Medication Diversion Across MOUD, Mental Health and Pain: Impact, Prevention, and Policy

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Disclosure Information (Required)

- Robert Sherrick, MD, DFASAM
- Dr. Sherrick works for a company that provides OTP services.

Learning Objectives

- Understand the definition of diversion and the effects of it on providers who work with patients taking opioids.
- Identify the current scientific literature on diversion and its prevention.
- Evaluate the impact of policies on the patient's experience of treatment.
- Recognize the quantitative effects of Medication Call Backs.
- List and evaluate components of a Diversion Control Policy.

Part 1

Diversion:

Definition, Impact on Patients and Providers, and Societal Consequences

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Definition of Diversion

- The unauthorized redirection of a legally prescribed or dispensed medication from the intended patient to another person.
- May apply to many drug classes:

  - Opioids
  - Benzodiazepines
  - Other sedatives
  - Stimulants
  - Muscle relaxants
  - Gabapentinoids
  - Steroids
  - GLP-1 agonists
  - Antibiotics
  - PDE5 inhibitors

- Wood D. Drug diversion. Aust Prescr. 2015 Oct;38(5):164-6. doi: 10.18773/austprescr.2015.058. Epub 2015 Oct 1. PMID: 26648654; PMCID: PMC4657309.

Diversion is Illegal

Offense Category	Maximum Imprisonment	Maximum Fine (Individual)	Maximum Fine (Organization)
Simple possession (no distribution)	Up to **1 year**	Up to **$100,000**	Up to **$200,000**
Distribution / diversion – lower level(e.g., small quantities, no mandatory minimum)	Up to **20 years**	Up to **$1 million**	Up to **$5 million**
Distribution with mandatory minimums(moderate quantities)	Up to **40 years**	Up to **$5 million**	Up to **$25 million**
High-level trafficking or serious harm(large quantities, death/serious injury)	**Life imprisonment**	Up to **$10 million**	Up to **$50 million**

- (Federal statutory framework under 21 U.S.C. §841)

Sharing vs. Diversion

- Sharing of most things is not illegal and often considered compassionate - food, clothing, OTC medications, etc.
- Sharing of non-controlled prescription medications is technically illegal but rarely prosecuted.
- Simple sharing of controlled substances is common.
  - 20% reported sharing, mostly to help others with their pain.
- Most prosecutions pursue larger distribution and criminal intent.

- Kennedy-Hendricks A, Gielen A, McDonald E, McGinty EE, Shields W, Barry CL. Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults. JAMA Intern Med. 2016;176(7):1027–1029. doi:10.1001/jamainternmed.2016.2543

Dealing vs. Diversion

- Diversion usually applies to medications obtained through medical providers (legitimately or illegitimately).
- Dealing usually refers to drugs manufactured by cartels.
- Commonly involves different drugs, amounts.
- Often confused with each other but are distinct entities.

Diversion Cannot be Prevented

- Some level of diversion is inevitable.
- The only way to prevent diversion completely is to stop all use of controlled substances.
- The benefits of controlled medications need to be balanced with the adverse effects of diversion.

- Cohen SP, Hooten WM. Balancing the Risks and Benefits of Opioid Therapy: The Pill and the Pendulum. Mayo Clin Proc. 2019 Dec;94(12):2385-2389. doi: 10.1016/j.mayocp.2019.10.006. PMID: 31806096; PMCID: PMC6911683.

Adverse Consequences of Diversion

- Diversion has adverse effects on -
  - Patients
  - Providers
  - Societal

- Lofwall MR, Walsh SL. A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. J Addict Med. 2014 Sep-Oct;8(5):315-26. doi: 10.1097/ADM.0000000000000045. PMID: 25221984; PMCID: PMC4177012.

Diversion Reinforces Stigma Towards Patients

- Direct effects of diversion on patients:
  - Overdose
  - Pediatric exposures
  - New onset SUD
  - Legal consequences, incarceration
  - Loss of access to MOUD services
  - Loss of access to pain treatment providers

- Patients on opioids can be seen as:
  - Deceptive or untrustworthy
  - Criminally inclined
  - Unable to use medications responsibly
  - Just substituting one drug for another, or “addicted” to their pain or MOUD medication

- Increased self-stigma
  - Shame about being on methadone or buprenorphine or taking pain medications
  - Reluctance to disclose treatment to employers, family, or healthcare providers
  - Reduced engagement or early discontinuation of care

- Cioe K, Biondi BE, Easly R, Simard A, Zheng X, Springer SA. A systematic review of patients' and providers' perspectives of medications for treatment of opioid use disorder. J Subst Abuse Treat. 2020 Dec;119:108146. doi: 10.1016/j.jsat.2020.108146. Epub 2020 Sep 22. PMID: 33138929; PMCID: PMC7609980.

How Does Diversion Affect Treatment Providers?

- Risk to certification and licensure
- Increased regulatory scrutiny
- Legal liability
- Patient harm
- Erosion of therapeutic relationship
- More conservative prescribing, dosing, or take-home policies
- Damage to public trust
- National and local political pressure, policy backlash

- Lofwall MR, Walsh SL. A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. J Addict Med. 2014 Sep-Oct;8(5):315-26. doi: 10.1097/ADM.0000000000000045. PMID: 25221984; PMCID: PMC4177012.

Societal Effects of Diversion

- High-profile diversion concerns can lead to providers being characterized as:
  - Sources of community harm
  - Contributors to illicit drug markets
  - Insufficiently controlled or poorly supervised
- Communities may resist treatment programs.
- Providers may be less willing to offer MOUD or pain treatment
- Patients may delay or avoid treatment altogether.

- Dickson-Gomez J, Spector A, Weeks M, Galletly C, McDonald M, Green Montaque HD. "You're Not Supposed to be on it Forever": Medications to Treat Opioid Use Disorder (MOUD) Related Stigma Among Drug Treatment Providers and People who Use Opioids. Subst Abuse. 2022 Jun 27;16:11782218221103859. doi: 10.1177/11782218221103859. PMID: 35783464; PMCID: PMC9243471.

Part 2

- What is known about diversion?
  - How often does diversion occur?
    - Diversion is difficult to quantify accurately
  - How serious is diversion?
  - Who regulates diversion control?
  - What is known about how to prevent diversion?
  - What is a Diversion Control Plan (for OTPs)?

How Frequent is Diversion for Rx Opioids?

- Among people prescribed opioids for pain, 10-20% report ever diverting.
- Among people who misuse prescription opioids, 55-60% obtain them from friends or relatives.
- Often given to someone with pain.

McCabe SE, West BT, Teter CJ, Ross-Durow P, Young A, Boyd CJ. Characteristics associated with the diversion of controlled medications among adolescents. Drug Alcohol Depend. 2011 Nov 1;118(2-3):452-8. doi: 10.1016/j.drugalcdep.2011.05.004. Epub 2011 Jun 12. PMID: 21665384; PMCID: PMC3190027.

How Frequent is Diversion Among PWUDs?

- 2015 study from Oslo - street recruited IV drug users
  - 27% reported illicit MOUD use - 16.8% methadone 12.5% buprenorphine
  - Illicit MOUD use was not associated with overdose risk (except infrequent buprenorphine use)

- 2009 study in Baltimore - OTP admissions and street recruits
  - 16% reported using diverted methadone average 2-3 times per week
  - Largely used to prevent withdrawal
  - No injection reported of either methadone or buprenorphine.

