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 face 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 epidemic. 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.
- 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 medication while they are incarcerated reduces overdose deaths and recidivism. For example, post-incarceration 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 legal 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 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 the most recent analysis, just 632 of the approximately 5,000 correctional facilities (12%) offer any medication to treat opioid use disorder. Specific reasons 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.

Improving access in jails is the most urgent priority in order to prevent people who have recently used opioids from going through withdrawal. Additionally, the stay in jails is often very short, so the window in which to start treatment can be narrow.

Recommendations for DEA: DEA can use its existing statutory authority to make methadone treatment substantially more available to people in jail without access to a formal opioid treatment program:

- DEA can treat jails similarly to hospitals to expand access to methadone in jails that are not opioid treatment programs. Under a provision of federal regulations, hospitals are permitted to provide methadone outside of an opioid treatment program to patients while they are hospitalized. Through rulemaking, DEA has the authority to treat jails in a similar manner, essentially treating methadone under the same controls applicable to other controlled substances currently available in jails, such as oxycodone. In the short term, this can be done through an exception procedure, which can be announced through agency guidance.
- DEA can expand the "three-day rule" to expand access to methadone in jails that are not opioid treatment facilities. Under federal regulations, patients can be treated with methadone for opioid use disorder for up to three days by any provider with a DEA registration. Through rulemaking, DEA has the authority to expand the period of time for which jails could treat patients with methadone without using an opioid treatment program. In the short term, this can also be done through an exception procedure.

Additionally, there is value in making it easier for both jails and prisons to establish opioid treatment programs and work with community-based opioid treatment programs. For these changes, DEA should coordinate with the Substance Abuse & Mental Health Services Administration (SAMHSA), which also regulates opioid treatment programs. Accordingly:

- DEA can take steps under its existing authority to make it easier for jails and prisons to become opioid treatment programs or work with community-based opioid treatment programs.
 - Opportunities include: providing guidance to state opioid treatment authorities
 on working with correctional facilities; clarifying the process for obtaining a single
 "hub license"; removing requirements that are not relevant for correctional facilities;
 reminding correctional facilities and pharmacies of the applicability of the "three-day
 rule" to correctional facilities; and standardizing advice from DEA regional offices.

The goal of these recommendations is to 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 analysesics and other controlled substances. By taking these steps, DEA can play a major role in the U.S. response to the opioid crisis.

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.^{1,2}

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.³

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.⁴ 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 lose their tolerance to the drug due to their less frequent use. As a result, the same amount of drug that they used previously may cause an overdose.

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.⁵ The risk is especially high in the immediate weeks after release;^{6,7} 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.⁸

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."

Finally, lack of treatment 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.

Studies from Scotland,¹⁰ Australia,¹¹ Rhode Island,^{12,13} and England¹⁴ 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.¹⁵ Other studies have found that treating incarcerated individuals also reduces recidivism rates.^{16,17}

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." ¹⁸

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. 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. Methadone is a long-acting full opioid agonist that reduces opioid craving and withdrawal and blunts or blocks the effects of opioids by occupying the opioid receptor sites. 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.²⁰

Based on the evidence supporting their use, numerous organizations—the National Commission on Correctional Health Care,²¹ the National Governors Association,²² the National Academy of Medicine, and the American Society for Addiction Medicine²³—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.²⁴ 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.²⁵ Accordingly, expanding access to medications in correctional facilities would facilitate compliance with federal antidiscrimination laws.

Although access to all three medications is important, 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 the most recent analysis, just 632 of the approximately 5,000 correctional facilities (12%) offer any medication to treat opioid use disorder. 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.^{27,28,29}

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.³⁰

Although very few jails and prisons currently treat people with methadone, these facilities do have substantial experience handling other controlled substances. Many are already registered with DEA to 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 requires that people being treated with methadone receive treatment at an opioid treatment program but offers alternative pathways to ensure that patients can start treatment and avoid withdrawal.

Under federal law, the United States Attorney General must set up a registration system for any practitioner who wishes to use narcotics, such as methadone, to treat people with an opioid use disorder. Under the direction of the Attorney General, DEA and SAMHSA established requirements for establishing and operating an opioid treatment program. Generally, DEA oversees the proper security and handling of the medication, while SAMHSA determines its appropriate clinical use. (Additionally, state opioid treatment authorities provide oversight at the state level.)

