop new approaches to work with correctional facilities that wish to become narcotic treatment programs or contract with community-based narcotic treatment programs. This can be done through a guidance document for state opioid treatment authorities, a conference with the state opioid treatment authorities to explicitly discuss the topic, or other communications.

B. DEA can clarify the process for obtaining a single "hub" license.

The current process, by which each facility must register separately to become a narcotic treatment program, is unnecessarily cumbersome. New York State is currently pioneering an approach along these lines that may have valuable lessons for other jurisdictions.

DEA Action: Through a guidance document, DEA can work with SAMHSA to outline the process by which one state entity (such as a state department of corrections) could receive a single 'hub' license that would expedite the establishment of satellite sites at various facilities within the correctional system. The guidance could also include the requirements that the 'spokes' must meet.

C. DEA can remove requirements that are not relevant for correctional facilities.

Correctional facilities that operate narcotic treatment programs must follow the same requirements as community-based narcotic treatment programs. Not all of these requirements are directly relevant to correctional facilities, however. We heard in numerous interviews that many correctional facilities spent significant time, effort, and money to comply with DEA

requirements for elements of physical security,[42] even though jails and prisons are by definition secure facilities. One facility had extensive back-and-forth with DEA over a requirement that an alarm ring at the local police station every time the methadone safe was opened.

While there is a legitimate concern about staff diverting medications (for example, staff who administer medications), the existing controlled substance regulations that a DEA-licensed correctional pharmacy would be subject to for other medications have safeguards to reduce diversion through inventory control and storage requirements.

DEA Action: DEA can assess whether there are reasonable accommodations that could be made for correctional facilities from the typical requirements for narcotic treatment programs. If so, the agencies can then issue a guidance document detailing the acceptable variations or encourage facilities to apply for exceptions to specific provisions.

D. DEA can provide guidance to jails, prisons, and community pharmacies about the applicability of the "three-day rule" to these facilities.

Our interviews demonstrated that there is uncertainty among some correctional facilities as to whether the three-day rule, which permits facilities to provide three days of methadone outside of a narcotic treatment program, applies to them. Additionally, we heard that some community-based pharmacies are hesitant to dispense methadone to correctional facilities under the three-day rule.

DEA Action: DEA can send an official document to correctional facilities and community-based pharmacies that describes the applicability of the three-day rule (emergency provision) to correctional facilities and provides clear assurance to pharmacies that providing methadone for this purpose is within the appropriate scope of pharmacy distribution.

E. DEA can provide standard advice for DEA regional offices.

We heard in numerous interviews that interpretation of DEA regulations and guidance by local DEA agents vary widely both within and across states. For example, narcotic treatment programs are generally allowed to provide their patients with take-home doses for use on days when the facility is closed (typically Sundays or holidays). One health provider that operates in multiple jails reported that one DEA regional office that it works with permits this approach; the community-based narcotic treatment program drops off doses at the correctional facility for use on days when it is closed. However, agents from another DEA office in the same state do not permit this practice. As a result, the patients in that facility on methadone go through withdrawal every Sunday.

Another correctional facility described how agents from the local DEA office would not provide guidance on which safes would meet DEA's requirements for storing methadone. DEA field agents instead said that the final decision would be communicated after the facility has been audited (at which point the facility and medical staff could incur enforcement violations). To get around this problem, the facility relied on advice that a different DEA regional office had provided to a different facility.

DEA Action: DEA can compile a list of frequently asked questions, including these, and provide them to DEA regional offices and post them publicly. DEA can also solicit additional topics where DEA regional offices have provided conflicting advice and provide clarifications as needed.

Notes

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