- 2013 study - rural Appalachian drug users
  - 95% reported diverted methadone use
  - Almost exclusively from prescriptions, not OTPs

Bretteville-Jensen, Anne Line et al. "Illicit use of opioid substitution drugs: prevalence, user characteristics, and the association with non-fatal overdoses." *Drug and alcohol dependence* vol. 147 (2015): 89-96. doi:10.1016/j.drugalcdep.2014.12.002

Dasgupta, Nabarun et al. "Post-marketing surveillance of methadone and buprenorphine in the United States." *Pain medicine (Malden, Mass.)* vol. 11,7 (2010): 1078-91. doi:10.1111/j.1526-4637.2010.00877.x

Gwin Mitchell, Shannon et al. "Uses of diverted methadone and buprenorphine by opioid-addicted individuals in Baltimore, Maryland." *The American journal on addictions* vol. 18,5 (2009): 346-55. doi:10.3109/10550490903077820

Hall, Martin T et al. "Factors associated with high-frequency illicit methadone use among rural Appalachian drug users." *The American journal of drug and alcohol abuse* vol. 39,4 (2013): 241-6. doi:10.3109/00952990.2013.805761

Johnson, Björn, and Torkel Richert. "Non-prescribed use of methadone and buprenorphine prior to opioid substitution treatment: lifetime prevalence, motives, and drug sources among people with opioid dependence in five Swedish cities." *Harm reduction journal* vol. 16,1 31. 2 May. 2019, doi:10.1186/s12954-019-0301-y

Jones CM, Baldwin GT, Manocchio T, White JO, Mack KA. Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths — United States, 2002–2014. MMWR Morb Mortal Wkly Rep 2016;65:667–671.

Rubel, Stephanie K et al. "Scope of, Motivations for, and Outcomes Associated with Buprenorphine Diversion in the United States: A Scoping Review." *Substance use & misuse* vol. 58,5 (2023): 685-697. doi:10.1080/10826084.2023.2177972

Winstock, Adam R et al. "Prevalence of diversion and injection of methadone and buprenorphine among clients receiving opioid treatment at community pharmacies in New South Wales, Australia." *The International journal on drug policy* vol. 19,6 (2008): 450-8. doi:10.1016/j.drugpo.2007.03.002

Zhao, Johnathan K et al. "Characteristics Associated with Nonmedical Methadone Use among People Who Inject Drugs in California." *Substance use & misuse* vol. 55,3 (2020): 377-386. doi:10.1080/10826084.2019.1673420

Why do people divert opioids?

- Inability to access MOUD treatment
  - Cost, transportation, waiting lists, involuntary discharge, lack of prescribers
- Self-treatment of OUD and/or desire to avoid formal treatment
  - Previous incorrect dosing
  - Perceived stigma around drug use disclosure
  - Distrust of treatment providers
- To avoid withdrawal when unable to access other opioids
- To "get high"
- Financial gain
- Altruism - helping someone who is experiencing withdrawal
  - "Moral economy of sharing"

Cicero, Theodore J et al. "Understanding the use of diverted buprenorphine." *Drug and alcohol dependence* vol. 193 (2018): 117-123. doi:10.1016/j.drugalcdep.2018.09.007

Johnson, Björn, and Torkel Richert. "Diversion of methadone and buprenorphine from opioid substitution treatment: the importance of patients' attitudes and norms." *Journal of substance abuse treatment* vol. 54 (2015): 50-5. doi:10.1016/j.jsat.2015.01.013

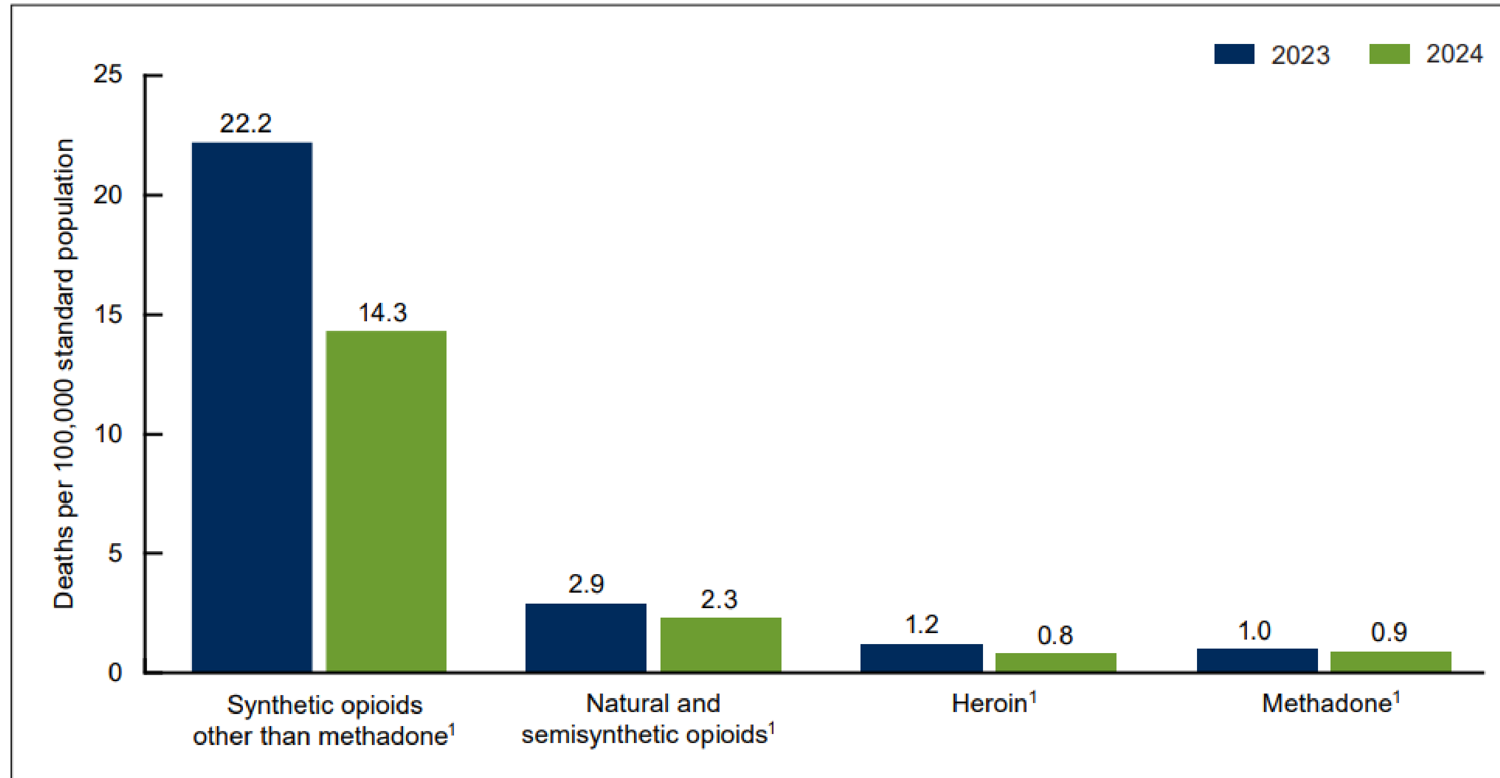
ddRubel, Stephanie K et al. "Scope of, Motivations for, and Outcomes Associated with Buprenorphine Diversion in the United States: A Scoping Review." *Substance use & misuse* vol. 58,5 (2023): 685-697. doi:10.1080/10826084.2023.2177972

How Dangerous is Diversion?

