

**Expanding Access to Methadone to  
Treat OUD in Carceral Settings Using  
the Hospital/Clinic Designation  
JCOIN Webinar, 7/16/24**

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# Disclosures

- Kelly S. Ramsey, MD, MPH, MA, FACP, DFASAM does not have any financial disclosures.



# Learning Objectives

- After this webinar, attendees will be able to:
- Describe the effectiveness for medications for opioid use disorder (MOUD) for the treatment of opioid use disorder (OUD)
- Describe what the use of the hospital/clinic designation in carceral settings means and how it expands access to methadone in carceral settings
- Describe how to operationalize use of methadone effectively for the treatment of opioid withdrawal syndrome (OWS) and OUD in carceral settings
- Understand best practice in carceral settings for the treatment of OUD with methadone

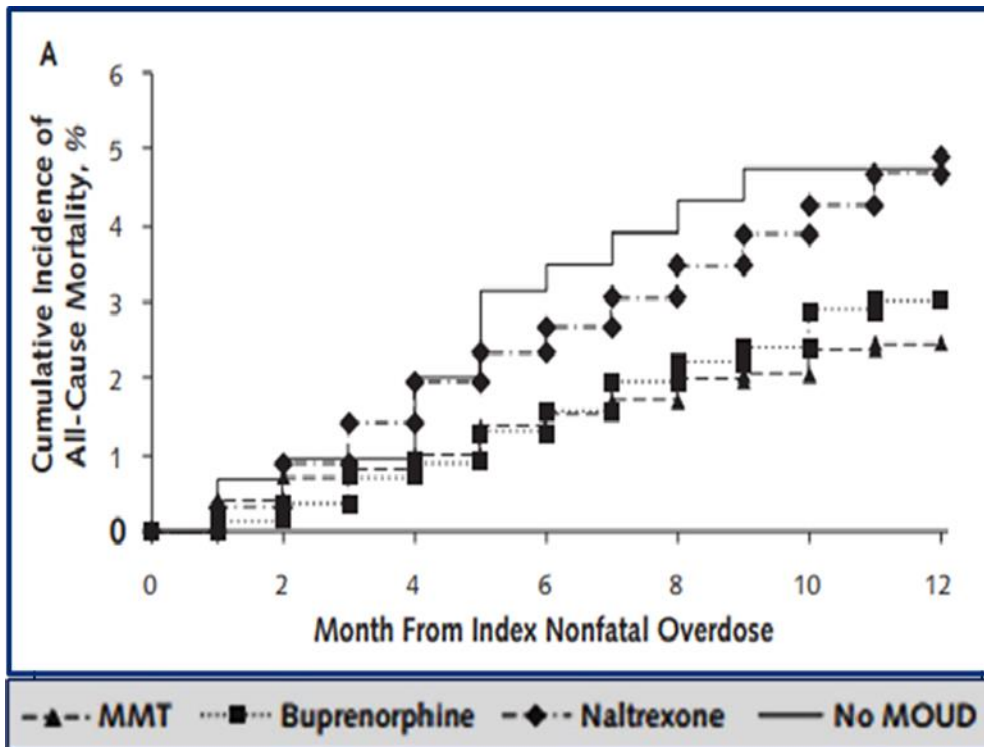


# Background and Level Setting

- Methadone is a lifesaving medication for treating OUD.
- It is clinical best practice to offer all FDA-approved medications for the treatment of OUD, including methadone, in all settings, including carceral settings.
- 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.
- 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.
- As described in JHU's 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.



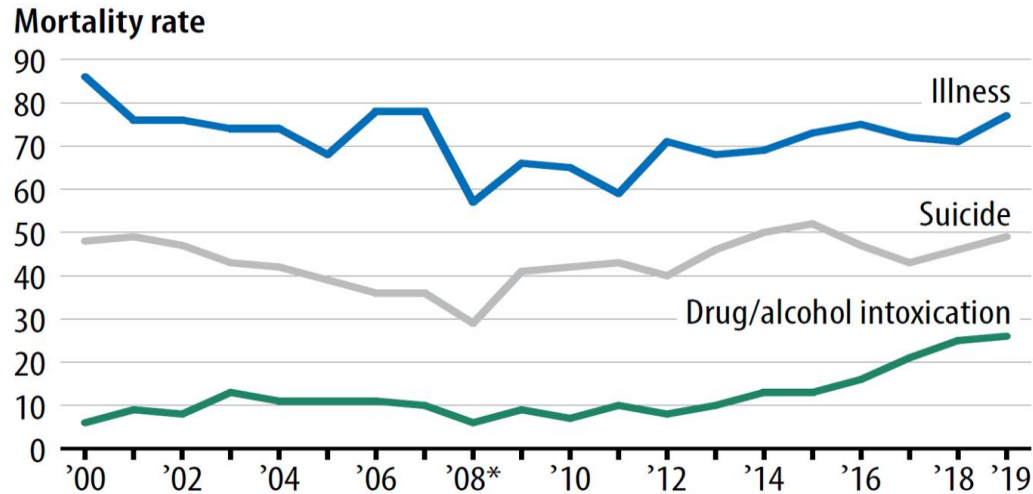
# Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study



- **Results:** Compared with no MOUD, MMT was associated with decreased all-cause mortality (adjusted hazard ratio [AHR], 0.47 [CI, 0.32 to 0.71]) and opioid-related mortality (AHR, 0.41 [CI, 0.24 to 0.70]). Buprenorphine was associated with decreased all-cause mortality (AHR, 0.63 [CI, 0.46 to 0.87]) and opioid-related mortality (AHR, 0.62 [CI, 0.41 to 0.92]). No associations between naltrexone and all-cause mortality (AHR, 1.44 [CI, 0.84 to 2.46]) or opioid-related mortality (AHR, 1.42 [CI, 0.73 to 2.79]) were identified.

# Mortality in Local Jails, 2000-2019, Statistical Tables

**Mortality rate per 100,000 local jail inmates, by cause of death, 2000–2019**



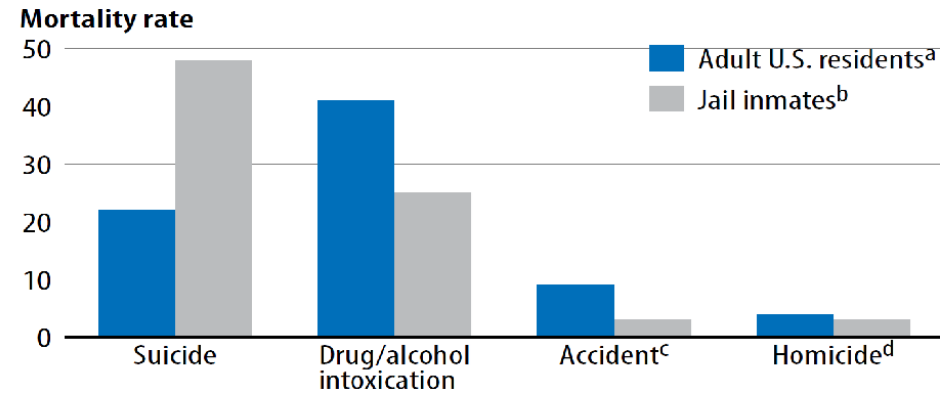
Note: Data may have been revised from previously published statistics. Mortality rates are per 100,000 inmates held in the custody of local jails. Mortality rates for 2001–2019 are based on the annual number of deaths and the average daily population (ADP). In 2000, the ADP was estimated by taking the average of January 1 and December 31 inmate population counts. See *Methodology*. See table 3 for rates.

