Implementing SAMHSA's 2024 Final Rule: Challenges and Outcomes for Opioid Treatment Programs

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Disclosure Information

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- No disclosures

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- No disclosures

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Mark Schaefer, EdS, MA

- No disclosures

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- Presenter 1: Robert Sherrick, MD, DFASAM
  - No disclosures
- Presenter 2: Hillary Tamar, MD, FASAM
  - No disclosures
- Presenter 3: Mark Schaefer, EdS, MA
  - No disclosures

Learning Objectives

- Identify the changes that the Final Rule made compared to prior regulations.
- Understand how to translate these changes into workable guidelines and policies.
- Be able to anticipate and manage barriers to implementation.
- Have a basic understanding of the early outcomes from these policy changes.

What is an OTP?

- Opioid treatment programs (OTPs) are the only type of entity that can dispense methadone for the treatment of opioid use disorder outside of an acute care hospital
  - Must be certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body
  - Strict regulatory oversight
  - Federally obligated to offer counseling to all patients alongside MOUD
  - Traditionally, patients new to treatment at an OTP have been asked to come into the clinic daily to take their medication in front of a nurse

https://www.cms.gov/medicare/payment/opioid-treatment-program
https://www.ncbi.nlm.nih.gov/books/NBK574914/
https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/faqs#:~:text=How%20does%20the%20final%20rule%20address%20the,required%20to%20provide%20clinically%20appropriate%20substance%20use
URLs last accessed: 03/06/25

Part 1a: History and Regulation of OTPs

1) Where do OTP regulations come from?
2) When were they written?
3) Who provides oversight to OTPs?

42 CFR Part 8: A Timeline

- **The regulations surrounding methadone treatment in the US were established from 1970-1974**
- **Until April 2024, they were not largely different than the original regulations from the 1970's**
  - Primary goal of these regulations: prevent diversion
  - Not the primary goal: helping people who use opioids
- **Most recent regulatory revision in 2001**
  - Shifted OTP oversight from the **FDA to SAMHSA**
  - Created accreditation model
- **SAMHSA's Final Rule**
  - Proposed December 2022
  - Released February 2024
  - Effective April 2024
  - Compliance October 2024

Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A, editors. Federal Regulation of Methadone Treatment. Washington (DC): National Academies Press (US); 1995. 5, Federal Regulation of Methadone Treatment.
Pelletier, L. R., & Hoffman, J. A. (2001). New Federal Regulations for Improving Quality in Opioid Treatment Programs. *Journal for healthcare quality : official publication of the National Association for Healthcare Quality*, *23*(6), 29–34.
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs
URLs last accessed: 03/06/25

While states can't choose to be less restrictive than the federal regulations, they can choose to be MORE restrictive

Comment by author

Who/What Regulates OTPs?

SAMHSA

- **42 CFR Part 8** - Federal regulations governing opioid treatment programs
  - Certification and accreditation process
  - Counseling and medical requirements

- **Federal Guidelines for OTPs** - "Guidance and recommendations to OTPs for implementing requirements outlined in the revised 42 CFR part 8 rule. These Guidelines are not intended to replace the judgment of healthcare practitioners and do not represent professional standards of care."

- **42 CFR Part 2 + HIPAA** – **C**onfidentiality of SUD patient records
  - Entities governed by both must follow whichever has the stricter standard

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/become-otp
https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://library.samhsa.gov/sites/default/files/federal-guidelines-opioid-treatment-pep24-02-011.pdf
https://www.hhs.gov/hipaa/for-professionals/faq/3005/how-does-hipaa-interact-federal-confidentiality-rules-substance-use-disorder-treatment-information-in-emergency/index.html#:~:text=Generally%2C%20the%20Part%202%20rules,2's%20restrictions%20without%20violating%20HIPAA.
URLs last accessed: 03/06/25

Who/What Regulates OTPs?

DEA

- Oversees DEA registration, record-keeping, inventory, medication ordering, security, procedure for receiving and dispensing medication, off-site delivery, etc.

Accreditation Bodies

- "To be certified by SAMHSA, an OTP must be accredited by a CSAT-approved accreditor."
- The two largest: CARF and The Joint Commission
- Have their own standards for OTPs

State

- Authority to oversee OTPs at the state level lies with the SOTA (appointed position – State Opioid Treatment Authority)
- Ensures regulatory compliance, reviews exception requests, acts as a liaison between OTPs and SAMHSA/DEA, oversees OTP closure/emergency preparedness

https://carf.org/accreditation/programs/opioid-treatment
https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-opioid-treatment-program-accreditation/
https://www.jointcommission.org/standards/standard-faqs/behavioral-health/performance-improvement-pi/000001605/
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-056)(EO-DEA169)_NTP_manual_Final.pdf
https://nasadad.org/wp-content/uploads/2023/05/SOTA-Role-5.1.2023.pdf
https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/accreditation-bodies; URLs last accessed: 03/06/25

Global Change: Language

Old Rule	VS	New Rule
• Medication-assisted treatment (MAT)		• Medication for opioid use disorder (MOUD)
• Maintenance treatment		• Comprehensive treatment
• Detoxification treatment		• Withdrawal management
• Drug abuse (verbiage removed, not replaced)		

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Global Change: Emphasis on Shared Decision-Making

Example

- "*Withdrawal management.* An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks."