- Higher frequency of non-prescribed buprenorphine is associated with a lower risk of overdose.
  - Buprenorphine involved in 2.6% of OD deaths, nearly all with other drugs involved.
  - PWOUD who have experience with diverted buprenorphine are more likely to enter treatment than those who don't.
- A cross-sectional sample of people who inject drugs (n=777) in California found that nonmedical methadone use was not associated with nonfatal overdose.
  - Methadone involved in 3.2% of OD deaths in the US in 2021.
- IV use is rare.
- States that expanded methadone TH dosing during the pandemic did not experience increased methadone-related overdose deaths compared to states that opted out.

Roy, Victor et al. "U.S. states opting out of expanded methadone take-home policies and associated mortality." *Journal of substance use and addiction treatment* vol. 179 (2025): 209800. doi:10.1016/j.josat.2025.209800
Zhao, Johnathan K et al. "Characteristics Associated with Nonmedical Methadone Use among People Who Inject Drugs in California." *Substance use & misuse* vol. 55,3 (2020): 377-386. doi:10.1080/10826084.2019.1673420
Carlson RG, Daniulaityte R, Silverstein SM, Nahhas RW, Martins SS. Unintentional drug overdose: Is more frequent use of non-prescribed buprenorphine associated with lower risk of overdose? Int J Drug Policy. 2020 May;79:102722. d
10.1016/j.drugpo.2020.102722. Epub 2020 Apr 17. PMID: 32311513; PMCID: PMC9387534.

How Dangerous is Diversion?



Garnett, Matthew F, and Arialdi M Miniño. "Drug Overdose Deaths in the United States, 2023-2024." *Centers for Disease Control and Prevention*, 29 Jan. 2026.

Diverted Methadone: Origins

- Around 90% of all methadone is the US is distributed to OTPs; 9% comes from pharmacy-dispensed pain prescriptions
- In 2009, methadone accounted for 2% of opioid prescriptions, and was involved in 30% of overdose deaths

↑ methadone prescribed for pain > ↑ methadone diversion > ↑ methadone overdose deaths

- Efforts to decrease methadone use for pain were associated with a decline in overdose deaths, even while the use of methadone to treat OUD markedly increased during the same period

Harris RA, Long JA, Bao Y, Mandell DS. Racial, Ethnic, and Sex Differences in Methadone-Involved Overdose Deaths Before and After the US Federal Policy Change Expanding Take-home Methadone Doses. JAMA Health Forum. 2023;4(6):e231235. doi:10.1001/jamahealthforum.2023.1235

Jones CM, Baldwin GT, Manocchio T, White JO, Mack KA. Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths — United States, 2002–2014. MMWR Morb Mortal Wkly Rep 2016;65:667–671.

Diversion Summary Facts

- Diversion of opioids is common, both prescription opioids and MOUD
- Only 3-5% report primary motivation is to “get high”
- IV use is uncommon for MOUDs
- OD death risk from diverted MOUD or rx opioids is rare compared to that of fentanyl

Patient Perspectives

- "Most MOUD patients consider diversion as mostly positive (83.7%) and morally right (76.8%)."

- Research consistently indicates that diverted MOUD is primarily used for the same reasons we prescribe it: to alleviate withdrawal, maintain abstinence, and stop the use of other opioids.

- Johnson, Björn, and Torkel Richert. "Diversion of methadone and buprenorphine from opioid substitution treatment: the importance of patients' attitudes and norms." *Journal of substance abuse treatment* vol. 54 (2015): 50-5. doi:10.1016/j.jsat.2015.01.013

Who Regulates Diversion Control?

- DEA – local agents have flexibility in interpretation of regulations
- Accreditation Bodies - OTPs, hospitals, SUD treatment programs, etc.
    - CARF, JCAHO
- States – can adopt regulations that are **more restrictive** than federal requirements
    - Example: **WI** –requires random MCBs for all OTP patients receiving 2+ TH doses per week, including buprenorphine patients, no less frequent than quarterly; requires bottle return
    - Example: **MN** – no less than 5% of OTP clients who receive unsupervised medication doses must physically return to the program each month for MCBs; requires bottle return
    - Four states have Medicaid prior authorization forms that require pill counts for buprenorphine coverage

Andraka-Christou, Barbara et al. "Toward a Typology of Office-based Buprenorphine Treatment Laws: Themes From a Review of State Laws." *Journal of addiction medicine* vol. 16,2 (2022): 192-207. doi:10.1097/ADM.0000000000000863

CARF OTP Standards Manual (2025)

Nguemeni Tiako MJ, Dolan A, Abrams M, Oyekanmi K, Meisel Z, Aronowitz SV. Thematic Analysis of State Medicaid Buprenorphine Prior Authorization Requirements. *JAMA Netw Open.* 2023;6(6):e2318487. doi:10.1001/jamanetworkopen.2023.18487

https://docs.legis.wisconsin.gov/code/admin_code/dhs/030/75.pdf; accessed 2/21/26

https://www.revisor.mn.gov/statutes/cite/245G.22#:~:text=An%20opioid%20treatment%20program%20must,clients%2C%20and%20any%20waiting%20list; accessed 2/21/26

Summary of Prescriber Requirements

- Some states have requirements for pill counts for buprenorphine patients.
- The DEA can visit your practice site unannounced for inspections.
- The DEA regularly prosecutes providers who prescribe too many controlled substances without regard to diversion.
- Expectations for diversion control measures for prescribers of controlled substances are vague.

What is a Diversion Control Plan for an OTP?

- "An OTP must maintain a current "Diversion Control Plan" (DCP) as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP."
  - Put more simply, a DCP is a **set of documented procedures** that decrease the possibility that controlled substances are transferred to someone who is not supposed to have them or used illicitly.
  - Must comply with this standard to maintain certification.

42 CFR § 8.12

How Detailed Are DCP Requirements for OTPs?

- **Not very**

- Practices **explicitly mentioned** in the federal regulations:
  - When evaluating patients for unsupervised doses, must consider absence of known recent diversion activity.
  - Take-home (TH) medication must be placed in labeled containers with the OTP's name, address, and phone number; must be packaged in way that reduces risk of incidental ingestion.
  - Methadone shall be formulated in way that reduces its potential for parenteral misuse.
  - Patient education must include safe medication transportation to the patient's home, safe storage at the patient's home.

21 U.S.C. 802(11); 21 U.S.C. 832(a)(3); 21 CFR § 1301.74(b); 42 CFR § 8.12

Specific DCP Requirements for OTPs

- SAMHSA's *Federal Guidelines for OTPs*:
  - **Do not** require medication callbacks be part of a DCP.
  - **Do not** say that measures included in a DCP must be effective, simply that you must have them, and that it must be clear who completes them.
- The DEA's *Narcotic Treatment Program Manual:*
  - Agrees that OTPs should have a DCP, **does not** tell you what it should be.
  - Directs you to SAMHSA for additional information
    - SAMHSA's *Federal Guidelines for OTPs* refers to the DEA for details.

21 U.S.C. 802(11); 21 U.S.C. 832(a)(3); 21 CFR § 1301.74(b); 42 CFR § 8.12
https://www.deadiversion.usdoj.gov/GDP/%28DEA-DC-056%29%28EO-DEA169%29_NTP_manual_Final.pdf; accessed 2/21/26

SAMHSA's comments on MCBs in Guidelines for OTPs

- SAMHSA's OTP guidelines are framed as recommendations, **not** professional standards of care.
- SAMHSA's 2024 *Federal Guidelines for OTPs* on MCBs:
  - "Currently, there is no rigorous evidence to support the effectiveness of random callbacks of take-home medication doses in reducing medication diversion."
  - If you perform MCBs, only do so when clinically indicated.
  - After a failed MCB, discuss your concerns with the patient and consider the full clinical picture before adjusting their unsupervised medication regimen.