\*In 2008, a high number of illness cases were missing cause of death information and were classified as missing.

Source: Bureau of Justice Statistics, Mortality in Correctional Institutions, 2000–2019.

[Mortality in Local Jails, 2000–2019 – Statistical Tables \(ojp.gov\)](https://www.ojp.gov/stat/mortality-in-local-jails-2000-2019)

**Adjusted mortality rate per 100,000 U.S. residents, by cause of death, 2019**



Note: Excludes persons age 17 or younger and federal prisoners. U.S. resident mortality rate is per 100,000 adult U.S. residents and is based on death certificates from all U.S. residents in 2019. Inmate mortality rate is per 100,000 inmates held in the custody of local jails and is based on the annual number of deaths and average daily population. See table 4 for crude and adjusted rates.

<sup>a</sup>To allow for direct comparisons of mortality rates, BJS adjusted the U.S. resident population to resemble the sex, race or ethnicity, and age distribution of the local jail population. See *Methodology*.

<sup>b</sup>Inmate mortality rates in figure 3 and table 4 were adjusted for sex, race or ethnicity, and age differences to be comparable to U.S. resident rates and may differ from other rates in the report. See *Methodology*.

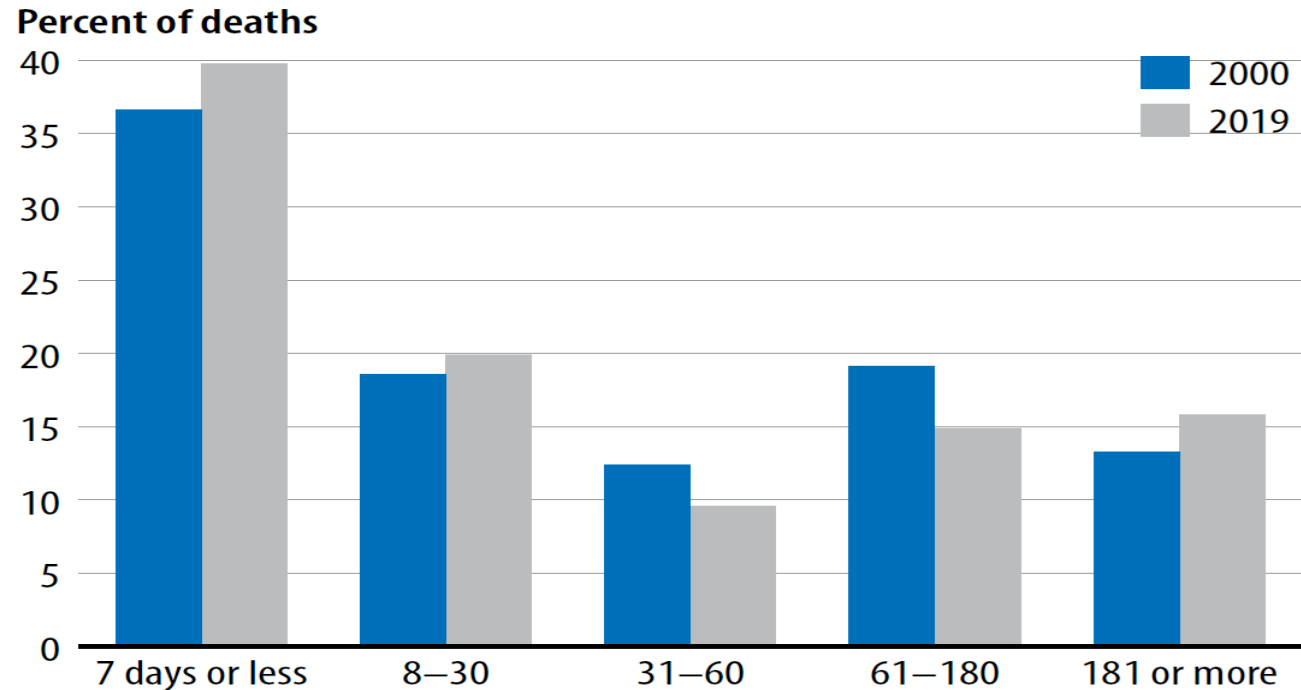
<sup>c</sup>Excludes causes of death that are unlikely to occur in a jail setting from the rates of both U.S. residents and jail inmates. See *Methodology*.

<sup>d</sup>Includes homicides committed by other inmates, incidental to the use of force by staff, and resulting from injuries sustained prior to incarceration.

Source: Bureau of Justice Statistics, Annual Survey of Jails, 2011–2018, Census of Local Jails, 2019, Mortality in Correctional Institutions, 2019, National Inmate Survey, 2007–2009 and 2011–2012, and Survey of Inmates in Local Jails, 2002; and Centers for Disease Control and Prevention, National Center for Health Statistics, CDC WONDER online database, Underlying Cause of Death 2019 (released in 2020).

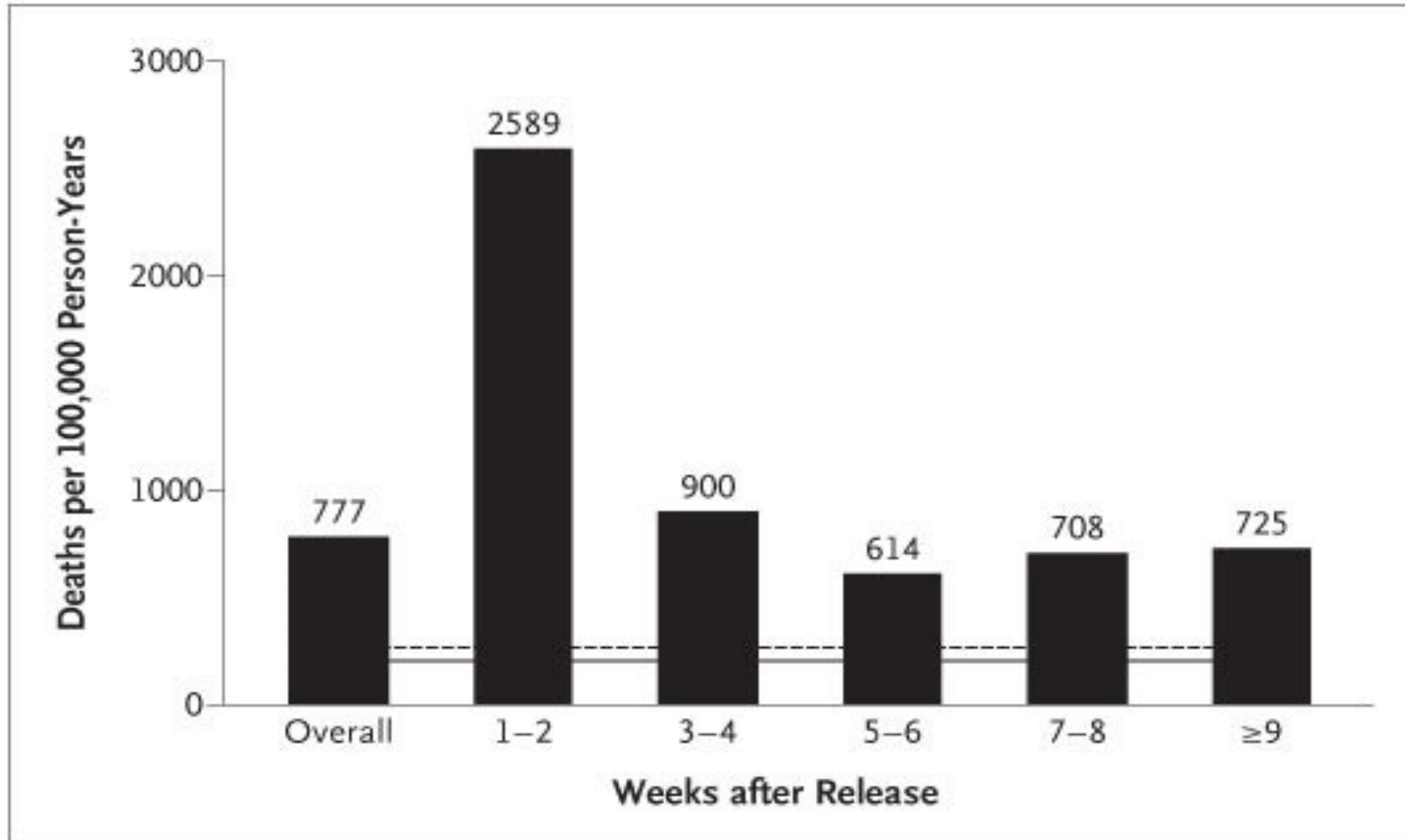
# Mortality in Local Jails, 2000-2019, Statistical Tables