For the most part, only opioid treatment programs may use methadone to treat a person's opioid use disorder. However, DEA has established two provisions for access to methadone outside of opioid treatment programs:

- 1. Use in hospitals. Under 21 C.F.R. § 1306.07(c), hospitals may treat hospitalized patients with methadone without restriction as long as the opioid use disorder is not the primary reason for their hospitalization. This ensures that patients can start or continue methadone treatment so that withdrawal from an underlying opioid use disorder does not affect their medical care. Hospitals must still handle methadone as they do other controlled substances, with specific requirements including registration with the DEA, security procedures, and detailed record-keeping. There is no limit on how long hospitals are able to treat a hospitalized patient with methadone.
- 2. Three-day rule. Under 21 C.F.R. § 1306.07(b), DEA-registered physicians may treat someone going through withdrawal with methadone for up to three consecutive days (72 hours). This policy is generally designed so that facilities such as emergency departments can stabilize patients, prevent withdrawal, and start care at times when opioid treatment programs are not easily accessed or not open, such as the weekend. DEA in March 2022 clarified that facilities can now apply for an exception that allows them to provide the patient with three days of methadone, rather than requiring them to return each day for three days.³¹ The treatment may not be continued after the initial three-day period.

These alternative approaches recognize the value in having methadone available outside of opioid treatment programs in certain circumstances.

The current regulatory system prevents jails and prisons from offering methadone.

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 2021.³²

Our interviewees described significant barriers for correctional facilities to become an opioid treatment program or work with community-based opioid treatment programs. Providers who do overcome these barriers 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 recommendations in the next section are drawn from these conversations. Our findings are consistent with other research that has documented that correctional facility staff find the current regulatory approach to methadone to be a significant barrier to their use of the medication.^{33,34}

Recommendations

- I. DEA can put forward a new pathway for jails to offer methadone; this can be done immediately by encouraging jails to apply for exceptions while the agency pursues rulemaking.
- II. DEA can simultaneously pursue several administrative actions that do not require rulemaking that will make it easier for jails and prisons to open opioid treatment programs or work with community-based opioid treatment programs.

Taken together, these actions will make it dramatically simpler for correctional facilities to offer methadone.

I. DEA can create an alternative approach for jails to offer methadone.

The need to improve access to methadone is especially acute in jails, given that they are inherently short-stay facilities that process people who are coming from the community (and often directly from illicit drug use). People with an opioid use disorder who are in jails are often experiencing acute withdrawal; time is of the essence in starting methadone treatment. Reentry back to the community often occurs after a short period of time (for example, the median length of stay in Rhode Island jails was just three days in 2019). Accordingly, jails need to be able to quickly stabilize people with an opioid use disorder (either by initiating or maintaining treatment) and prepare them for a successful return to the community.

The need to quickly start methadone treatment in jails is similar to the two other circumstances where DEA has granted an alternative approach: use of methadone in hospitals, and the three-day rule.

These two alternative pathways recognize that there is value in treating patients with methadone outside of opioid treatment programs. Treatment in short-term settings can prevent patients from going through withdrawal and allows them to be connected to community-based opioid treatment programs at a later point in time. Additionally, offering all of the other services associated with opioid treatment programs—such as counseling and drug testing—may not be needed in these circumstances given that they are for short periods of time.

We see two options for DEA to increase access to methadone in jails outside of the opioid treatment program paradigm. These options recognize the similarity that jails have to the two alternative approaches that already exist in regulation. For both of these options, we describe how DEA could implement the reforms quickly and then make the changes permanent through new regulations.

A. DEA can treat jails similarly to hospitals.

As previously discussed, under 21 C.F.R. § 1306.07(c), hospitals are allowed to use methadone without meeting all of the requirements of an opioid treatment program. In its regulation, DEA provides hospitals with the ability to treat people with an opioid use disorder without restriction, so long as the addiction is an "incidental adjunct" to

another condition. People with an opioid use disorder in a jail have similarities to those in a hospital—the addiction is not their primary condition. Like in a hospital, people in jail who have recently used opioids will be going through withdrawal imminently. In hospitals, another medical or surgical issue is the primary condition responsible for their presence in the hospital; in jails or prison, the incarceration is the reason for their presence in the jail and could be considered the primary condition.

DEA can give jails a similar exception to the one that hospitals have; incarceration could be considered the "incidental adjunct" that would permit treatment with methadone.

To be eligible for the exception, the jail would need to have an appropriate DEA registration, such as a pharmacy or clinic, that permits the handling of controlled substances. This would ensure that the jail, among other requirements, is in compliance with state and federal requirements for storage and record-keeping of controlled substances. These are the same requirements that a hospital must meet for it to use methadone to treat patients with OUD while they are hospitalized.

Short-term DEA Action:

DEA has two options to advance this policy in the short-term.

- The agency can clarify in a public guidance document that an individual's incarceration can be considered an "adjunct condition." Therefore, the administration or dispensing of narcotic drugs for maintenance of incarcerated individuals at prisons by practitioners or other authorized staff would be permitted under 1306.07(c), and the prison would not be required to be separately registered with DEA as an opioid treatment program.
- Using the authority given the agency in 21 C.F.R. § 1307.03, DEA can announce that
 correctional facilities could petition the agency and request an exception to the
 regulation at 1306.07(c) for maintenance and detoxification treatment of individuals
 incarcerated at jails. The exception would permit jails to treat people with methadone
 under 1306.07(c), with incarceration serving as the "incidental adjunct."