Substance Abuse and Mental Health Services Administration. (2024). *Federal guidelines for opioid treatment programs* (PEP24-02-011). U.S. Department of Health and Human Services.

Do MCBs Effectively Prevent Diversion?

- **Hard to know: there's not much data, and the data we have is heterogeneous**
- The data we have:
  - In a study that spanned 12 years (n=21), 65 MCBs were completed; no patients failed to respond
  - Buprenorphine pill counts conducted for 69 patients; 34.7% failure rate
    - All patients who failed MCBs were positive for bup/norbup on urine testing
  - Of 9 randomly chosen, "clinically stable" methadone patients chosen to complete a MCB, 7 returned less medication than expected
    - Explanations provided by patients: splitting dose at home, using more than prescribed followed by buying illicit medication

Cotton, Ann J et al. "Methadone "callbacks" within a veterans affairs opioid treatment program: Detecting methadone misuse." *The American journal on addictions* vol. 26,1 (2017): 50-52. doi:10.1111/ajad.12479
Fareed, Ayman et al. "Factors affecting noncompliance with buprenorphine maintenance treatment." *Journal of addiction medicine* vol. 8,5 (2014): 345-50. doi:10.1097/ADM.0000000000000057
Frank, D., Mateu-Gelabert, P., Perlman, D.C. *et al.* "It's like 'liquid handcuffs": The effects of take-home dosing policies on Methadone Maintenance Treatment (MMT) patients' lives. *Harm Reduct J* **18**, 88 (2021).
Schwartz, R P et al. "A 12-year follow-up of a methadone medical maintenance program." *The American journal on addictions* vol. 8,4 (1999): 293-9. doi:10.1080/105504999305695
Varenbut, Michael et al. "Tampering by office-based methadone maintenance patients with methadone take home privileges: a pilot study." *Harm reduction journal* vol. 4 15. 30 Oct. 2007, doi:10.1186/1477-7517-4-15

Do MCBs Effectively Prevent Diversion?

- The data we have, continued:
  - Study investigating feasibility of OTP/community pharmacy collaboration (n=20)
    - Only stable patients included, no MCBs failed
  - Both random (n=82) and for-cause (n=60) MCBs conducted
    - Patients with more THs failed 6% of random MCBs vs. 44% of for-cause MCB
    - For-cause MCBs more likely to result in failure; for-cause failure was more likely for patients with more THs
  - Report on 12-month outcomes for 92 "highly stable" methadone patients
    - All patients were expected to call into a telephone line every weekday to ascertain if they were up for a MCB, which occurred monthly
    - 4% of MCBs met failure criteria, more than half were "no shows"
    - Dislike of MCB procedure was a leading reason for treatment dropout

Cotton, Ann J et al. "Methadone "callbacks" within a veterans affairs opioid treatment program: Detecting methadone misuse." *The American journal on addictions* vol. 26,1 (2017): 50-52. doi:10.1111/ajad.12479
King, Van L et al. "A 12-month controlled trial of methadone medical maintenance integrated into an adaptive treatment model." *Journal of substance abuse treatment* vol. 31,4 (2006): 385-93. doi:10.1016/j.jsat.2006.05.014
Wu, Li-Tzy et al. "Opioid treatment program and community pharmacy collaboration for methadone maintenance treatment: results from a feasibility clinical trial." *Addiction (Abingdon, England)* vol. 117,2 (2022): 444-456. doi:10.1111/add.15641

Possible Diversion Control Plan Measures

- Prevention of dual enrollment
- Suspicious order reporting
- PDMP utilization
- Coordination of care with mutual prescribers
- Prevention of loitering
- Lockboxes
- Bottle or wrapper return
- Policies and procedures for staff medication handling
- Labeled TH containers
- Child-proof packaging
- Liquid formulations of methadone
- Patient education on safe storage and transport
- The use of standard criteria, including an absence of diversion activity, when considering unsupervised medication use
- Directly observed dosing, frequent pharmacy pickups
- Cameras in common areas and at dosing windows
- Urine drug screening with substitution prevention measures
- Use of saliva testing when urine substitution is suspected
- MCBs

Substance Abuse and Mental Health Services Administration. (2024). *Federal guidelines for opioid treatment programs* (PEP24-02-011). U.S. Department of Health and Human Services.
21 U.S.C. 802(11); 21 U.S.C. 832(a)(3); 21 CFR § 1301.74(b); 42 CFR § 8.12

Summary of OTP DCP Requirements

- While OTPs must have a DCP, what it needs to include is **vague.**
- MCBs are not actually required.
- Of all the regulatory bodies who survey OTPs, it's the states who are primarily assigning prescriptive requirements to DCPs (not Montana).
- The DEA agent may require MCBs as part of a DCP.
- There is strong community support for MCBs.

If MCBs Aren't Required, Why Do OTPs Complete Them?

- **Identify possible diversion**
- **Community perception**

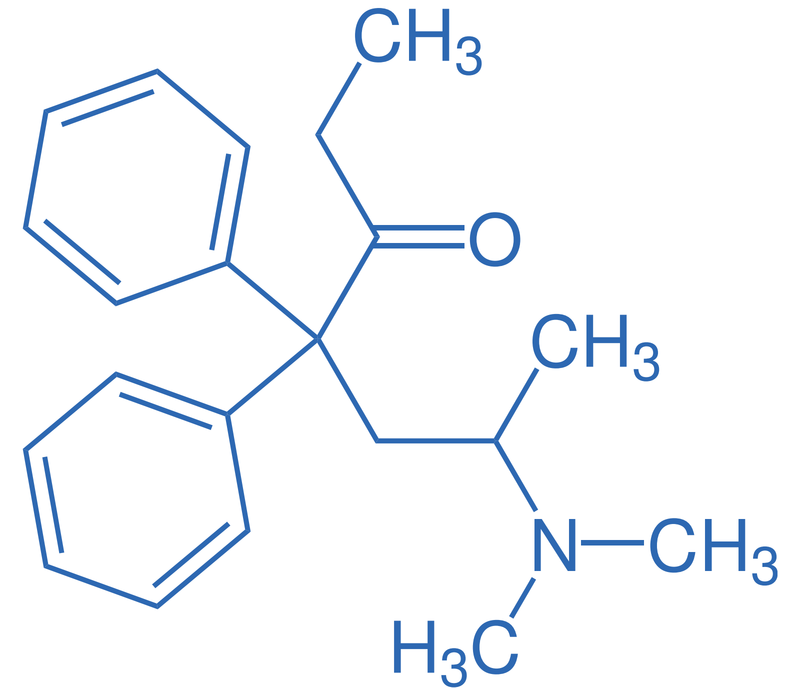
- MCBs have long been part of DCPs and are now considered the standard of care (legacy practice)
- Reduce legal risk
- Ensure that DEA inspections are passed smoothly

Part 3

Policies and Levers:

Patient Perspectives and Impact

A Patient’s Perspective



Methadone

https://youtu.be/As4tn0XIhhE?si=LZHuq34L15aeITLi

Patient Perspectives

- Patients and providers share the goals of access and retention.
- Policies intended to prevent diversion should be evidence based.
- A collaborative space is needed to address the treatment gap.
- MOUD policy requires a higher level of patient collaboration.
- Patient Bill of Rights; a framework for collaborative treatment

Challenges

- Patients often carry a sense of irrelevance regarding policy
- Diversion is seldom weighed against failure to treat
- Patients and providers often diverge on the utility of MCBs
- Insufficient research that centers patient perspectives

Problematic Policies

- Frequent clinic and/or pharmacy visits
- Frequent and/or excessive use of UDS tests
- Rigid payment policies – payment before medication
- Discharge from treatment based on UDS results
- Requiring counseling to obtain medication
- Medication call-backs

Patient Bill of Rights

Ethical Care & Dignity

- No punitive responses to drug use or complaints
- Respect, privacy, and patient autonomy
- End invasive monitoring without consent

Financial & Access Equity

- No forced withdrawal due to inability to pay
- Transparent billing & hardship protections
- Access to adequate, individualized dosing

Reform Priorities

- Voluntary, non-punitive drug testing
- End mandatory counseling requirements
- Expand medication options & pharmacy access

Advocacy & Representation

- Patient voices in policy decisions
- Consumer advisory boards
- Clinic support against discrimination

Part 4

Implementing Medication Call Backs: Challenges and Concerns

What Does an MCB Look Like?