**Percent of deaths of local jail inmates, by time served before death, 2000 and 2019**



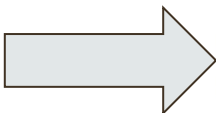
Note: Data may have been revised from previously published statistics. Percentages are based on nonmissing data. See table 6 for percentages. Source: Bureau of Justice Statistics, Mortality in Correctional Institutions, 2000 and 2019.

# Mortality Rates among Former Inmates of the Washington State Department of Corrections during the Study Follow-up (Overall) and According to 2-Week Periods after Release from Prison





# Leading Causes of Death after Release From Prison



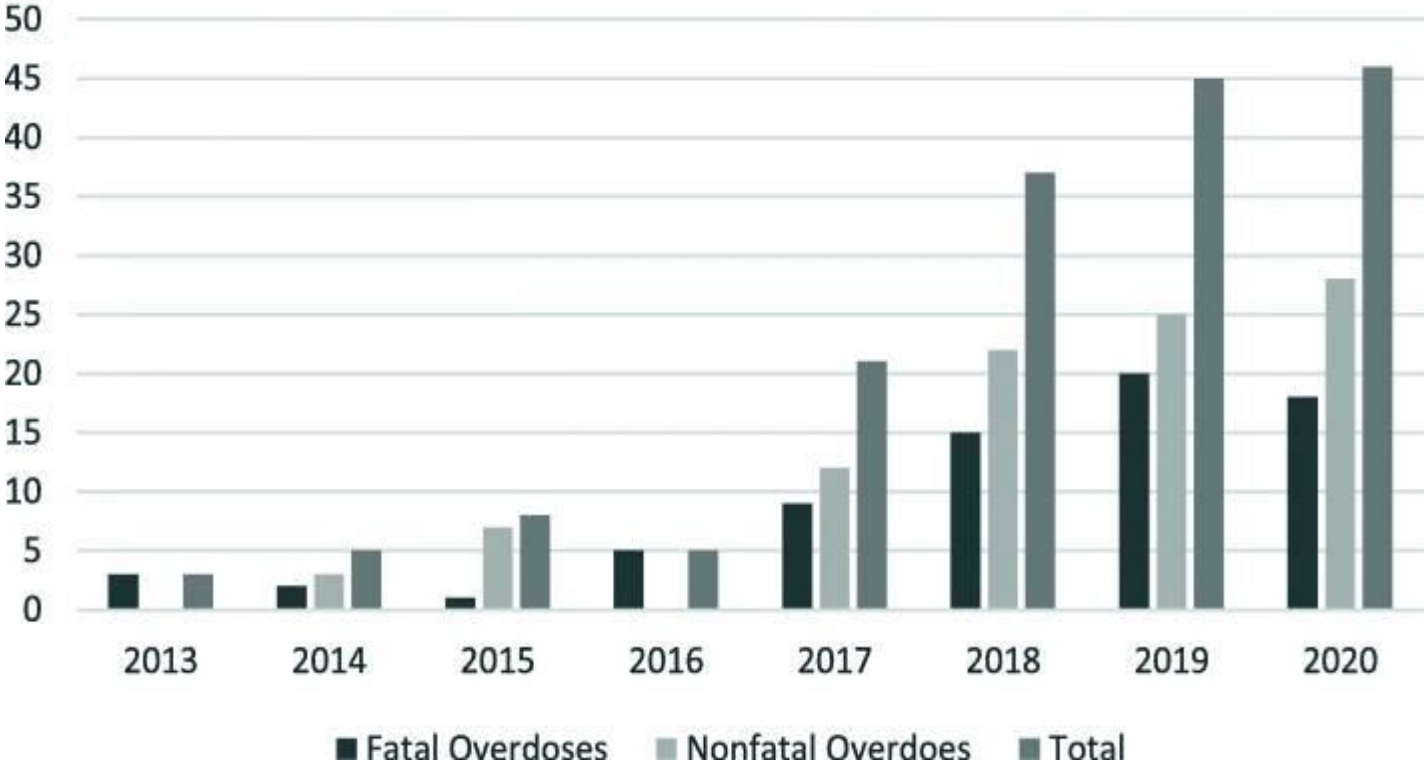
**Table 3. Leading Causes of Death after Release from Prison.**

Cause	Overall		Within 2 Weeks after Release		More than 2 Weeks after Release	
	no. of deaths	no./100,000 person-years (95% CI)	no. of deaths	no./100,000 person-years (95% CI)	no. of deaths	no./100,000 person-years (95% CI)
All causes	443	777 (707–852)	38	2589 (1884–3558)	405	729 (661–803)
Overdose*	103	181 (149–219)	27	1840 (1213–2677)	76	137 (109–171)
Cocaine	50	87 (66–116)	15	1021 (616–1695)	35	63 (45–88)
Psychostimulants	19	33 (21–52)	5	341 (142–818)	14	25 (15–42)
Heroin	18	32 (20–50)	6	409 (184–91)	12	23 (14–40)
Methadone	18	32 (20–50)	5	341 (142–818)	13	23 (14–40)
Other opioids	13	23 (13–40)	5	341 (142–818)	8	14 (7–29)
Other narcotics	41	72 (53–98)	11	749 (415–1353)	30	54 (38–77)
Alcohol	20	30 (19–48)	3	204 (66–634)	14	25 (15–42)
Antidepressants (tricyclic or tetracyclic)	13	23 (13–39)	6	409 (184–910)	7	12 (6–26)
Multiple drugs	27	47 (32–6)	11	749 (415–1353)	16	29 (18–47)
Cardiovascular disease	56	98 (76–128)	1	68 (10–484)	55	99 (76–129)
Atherosclerotic heart disease	13	23 (13–29)	0		13	23 (14–40)
Acute myocardial infarction	10	18 (9–33)	0		10	18 (10–36)
Cerebrovascular disease	9	16 (8–30)	0		9	16 (8–31)
Hypertensive diseases	9	16 (8–30)	1	68 (10–437)	8	14 (7–29)
Endocarditis	2	4 (1–14)	0		2	4 (1–14)
Homicide	54	95 (73–124)	2	136 (34–545)	52	94 (71–123)
Handgun or other firearm involved	36	63 (46–87)	2	136 (34–545)	34	61 (44–86)
Suicide	40	70 (51–96)	2	136 (34–545)	38	69 (50–94)
Handgun or other firearm involved	10	18 (9–33)	1	68 (10–484)	9	16 (8–31)
Cancer	39	68 (50–94)	0		39	70 (51–96)
Lung or bronchial	19	33 (21–52)	0		19	34 (22–54)
Pancreatic	4	7 (3–19)	0		4	7 (3–19)
Liver	3	5 (2–16)	0		3	5 (2–17)
Prostate	2	3 (1–14)	0		2	4 (1–14)
Motor vehicle accident	35	61 (44–85)	0		35	63 (45–88)
Liver disease	23	40 (27–61)	2	136 (34–545)	21	38 (25–58)
Viral hepatitis	12	21 (12–31)	1	68 (10–484)	11	20 (11–36)
Alcoholic liver disease	10	18 (9–33)	1	68 (10–484)	9	16 (8–31)
Other accident	17	30 (19–48)	0		17	31 (19–49)
Drowning	6	11 (5–23)	0		6	11 (5–24)
Human immunodeficiency virus	7	12 (6–26)	0		7	12 (6–26)
Diabetes mellitus	6	11 (5–23)	1	68 (10–484)	5	9 (4–22)
Legal intervention involving firearms	5	9 (4–21)	0		5	9 (4–22)
Chronic obstructive pulmonary disease	5	9 (4–21)	0		5	9 (4–22)
Other or undetermined	53	93 (71–122)	3	204 (66–634)	50	90 (68–119)