Longer-term DEA Action:

DEA can revise the regulation in 21 C.F.R. § 1306.07(c) to give jails a similar exemption to the one that hospitals have; the incarceration would serve as the "incidental adjunct."

B. DEA can expand the "Three-Day Rule" for jails.

As discussed earlier, providers outside of an opioid treatment program may use methadone to treat someone with an opioid use disorder for up to three days (72 hours). This rule recognizes the benefits of using methadone when access to an opioid treatment program may be challenging, in order to prevent someone from going through withdrawal and to start treatment at a time and place where the patient is open to it.

Although providers in jails can also take advantage of this three-day period to treat people with methadone, we heard in our interviews that many jails were reluctant to rely upon this provision since they found it difficult to transition treatment to an opioid treatment program within the three-day period.

In order to make it easier to treat people in jail with an opioid use disorder, DEA can permit registered providers to treat people in jail for a longer period of time—for example, up to 28 days—without restriction. (Note that the mean length of stay in jail was 28 days in 2020).³⁶ This would give providers in jails the confidence that they would have sufficient time to transition care to a community-based opioid treatment program.

In fact, the National Drug Control Strategy specifically calls upon the Office of National Drug Control Policy to work with DEA to explore the possibility of extending the "three-day rule" to a longer period of time in correctional facilities.

Short-term DEA Action:

As discussed above, 21 C.F.R. § 1307.03 gives DEA the authority to make exceptions to the agency's usual requirements. DEA can publicly state that it would approve exception requests to the usual three-day period in 1306.07(b) for the treatment of people in correctional facilities by registered providers. The exception request could be for up to 28 days, or any other time period that DEA selected.

Longer-term DEA Action:

DEA can revise the regulation in 21 C.F.R. § 1306.07(b) to extend the period of time during which people in correctional facilities could be treated with methadone to 28 days or another time period that the agency deems appropriate.

Overall, either of these approaches would have significant benefits. In particular, they would permit jails to have a stock supply of methadone to start treatment quickly, before patients on opioids (either methadone or illicit opioids) begin to go through withdrawal and before they are discharged back to the community.

We recognize that these options will not work in the short term for many smaller jails that do not have a DEA registration that allows the handling of controlled substances. If these facilities do want to be able to start treatment with methadone, they could go through the process of applying for a DEA registration that would allow them to have controlled substances, or they could enter into a guest-dosing agreement with a community-based opioid treatment program.

Either of the approaches would be a dramatic improvement over the current situation where the vast majority of jails do not offer methadone.

II. DEA can make it easier for correctional facilities to establish opioid treatment programs or work with community-based programs.

In addition to the above alternative approaches for jails, DEA and SAMHSA can make it easier for both jails and prisons to establish opioid treatment programs or work with community-based opioid treatment programs, either of which would allow correctional facilities to provide methadone for extended periods of time. DEA should coordinate with SAMHSA, which also regulates opioid treatment programs, on these changes. All of the following actions, which are drawn from our conversations with correctional health providers, can be done under existing regulations.

A. DEA can provide guidance to state opioid treatment authorities on working with correctional facilities.

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 opioid 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 encourage state opioid treatment authorities to develop new approaches to work with correctional facilities that wish to become opioid treatment programs or use community-based opioid treatment programs. This can be done through a guidance document for state opioid treatment authorities or a conference with the state opioid treatment authorities to explicitly discuss the topic.

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

The current process, by which each facility must register separately to become an opioid 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 an official guidance document, DEA can 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.

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

Correctional facilities that operate opioid treatment programs must follow the same

requirements as community-based opioid 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,³⁷ 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 opioid treatment programs. If so, the agencies can then issue a guidance document detailing the acceptable variations or encourage facilities to apply for exceptions using the process previously described.

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 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, opioid 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 opioid 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.

Additional Thoughts

Establishing an advisory committee of correctional health experts

To better understand these issues, and to identify if changes are having the desired effects, DEA and SAMHSA can establish an advisory committee of health care providers that work in correctional health, custodial staff, state regulators, and formerly incarcerated patients to periodically discuss with DEA and SAMHSA the use of methadone in correctional settings.

Planning for evaluation

DEA and SAMHSA can also plan for an evaluation of any changes made to how correctional facilities handle methadone. DEA and SAMHSA can require that facilities that request exemptions suggested in this white paper participate in data collection (for example, to track numbers of people receiving methadone through these pathways and to document any instances of adverse events).

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