- Nurse notifies patient by phone with instructions.
  - Return the next day with all medication, do not take your dose for that day.
- Patient presents with doses, provides a drug screen sample.
- Nurse inspects all doses.
  - Evidence of tampering.
  - Correct number of doses.
  - Doses taken in order (for methadone).
- Patient takes observed dose at window (for OTPs).

Preparing Patients for MCBs

- Regular review of requirements:
  - Working phone and voice mail.
  - Arrangements for transportation, work, childcare, etc.
  - Notify if you are going to be out of town.
  - Take doses in order (for methadone).
  - Bring in all doses the day after the call – do not take that day's dose.
  - Be prepared to leave a drug screen sample.

Reasons for MCB Failure

- Patient did not come in.
- Doses tampered or missing.
- Doses taken out of order (methadone).
- Patient does not provide a drug screen sample.

Consequences of MCB Failure

- For methadone, decrease to daily observed dosing.
- For buprenorphine, possible increase in pharmacy pickups, UDSs, follow up visits, counseling.
  - Or discontinuation of medication, referral to higher level of care
- For pain medications, patients are commonly offered a short taper and discontinuation
  - Referral to Addiction Medicine specialist or conversion to buprenorphine

Perspectives on Random MCBs

When routine random MCBs are implemented:

"A failed random Medication Call Back should be considered a failure on the part of the clinic and not the patient."

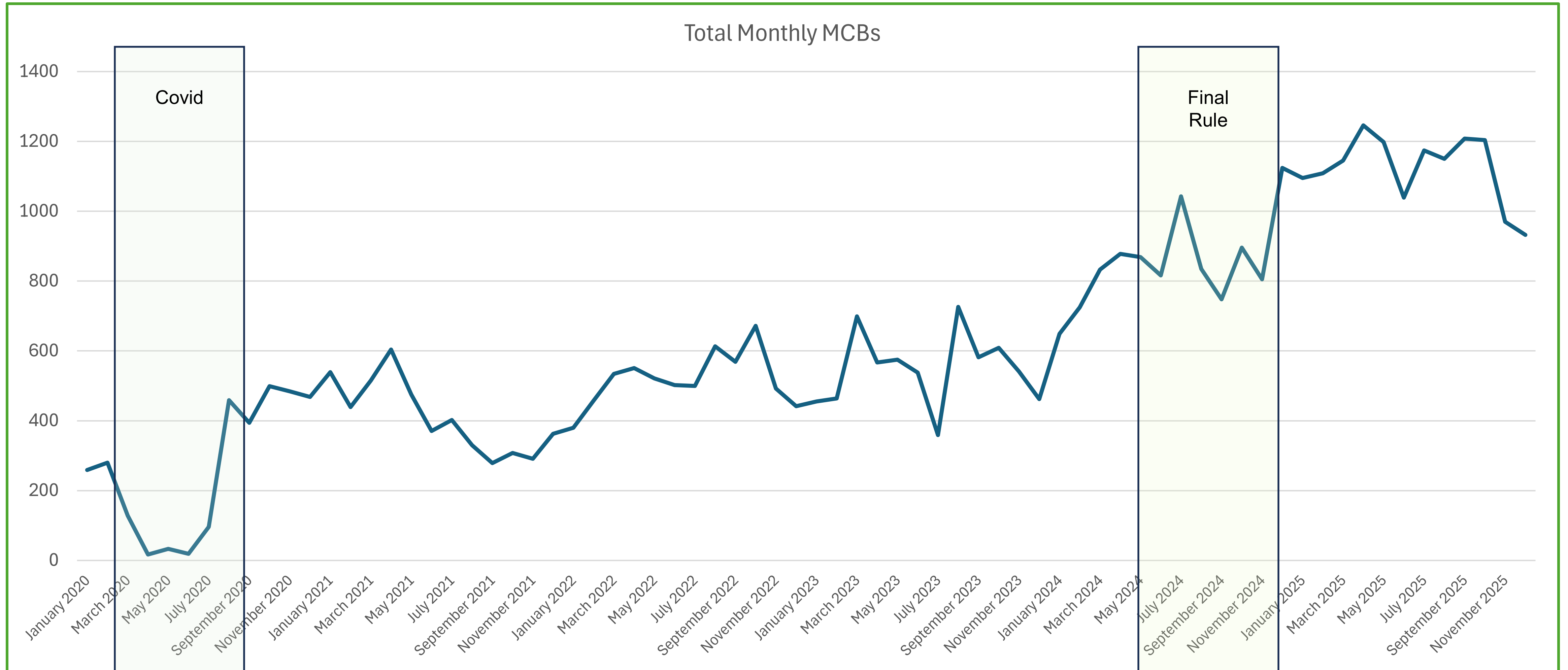
Part 5

Review of MCB Data, the Effects of the Covid Crisis, and Implementation of the Final Rule