\* For deaths from overdose that involved more than one drug, the death is listed for each drug involved.

# Fentanyl-Related Overdose During Incarceration: A Comprehensive Review

Number of Reported Overdoses by Year



# Post-incarceration outcomes of a comprehensive statewide correctional MOUD program: a retrospective cohort study

	Total % (n)	30 days post-release		$\chi^2$ ; p-value	365 days post-release		$\chi^2$ ; p-value
		Ever engaged % (n)	Never Engaged % (n)		Ever engaged % (n)	Never Engaged % (n)	
<b>Methadone</b>							
Continued	68.0% (608)	87.0% (529)	13.0% (79)	86.67; p < .001	91.8% (558)	8.2% (50)	16.78; p < .001
Induction	32.0% (286)	59.4% (170)	40.6% (116)		82.5% (236)	17.5% (50)	
<b>Total</b>	<b>56.7% (894)</b>	<b>78.2% (699)</b>	<b>21.8% (195)</b>		<b>88.8% (794)</b>	<b>11.2% (100)</b>	
<b>Buprenorphine</b>							
Continued	53.5% (366)	76.5% (280)	23.5% (86)	44.29; p < .001	83.9% (307)	16.1% (59)	2.14; p = .144
Induction	46.5% (318)	52.2% (166)	47.8% (152)		79.6% (253)	20.4% (65)	
<b>Total</b>	<b>43.3% (684)</b>	<b>65.2% (446)</b>	<b>34.8% (238)</b>		<b>81.9% (560)</b>	<b>18.1% (124)</b>	
<b>Buprenorphine or Methadone</b>							
Continued	61.7% (974)	83.1% (809)	16.9% (165)	140.89; p < .001	88.8% (865)	11.2% (109)	18.86; p < .001
Induction	38.3% (604)	55.6% (336)	44.4% (268)		81.0% (489)	19.0% (115)	
<b>Total</b>	<b>100% (1578)</b>	<b>72.6% (1145)</b>	<b>27.4% (433)</b>		<b>85.8% (1354)</b>	<b>14.2% (224)</b>	

MOUD: medications for opioid use disorder. Continued = continued MOUD from the community; Induction = MOUD induction at pre-release or at commitment.

**Table 2: Percentage engaged in MOUD at 30 days and 12-Months Post-Release by MOUD continuance or induction for individuals who enrolled in MOUD (methadone or buprenorphine) and were released, December 1, 2016 to December 31, 2018 (N = 1578).**

# Post-incarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System

Table 1. Characteristics and Number of Deaths From Accidental Overdose in Rhode Island, Both Overall and Among Individuals With Recent Incarceration<sup>a</sup>

Characteristic	Decedents With Recent Incarceration, No. (%)		Overall No. of Decedents (%)	
	First 6 mo of 2016 (n = 26)	First 6 mo of 2017 (n = 9)	First 6 mo of 2016 (n = 179)	First 6 mo of 2017 (n = 157)
Sex				
Male	24 (92.3)	7 (77.8)	123 (68.7)	94 (59.9)
Female	2 (7.7)	2 (22.2)	56 (31.3)	63 (40.1)
Race/ethnicity <sup>b</sup>				
White	25 (96.2)	8 (88.9)	168 (93.9)	137 (87.3) <sup>c</sup>
Other	1 (3.8)	1 (11.1)	11 (6.1)	20 (12.7)
Age, y				
18-29	8 (30.8)	2 (22.2)	43 (24.0)	23 (14.6) <sup>d</sup>
30-39	9 (34.6)	4 (44.4)	34 (19.0)	54 (34.4)
40-49	6 (23.1)	3 (33.3)	40 (22.3)	35 (22.3)
≥50	3 (11.5)	0 (0.0)	62 (34.6)	45 (28.7)
Died of overdose attributed to fentanyl	16 (61.5)	8 (88.9)	92 (51.4)	92 (58.6)
Length of incarceration, median (IQR), mo	30 (4-70)	23 (9-113)	NA	NA
Time since release from incarceration to death, median (IQR), d	112 (12-223)	190 (49-241)	NA	NA
Died within 30 d of release from incarceration	10 (38.5)	1 (11.1)	NA	NA

Abbreviations: IQR, interquartile range; NA, not applicable.

<sup>a</sup> Recent incarceration was defined as within 12 months of release from the Rhode Island Department of Corrections.

<sup>b</sup> Race as recorded by the Rhode Island Office of State Medical Examiners at the time of autopsy or case review.

<sup>c</sup>  $\chi^2$  Test comparing all decedents, January 1 to June 30, 2016, vs January 1 to June 30, 2017,  $P = .04$ .

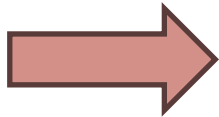
<sup>d</sup>  $\chi^2$  Test comparing all decedents, January 1 to June 30, 2016, vs January 1 to June 30, 2017,  $P = .007$ .

- There was a 60.5% reduction in mortality (RR, 0.4,  $P=0.01$ )
- The NNT to prevent a death from overdose was 11.

# Post-incarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System

Table 2. Characteristics of Individuals Incarcerated in Rhode Island From January 1 to June 30, 2016, and From January 1 to June 30, 2017

Characteristic	First 6 mo of 2016	First 6 mo of 2017
Admission for incarceration, No.	4822	4512
Release from incarceration, No.	4005	3426
No. of inmates receiving MAT monthly, mean (SD)	80 (18) <sup>a</sup>	303 (39)
No. of inmates receiving a specific MAT drug monthly, mean (SD)		
Buprenorphine	4 (3)	119 (15)
Methadone	74 (16)	180 (25)
Naltrexone	2 (1)	4 (1)
Naloxone kits dispensed at release from incarceration, No.	72	35



Abbreviations: MAT, medications for addiction treatment; RIDOC, Rhode Island Department of Corrections.

<sup>a</sup> Some medications for treatment of addiction were in use at RIDOC in specialized circumstances. Treatment with an opioid agonist is standard of care for pregnant women with opioid use disorder. Pregnant women with opioid use disorder incarcerated at RIDOC are typically treated with methadone and less frequently with buprenorphine. A pilot study providing naltrexone by injection had been ongoing since December 2015 prior to the start of the MAT program at RIDOC.

# 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 hospital/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.

# What Are the Options for Providing Methadone in Carceral Settings?

- The carceral setting can become an opioid treatment program (OTP) and must follow all 42 CFR Part 8 rules that an OTP must follow
- The carceral setting establishes a relationship with a community OTP to provide methadone for patients in its setting
- The carceral setting utilizes the hospital/clinic designation to provide methadone for its patients



# What Diagnoses May Be Utilized in This Setting as an Additional Diagnosis?

- *What diagnoses may be utilized in this setting as an additional diagnosis?*
  - **That hasn't been determined yet**
  - **The DEA and SAMHSA are discussing this issue**
  - **We are awaiting SAMHSA guidance on this issue**
  - *Hopefully, any other diagnosis besides OWS and OUD may be utilized*





# 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.
- To the extent States have licensing requirements for hospitals/clinics, the facility will need to be appropriately 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 on methadone arrives at the carceral facility or 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.
- 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](#), reissued April 2024.

## **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.



# Fentanyl and Methadone: Important Considerations

- Individuals have higher tolerance to opioids due to fentanyl's potency
- The variable potency of fentanyl and other highly potent synthetic opioids (HPSO) increases the risk for overdose
  - **The DEA has seized pills with over 500 morphine milligram equivalents (MME); 42% of tested pills had over 200 MME**
  - **The lethal dose (LD50) is the amount of an ingested substance that kills 50% of a test sample. LD50 for an opioid-naïve adult is approximately 250 MME.**
- There is increased complexity due to adulterants in the unregulated drug supply, such as xylazine and medetomidine



# Fentanyl and Methadone: Important Considerations

- There are challenges with buprenorphine initiation due to precipitated opioid withdrawal syndrome if traditional initiation strategies are utilized instead of innovative low dose and high dose initiation strategies
- A medication that is not a full agonist, buprenorphine, may have limited effectiveness compared with a full agonist medication, methadone
- Providing a “blocking dose” to treat acute opioid withdrawal syndrome and opioid cravings may be more difficult to achieve without use of methadone



## Fentanyl and Methadone: The Patient Perspective

*“We have an opportunity to change people’s lives, and if we don’t get methadone right, we’re screwed. I mean, buprenorphine isn’t going to do it. The fentanyl is too strong, and people that have been using drugs for long periods of time must have methadone. That’s what I hear from other people, what I know from myself. So, buprenorphine being pushed is great. I’m glad it’s available. But we’ve got to have methadone.”*

- Louise Vincent, Executive Director, National Survivor’s Union,  
January 2022



# Shared Decision Making Model

- Patients should be part of the treatment team.
- Involving patients in their care improves outcomes.
- Patients should be informed fully about the risks and benefits of slower vs. faster methadone titration
- Patients need to know that they will still have opioid withdrawal symptoms for a while until their dose is stabilized but that the goal is for them to not have any withdrawal.
- Part of the treatment plan involves interventions to minimize overdose risk
  - **Naloxone, frequent nursing assessments, informed patients**
- The best way to minimize the risk of a lawsuit is to fully inform the patient of all treatment options, help the patient make informed consent decisions, and fully document clinical actions and clinical reasoning.





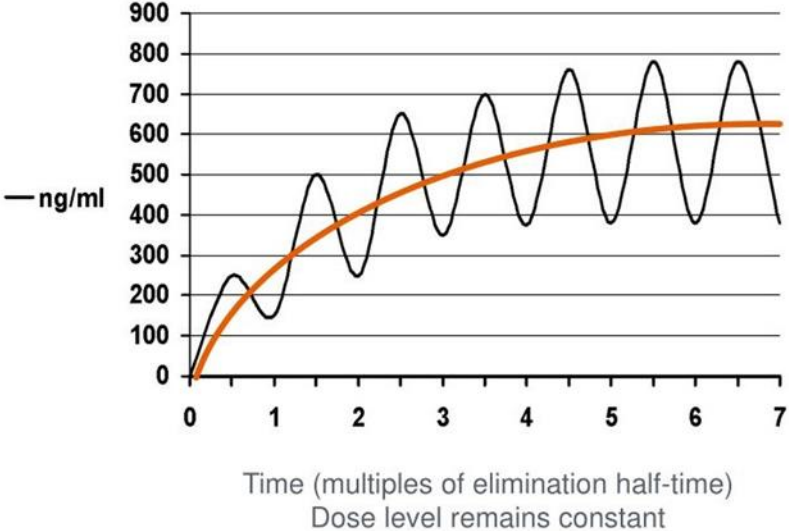
# What Are Some Factors That County Jails and State Prisons Should Consider for Utilization of Methadone?

- Clinicians unfamiliar with methadone should seek support from clinicians with training and expertise in addiction medicine before starting patients on treatment. Clinicians also should 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.



# Methadone Accumulation Over 7 Days

STEADY-STATE SIMULATION –  
MAINTENANCE PHARMACOTHERAPY  
ATTAINED AFTER 4-5 HALF-TIMES - 1 “DOSE” Q HALF-LIFE



Source: Goodman and Gilman

# 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 workflows for initiation and adjustment of the methadone dose;
  - c) A protocol and workflow for communicating with patients’ community-based opioid treatment program (if applicable), especially during intake at the carceral setting (for dose verification) and before release;