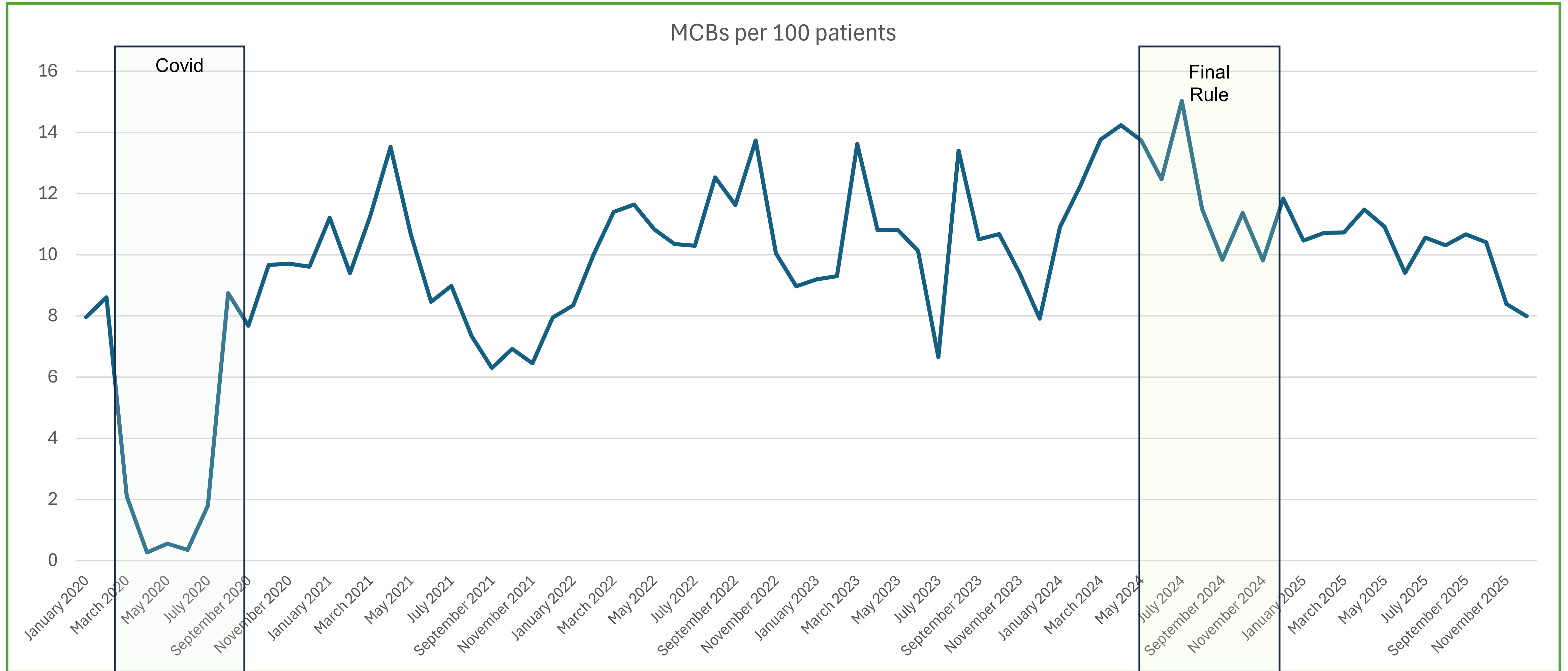
MCB Data Availability

- From one group of connected OTPs, spanning 2020-2025.
- Clinic growth from 35 in 2020 to 67 at the end of 2025 - 13 states.
- Total patients 12,000 in 2020 increased to 22,000 in 2025.
- MCBs randomly scheduled for all patients on methadone with weekly or higher THs once a year; also performed for cause.
- Data does not indicate whether the MCB is for random vs. for cause. Nurses estimate that less than 10% of MCBs are for cause.
- Data does not indicate the reason for failure.
- Over 44,000 MCBs included in total sample.