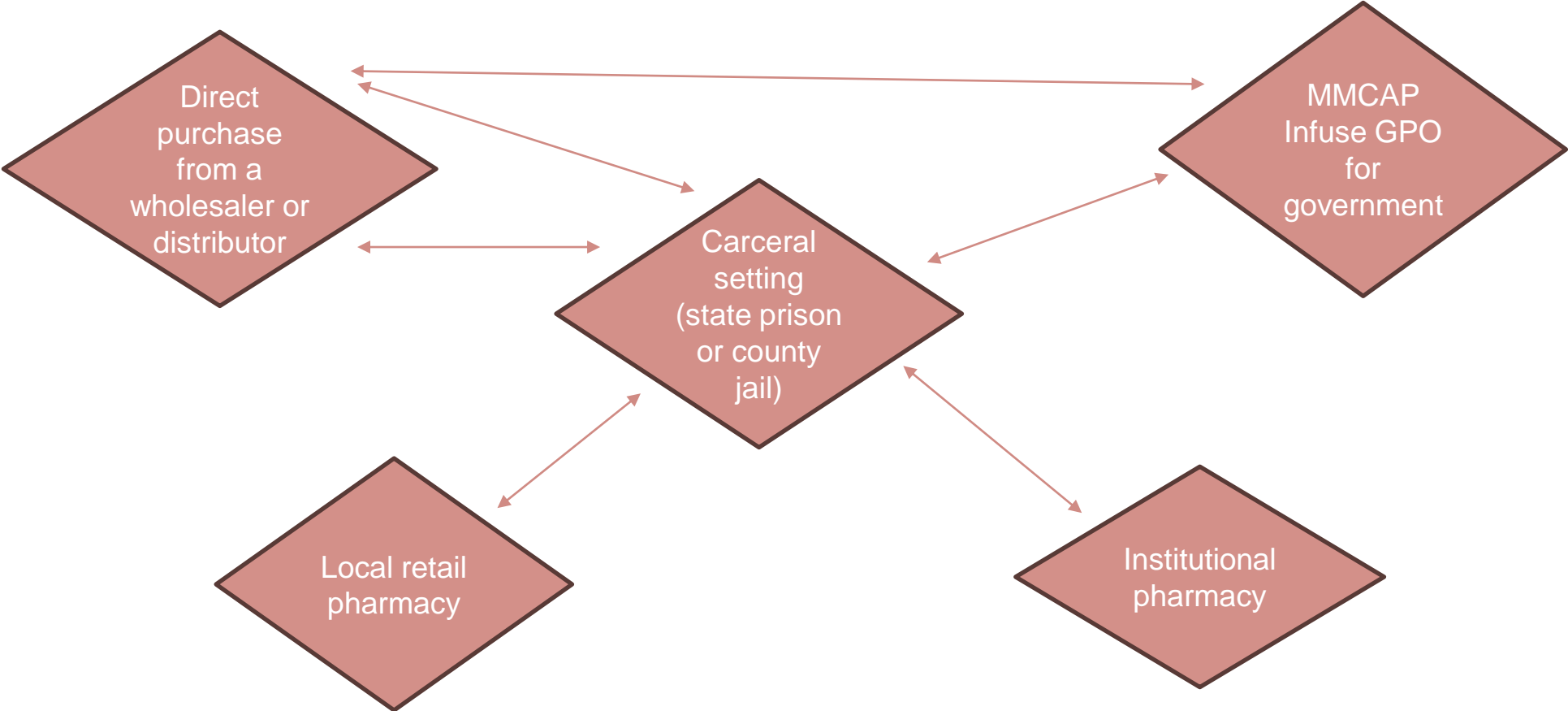
# What Should My Carceral Setting Have in Place to Make the Hospital/Clinic Approach Work?

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



# Options for Medication Purchasing in Carceral Settings

MMCAP Infuse negotiates the contract prices with the wholesaler or distributor



not an option for methadone for OUD

controlled substances cannot exceed 5% of their dispensing volume



# Ordering Methadone in Carceral Settings: DEA Lens

- A DEA-registered hospital clinic is allowed to order schedule II controlled substance medications, including methadone, from a DEA-registered manufacturer or distributor as they would order any other controlled substance medication.
- A paper DEA-form 222 ([21 CFR 1305.12](#)) or CSOS ([21 CFR 1305 Subpart C - Electronic Orders](#)) may be used to create the order. Additional information about CSOS may be found on this webpage - [Controlled Substance Ordering System Homepage \(deaecom.gov\)](#).
- It is possible that the DEA-registered manufacturer or distributor supplying the methadone will want to have a conversation with the DEA-registered hospital/clinic about the need to order any controlled substance, including methadone. Registrants are required to make a good faith inquiry either with the DEA or the appropriate state controlled substances registration agency to determine if the hospital/clinic is registered and allowed to possess the controlled substance. [21 CFR 1301.74\(a\)](#).
- Registrants also are required to design and operate a system to disclose suspicious orders of controlled substances and report these suspicious orders to the DEA. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [21 CFR 1301.74\(b\)](#).

# Ordering Methadone in Carceral Settings: DEA Lens

- There is a federal regulation that allows a pharmacy, whose primary business activity is dispensing, to distribute controlled substances (presumably to other pharmacies). The volume of such distributions cannot exceed 5% of their dispensing volume.
- The idea behind the 5% rule is to provide pharmacies with flexibility to move stock to ensure proper filling of prescriptions. It's limited to ensure that pharmacies don't become distributors. A distributor engages in a different business activity for which a separate DEA registration is required.
- Any carceral setting can order directly from a DEA-registered distributor. This would circumvent the 5% rule of the dispensing pharmacies.
- In contrast, institutional pharmacies are dispensing pharmacies and must abide by the 5% rule.



# MMCAP Infuse Group Purchasing Organization (GPO) for Government

- **MMCAP Infuse** is a national cooperative group purchasing organization (GPO) for government facilities that provide healthcare services. MMCAP Infuse was established in 1985, is operated by the State of Minnesota, Office of State Procurement, and is self-funded. It has over 35,000 member ship-to facilities across all 50 states. Use of MMCAP Infuse is free for our members and purchasing from our contracts is voluntary.
- MMCAP Infuse's mission is to ensure best value for pharmaceuticals and healthcare products and services to government facilities across the nation through executing contracts that leverage aggregated member volume to drive deeper discounts.
- **MMCAP Infuse contracts are competitively bid** following State of Minnesota stringent procurement guidelines. The resulting comprehensive healthcare contract portfolio is available for use by our member states for state agencies, as well as counties, cities, school districts and other political subdivisions.
- **Administrative Fees Shared with Members**
- Two-thirds of the administrative fees MMCAP Infuse collects from our suppliers are returned to members. This shareback is provided in the form of a wholesaler credit. A portion of the fees MMCAP Infuse collects funds our operations, with 100% of unused vendor fees returned to MMCAP Infuse member facilities based on their contract purchases.
- **MMCAP Infuse** has over 35,000 member ship-to facilities in all 50 states, with 12,590 purchasing members. Member facilities, including state agencies, counties, cities, and school districts, are responsible for providing healthcare services. Public health facilities comprise nearly half of membership, followed by educational institutions at 23.81%, correctional facilities at 11.09%, and public safety at 9.82%. – (Updated: 04/01/2024)
- MMCAP Infuse employs six regional Senior Healthcare Consultant (SHCs). This team of experienced healthcare and regional management professionals assists with contract usage and value optimization monitoring, preparing business reviews for each account, monitoring off-contract purchasing, and ensuring pricing attachment, as well as quickly resolving any account issues.





# Ordering Methadone in Carceral Settings: the Washington State Department of Corrections (WA DOC) Example

- WA DOC has central pharmacy within their system which functions like the pharmacy in a hospital. The clinicians enter orders into their electronic ordering system. They are "orders," not prescriptions, which then are filled by their central pharmacy (like in a hospital). They enter the methadone orders in our electronic system like they would for any other order.
- Their controlled substances supply is ordered and stocked at the facility level, so when they enter an order in their system, it doesn't get shipped from the central pharmacy like their other medications, but instead is filled from facility stock that is kept on hand.
- Methadone is ordered from the medication distributors like any other medication and stocked in their facilities. Then, when an order is placed, it is filled from the stock they carry on hand, like in a hospital.



## Ordering Methadone in Carceral Settings: the Washington State Department of Corrections (WA DOC) Example

- The WA DOC system which functions with their own central pharmacy system may be different than a lot of other jails and prisons, who may not have their own central pharmacy system. Many other carceral systems may fill prescriptions from outside pharmacies instead.
- WA DOC is still trying to figure out the process on how to give a supply at release. It will need to be dispensed from their local stock supply and given to the patient at time of release, but the logistics are more complicated. The WA DOC Addiction Medicine Medical Director is working with a local hospital to figure out how to mirror their process in the WA DOC facilities.



# DEA Audits: What Carceral Settings Should Know

- **What is a DEA audit?**

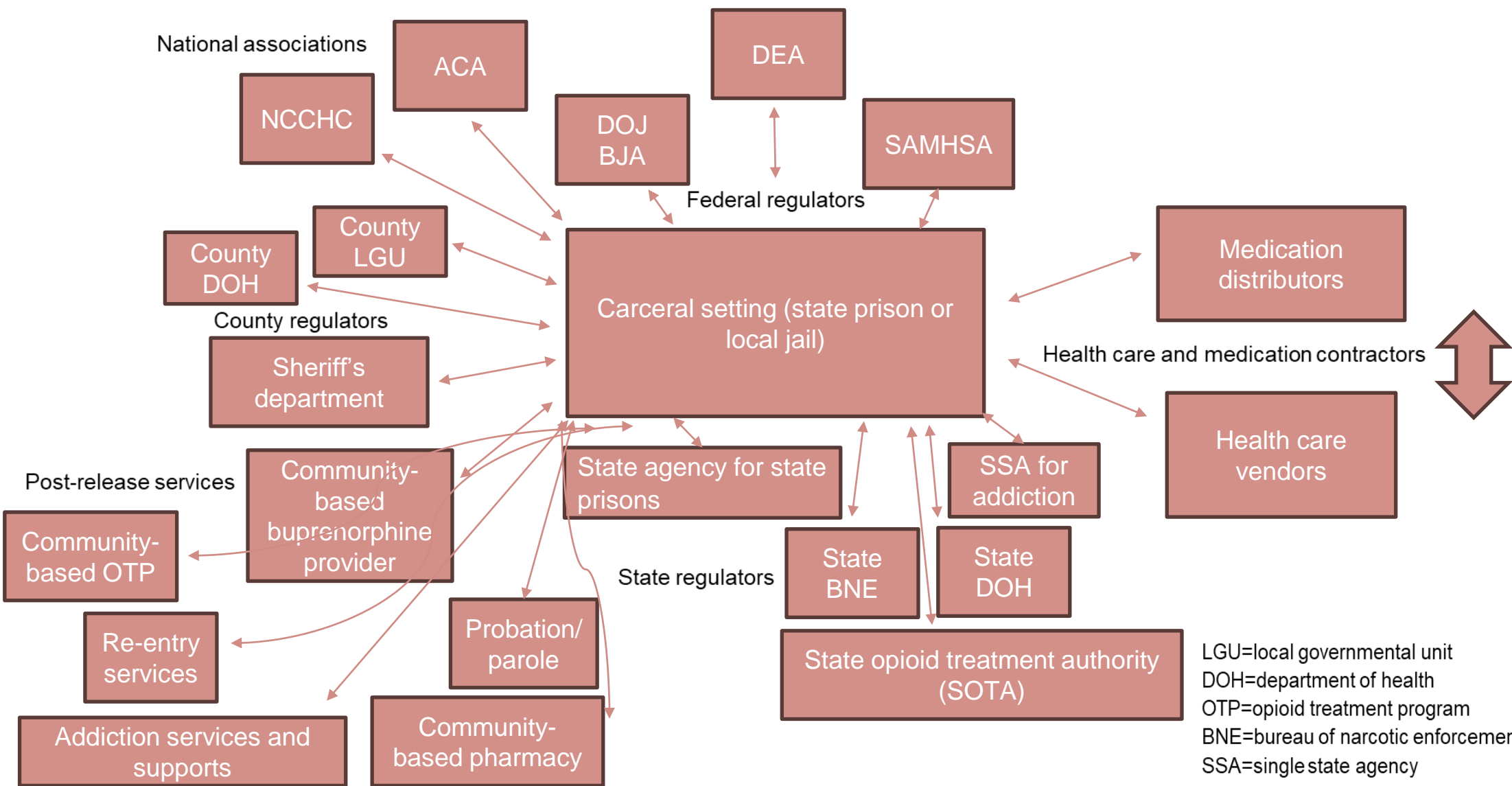
- The DEA performs routine inspections and audits of medical and pharmaceutical practitioners to ensure they comply with the Controlled Substances Act (CSA). These audits are regular, but administrative action can be taken against you for any violations ([DEA Audits and Investigations Defense Attorney \(egattorneys.com\)](#)). Local DEA offices make periodic unannounced inspections to audit registered controlled substance storage locations and laboratories (21 CFR Part 1316). DEA Diversion investigators ensure that the controlled substance registrant is compliant with the CSA ([Inspections, Investigations, and Audits | Environment, Health & Safety \(ucla.edu\)](#)).

- **Resources for a DEA audit:**

- [Mission \(dea.gov\)](#)
- [Pharmacy Audit Checklist | CompleteRx](#)
- [August-2017-Rutgers-Home-Study-DEA-Inspection-slides-FINAL.pdf](#)
- [OBP/DEA Audit Checklist \(uc.edu\)](#)
- [How to Prepare for a DEA Audit \(iu.edu\)](#)
- [guidelines for dea inspection preparation updated 7.28.22.pdf \(colorado.edu\)](#)
- [Auditors - Become an Auditor \(aca.org\)](#)



# Complexities of Relationships in Carceral Settings



LGU=local governmental unit  
 DOH=department of health  
 OTP=opioid treatment program  
 BNE=bureau of narcotic enforcement  
 SSA=single state agency



# Medication Distributors in the US

- About 92 percent of prescription medications in the United States are distributed through wholesalers, with three — AmerisourceBergen, Cardinal Health, and McKesson Corporation — accounting for more than 90 percent of wholesale medication distribution in the United States.
- Carceral settings utilizing the hospital/clinic designation to expand access to methadone can use a DEA-registered distributor to order stock methadone.
- There is no public listing of DEA-registered distributors.



# Health Care Vendors in US Carceral Settings

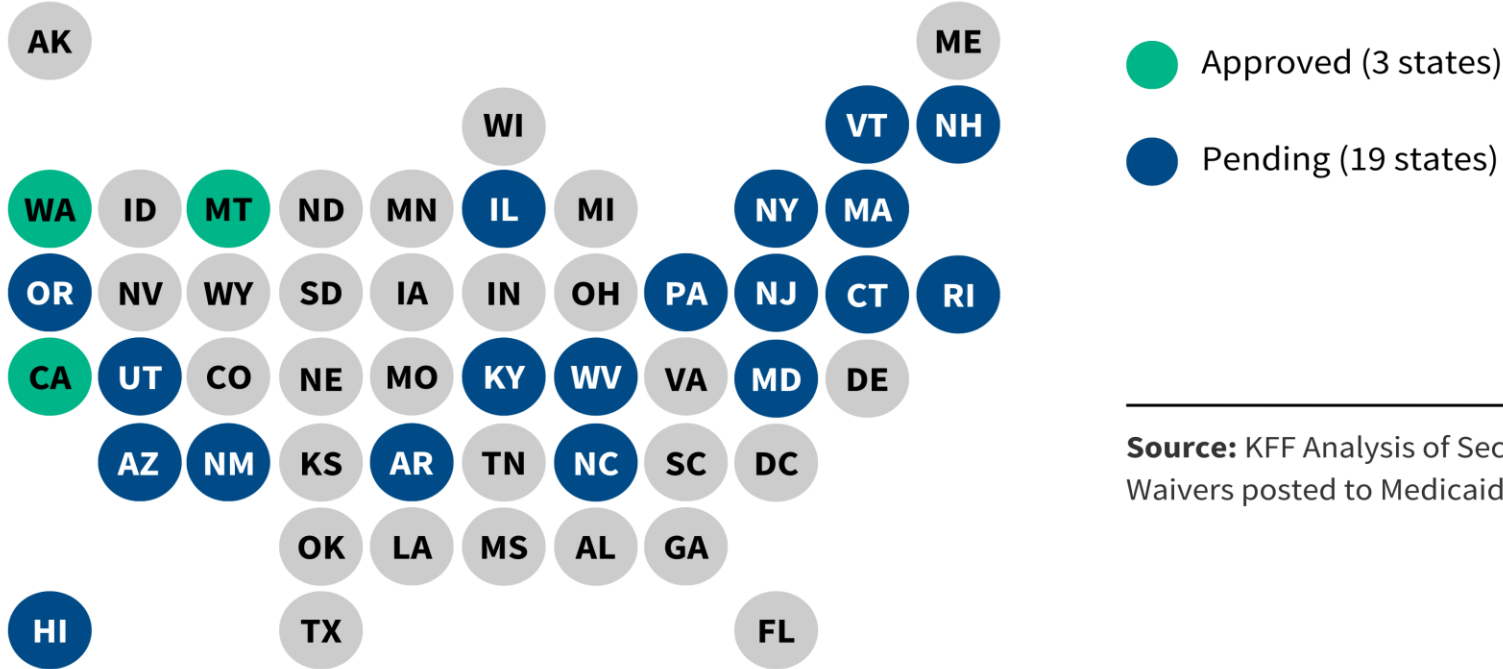
- By 2010, nearly half the U.S. jails surveyed by Reuters had turned to privatized medical care. By 2018, 62% utilized privatized services.
- A handful of companies dominate the jail healthcare business:
  - Wellpath Holdings Inc.,
  - NaphCare Inc.,
  - Corizon,
  - PrimeCare Medical Inc., and
  - Armor Correctional Health Services Inc.
  - The largest, Wellpath, is owned by a private equity firm. An investment firm owns Corizon. NaphCare, PrimeCare, and Armor are privately owned.