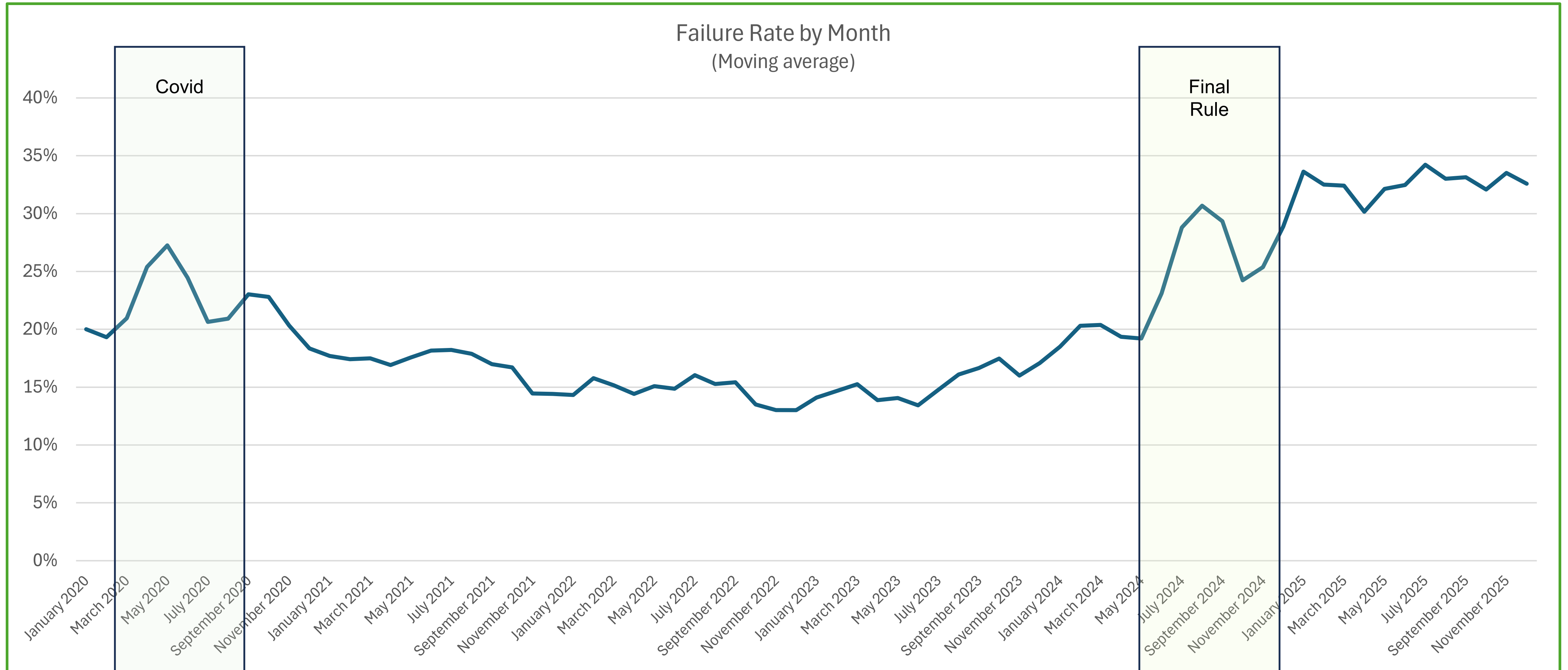
Monthly MCB Counts - 2020-2025



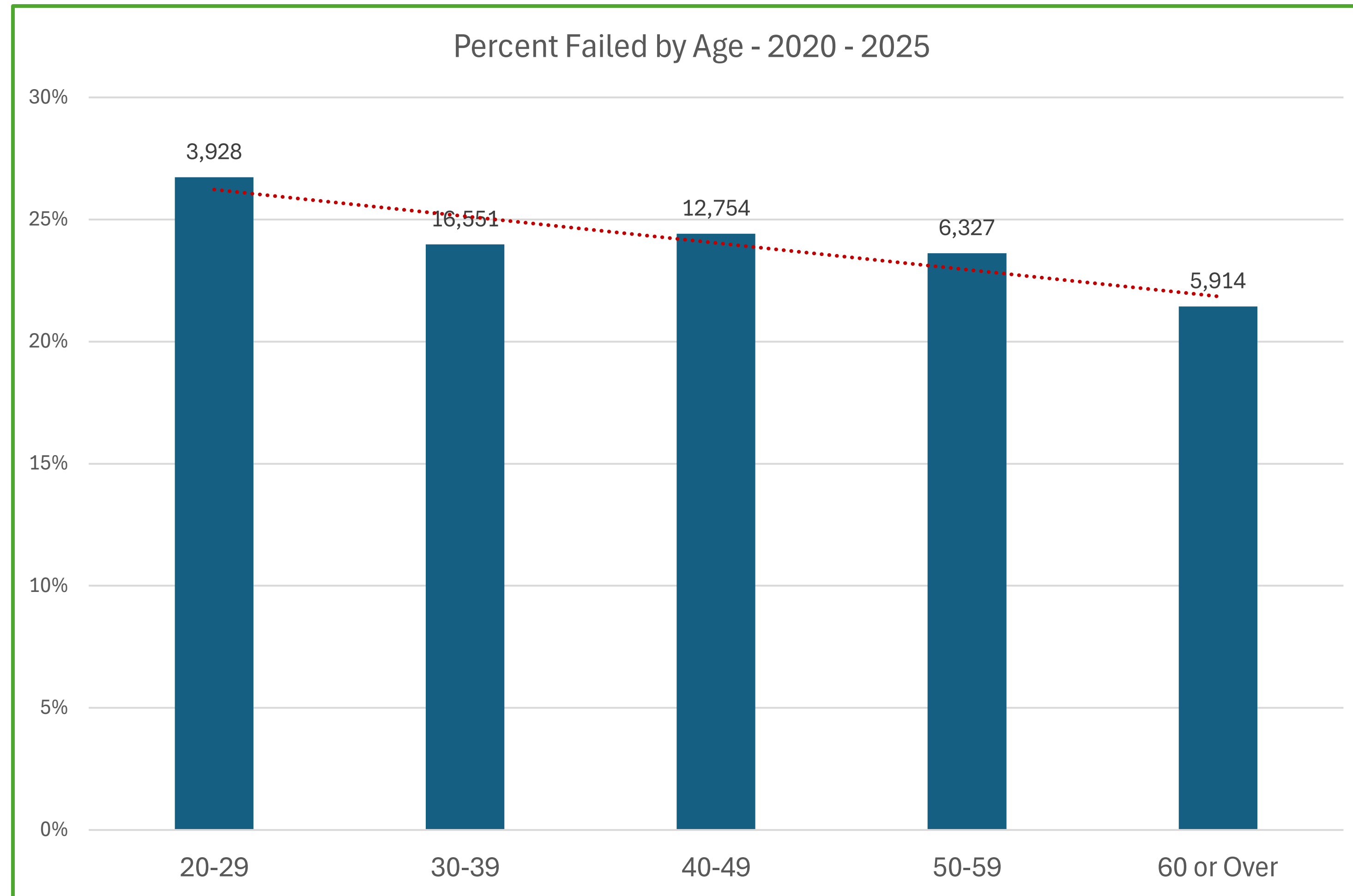
MCBs per 1000 Patients - 2020-2025



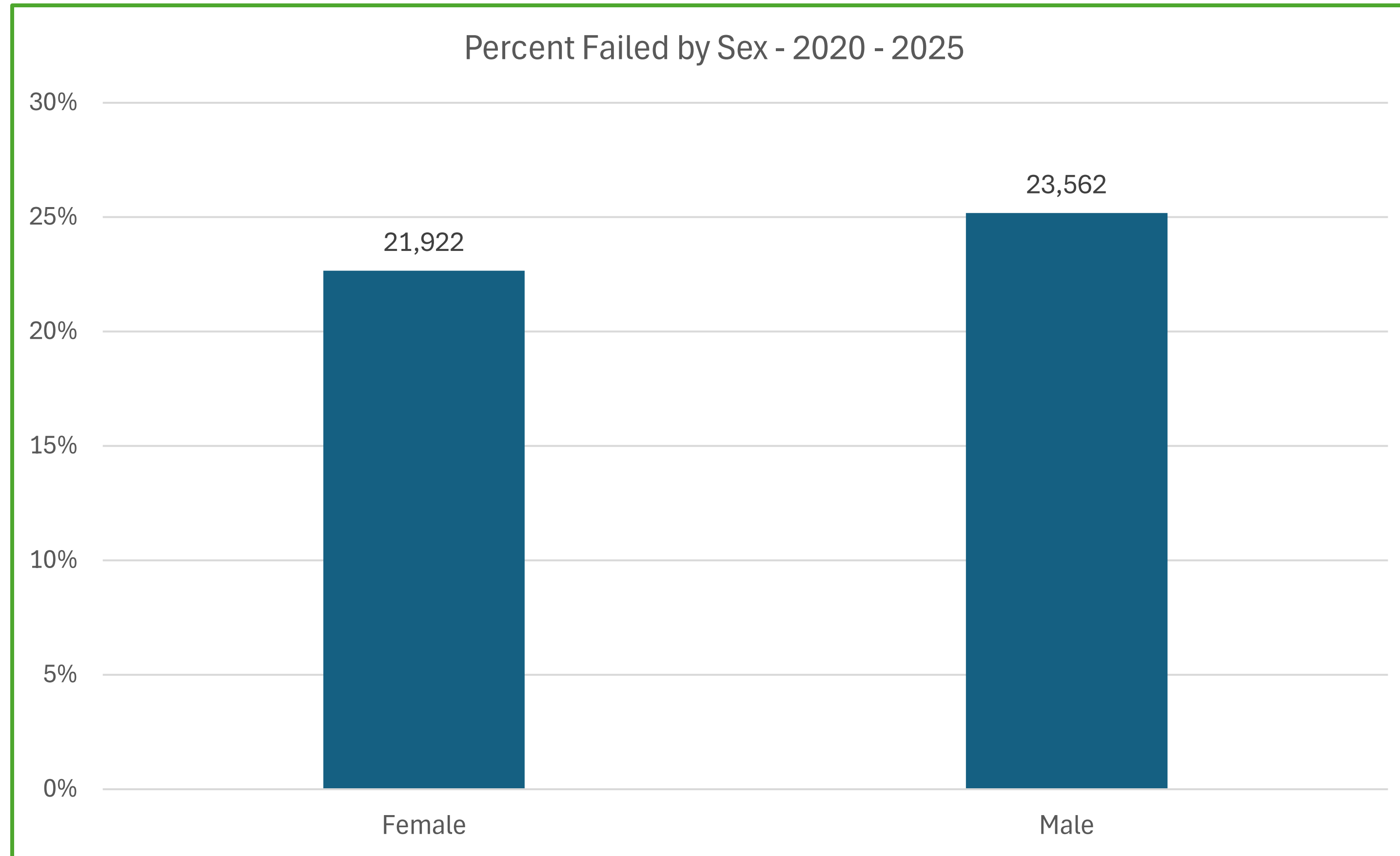
MCB Failure Rate - 2020-2025



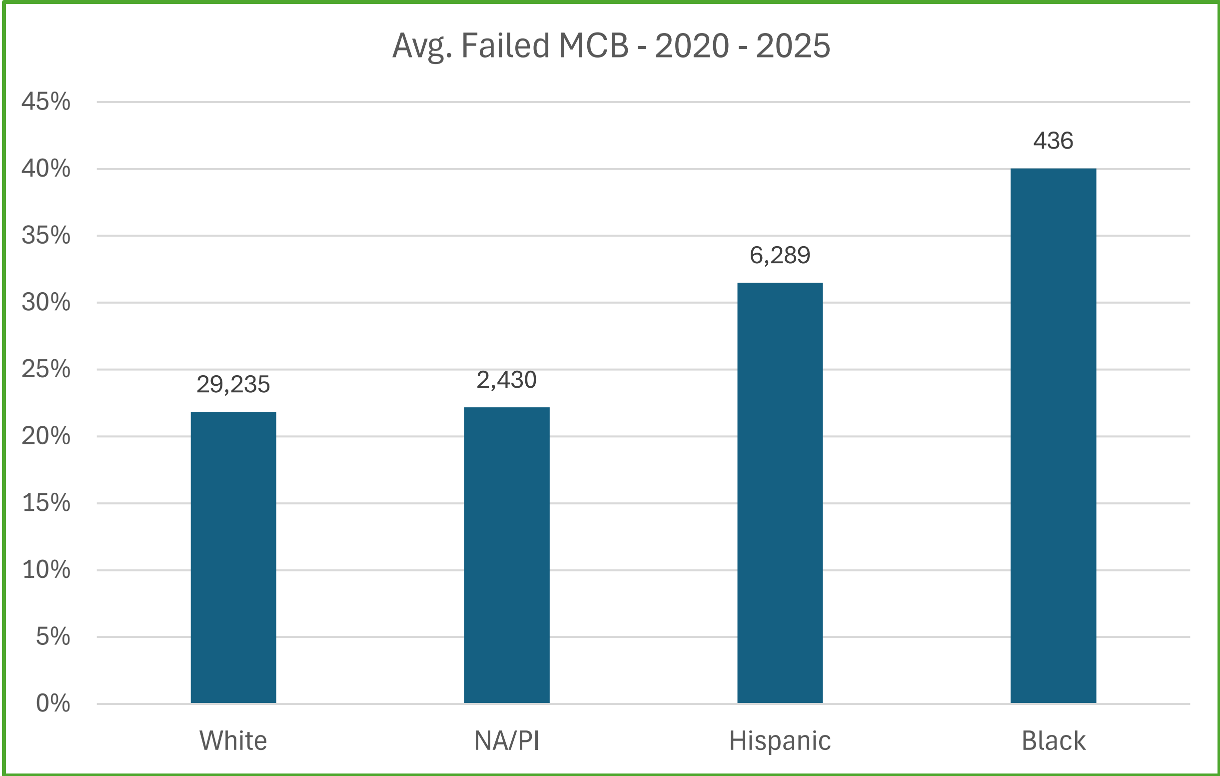
MCB Failure Rate by Age - 2020-2025



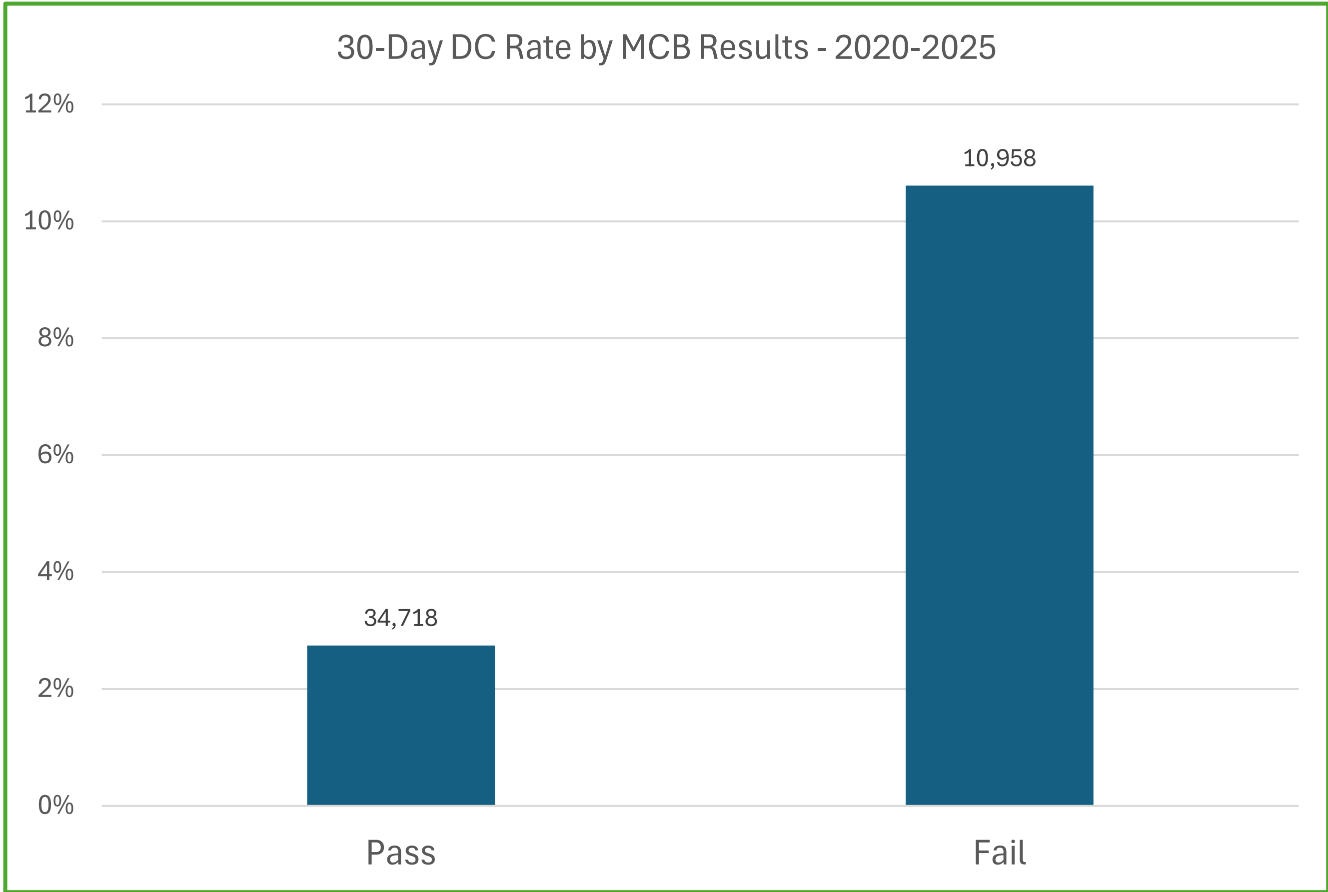
MCB Failure Rate by Sex - 2020-2025



MCB Failure Rate by Race - 2020-2025



DC Rate After MCB - 2020-2025



Patients who fail an MCB are 4 times more likely to discharge within the next 30 days compared to those who pass.

MCB Consequences

- A failed MCB is associated with a high risk of treatment discontinuation.
- Therefore, MCBs may force patients out of treatment.
- Treatment discontinuation is associated with risk of overdose death and other adverse consequences.

- Santo T Jr, Clark B, Hickman M, Grebely J, Campbell G, Sordo L, Chen A, Tran LT, Bharat C, Padmanathan P, Cousins G, Dupouy J, Kelty E, Muga R, Nosyk B, Min J, Pavarin R, Farrell M, Degenhardt L. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. JAMA Psychiatry. 2021 Sep 1;78(9):979-993. doi: 10.1001/jamapsychiatry.2021.0976.

Possible Diversion Control Plan Measures

- Prevention of dual enrollment
- Suspicious order reporting
- PDMP utilization
- Coordination of care with mutual prescribers
- Prevention of loitering
- Lockboxes
- Bottle or wrapper return
- Policies and procedures for staff medication handling
- Labeled TH containers
- Child-proof packaging
- Liquid formulations of methadone
- Patient education on safe storage and transport
- The use of standard criteria, including an absence of diversion activity, when considering unsupervised medication use
- Directly observed dosing, frequent pharmacy pickups
- Cameras in common areas and at dosing windows
- Urine drug screening with substitution prevention measures
- Use of saliva testing when urine substitution is suspected
- MCBs

Substance Abuse and Mental Health Services Administration. (2024). *Federal guidelines for opioid treatment programs* (PEP24-02-011). U.S. Department of Health and Human Services.
21 U.S.C. 802(11); 21 U.S.C. 832(a)(3); 21 CFR § 1301.74(b); 42 CFR § 8.12

MCBs - Risk vs. Benefit

- MCBs increase treatment discontinuations.
- No published evidence that they decrease diversion or improve patient outcomes.
- MCBs place a considerable burden on patients.
- MCBs may have disparate impacts across racial and socioeconomic groups.
- Consideration should be given to removing regular MCBs from diversion control policies.

- Frank, D., Mateu-Gelabert, P., Perlman, D.C. et al. "It's like 'liquid handcuffs": The effects of take-home dosing policies on Methadone Maintenance Treatment (MMT) patients' lives. Harm Reduct J 18, 88 (2021). https://doi.org/10.1186/s12954-021-00535-y

Questions?

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