# Medicaid Pre-Release (1115) Waivers: A Potential Solution to Costs?

## States Use Medicaid “Pre-Release” Waivers to Help Incarcerated Individuals Get Care and Transition Back into Their Communities

Status of state waiver requests as of April 2024



Source: KFF Analysis of Section 1115 Waivers posted to Medicaid.gov.



# Stigma Towards People Who Use Substances and Towards the Effective Treatments for OUD

*“While attitudes around drug use, particularly use of substances like cannabis, have significantly changed in recent decades, the use and possession of most drugs continue to be penalized. Punitive policies around drugs mark people who use them as criminals, and so contribute to the overwhelming stigma against people contending with an often debilitating and sometimes fatal disorder — and even against the medical treatments that can effectively address it.”*

- Nora Volkow, MD, Director of NIDA

Volkow, N. Stat News, 2021

*“Buprenorphine, methadone, and naltrexone save lives and are effective in reducing illicit opioid use, reducing relapse, protecting from overdoses, promoting treatment engagement, reducing criminal involvement, and improving functioning. Moreover, these effects are evident in every subpopulation with OUD. Thus, we must recommit to addressing the barriers to treatment, including stigma and the shortage of clinicians capable of providing MOUD.”*

- National Academies for Science, Engineering, and Medicine (NASEM), Medications for Opioid Use Disorder Save Lives (2019)

NASEM, 2019





# Conclusions

- Methadone is a life-saving medication for individuals with opioid use disorder.
- Carceral settings should be providing the community standard of care for the treatment of acute opioid withdrawal syndrome (OWS) and opioid use disorder (OUD), including use of methadone.
- The updated 42 CFR Part 8 rules clearly allow carceral settings to utilize the hospital/clinic designation to provide patients with methadone for the treatment of acute OWS and/or ongoing treatment of OUD, without becoming an OTP or having a relationship with a community-based OTP. The patient must have another diagnosis besides OWS or OUD (SAMHSA guidance forthcoming).
- Carceral settings who use the hospital/clinic designation should have policies and procedures, protocols, and workflows in place detailing how the specific federal, state (as applicable), and county (as applicable) regulations regarding methadone in carceral settings will be addressed.



# Clinical Resources on Treating Opioid Use Disorder with Methadone

- [TIP 63: Medications for Opioid Use Disorder \(samhsa.gov\)](https://www.samhsa.gov)
- [Resources for Opioid Treatment Providers | HHS.gov](https://www.hhs.gov)
- [Opioid Use Disorder Treatment - Providers Clinical Support System-Medications for Opioid Use Disorders \(pcssnow.org\)](https://www.pcssnow.org)
- [Methadone and Buprenorphine-Associated Drug-Drug Interaction - Providers Clinical Support System-Medications for Opioid Use Disorders \(pcssnow.org\)](https://www.pcssnow.org)
- [The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder – 2020 Focused Update](https://www.asam.org)
- [Methadone - StatPearls - NCBI Bookshelf \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov)
- [Methadone Treatment of Opiate Addiction: A Systematic Review of Comparative Studies - PMC \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov)
- [Within- and between- subject variability in methadone pharmacokinetics and pharmacodynamics in methadone maintenance subjects \(wiley.com\)](https://onlinelibrary.wiley.com)
- [Contribution of Cytochrome P450 and ABCB1 Genetic Variability on Methadone Pharmacokinetics, Dose Requirements, and Response | PLOS ONE](https://doi.org/10.1371/journal.plosone.0151111)
- [Interindividual Variability of the Clinical Pharmacokinetics of Methadone | Clinical Pharmacokinetics \(springer.com\)](https://doi.org/10.1007/s00269-012-0888-1)



# Clinical Resources on Treating Opioid Use Disorder with Methadone

- [Methadone—metabolism, pharmacokinetics and interactions - ScienceDirect](#)
- [Steady-state pharmacokinetics of \(R\)- and \(S\)-methadone in methadone maintenance patients \(wiley.com\)](#)
- [Recommendations for buprenorphine and methadone therapy in opioid use disorder: a European consensus: Expert Opinion on Pharmacotherapy: Vol 18 , No 18 - Get Access \(tandfonline.com\)](#)
- [Medication Treatment of Opioid Use Disorder - ScienceDirect](#) [Determining Effective Methadone Doses for Individual Opioid-Dependent Patients | PLOS Medicine](#)
- [Moderate- vs High-Dose Methadone in the Treatment of Opioid Dependence: A Randomized Trial | Substance Use and Addiction Medicine | JAMA | JAMA Network](#)
- [Buprenorphine & methadone dosing strategies to reduce risk of relapse in the treatment of opioid use disorder - ScienceDirect](#)
- [Safety and Efficacy of Rapid Methadone Titration for Opioid... : Journal of Addiction Medicine \(lww.com\)](#)
- [Methadone Metabolism and Drug-Drug Interactions: In Vitro and In Vivo Literature Review - ScienceDirect](#) [Methadone Interactions Checker - Drugs.com](#)
- [ASAM eLearning: PCSS MOUD Online Case-based Learning Collaboratives Session 4: Methadone in the era of Fentanyl - Wednesday, June 26, 2024](#)



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- [42 CFR Part 8 Final Rule | SAMHSA](#)
- [Expanding Access to Methadone Treatment for Opioid Use Disorder in Carceral Settings - Opioid Principles \(jhsph.edu\)](#)
- [FAQ-Methadone-in-Carceral-Settings.pdf \(jhsph.edu\)](#)
- [\(69\) Expanding Methadone Access in Correctional Facilities | 3.28.24 – YouTube](#)



**Thanks!**

**Questions?**

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