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
URL last accessed: 03/06/25

Global Change: Addition of Harm Reduction

Example

- "*Comprehensive treatment* is treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services."

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
URL last accessed: 03/06/25

Change: Admission Exams

Old Rule

- "OTPs shall require each patient to undergo a complete, fully documented physical evaluation... before admission to the OTP."

VS

New Rule

- A screening examination must be completed before MOUD is started
  - Full examination within 14 days of admission to an OTP
- "Full examination may be completed via telehealth... if a practitioner... determines that an adequate evaluation of the patient can be accomplished via telehealth."

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Admission Platform

Old Rule

- Methadone intakes must be completed in-person

VS

New Rule

- Methadone admissions may use an audiovisual platform
- Audio only may be used for buprenorphine and naltrexone

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Admission Dosage

Old Rule

- "The initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams..."

VS

New Rule

- "Initial dose of methadone has been increased to 50mg on the first day... allowance for higher doses if clinically indicated"

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Take-Home Criteria

Old Criteria – "The 8 Point Criteria"

(i) Absence of recent use of drugs (opioid or nonnarcotic), including alcohol

(ii) Regularity of clinic attendance **(for how long? how regular?)**

(iii) Absence of serious behavioral problems at the clinic **(vague)**

(iv) Absence of known recent criminal activity, e.g., drug dealing **(how recent? vague)**

(v) Stability of the patient's home environment and social relationships **(vague)**

(vi) Length of time in comprehensive maintenance treatment **(why?)**

(vii) Assurance that take-home medication can be safely stored within the patient's home **(can't verify)**

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion **(vague)**

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Take-Home Criteria

New Criteria

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely

(ii) Regularity of attendance for supervised medication administration

(iii) Absence of serious behavioral problems that endanger the patient, the public or others

(iv) Absence of known recent diversion activity

(v) Whether take-home medication can be safely transported and stored

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Take-Home Amount

Old Regulations

Time In Treatment	Number of Take-Homes Allowed
1-90 days	1 Take-Home/week
91-180 days	2 Take-Homes/week
181-270 days	3 Take-Homes/week
271 days-1 year	Up to a 6-day supply
1-2 years	Up to a 2-week supply
2+ years	Up to a 1-month supply

https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URL last accessed: 03/06/25

Change: Take-Home Amount

New Regulations

Time In Treatment	Number of Take-Homes Allowed
1-14 days	7 Take-Homes
15-30 days	14 Take-Homes
31+ days	28 Take-Homes

https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Change: Split Dosing

Old Rule

- No comment

VS

New Rule

- "Split dosing is indicated among, but not limited to:"
  - fast metabolizers
  - accelerated metabolism due to medications
  - pregnancy
  - concurrent treatment of chronic pain

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Everything Else

- Updated admission criteria
  - Elimination of requirement that patients have a one-year history of OUD
  - Expanded criteria for admission: "The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose."
  - Unlimited admissions for withdrawal management

- Interim maintenance (medication without counseling) now allowed for a maximum of 180 days in a 12-month period, for all OTPs.
  - Treatment plan required by day 120
  - Take-homes allowed
  - Cannot discharge patients without medical provider approval

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Everything Else

- MOUD access is no longer contingent on... laboratory testing, "provided such refusal does not have the potential to negatively impact treatment with medications."

- Federally recognized Indian Tribes and territorial governments may become OTP accreditation bodies

- Modified definition of an OTP qualifying practitioner: "A provider who is appropriately licensed by the state to prescribe (including dispense) medications
  - Medical directors will continue to be physicians

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Everything Else

- No major changes to urine drug screens, pregnancy, and dosing in hospitals/long-term care facilities/correctional settings

- Revised definition of medication unit:
  - May provide the full range of OTP services, based on space and privacy available in the mobile unit

- "Patient refusal of counseling shall not preclude them from receiving MOUD."
  - But, "a complete psychosocial assessment must be conducted within 14 days."

https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf
https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
URLs last accessed: 03/06/25

Part 2: Designing Policies and Procedures to Implement the Final Rule

- How do you design a set of policies and procedures using the changes in the Final Rule?
  - Take-home allowances
  - Use of other drugs and TH levels
  - Initial dosing allowance
  - Telemedicine intakes and assessments
  - Split dosing

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12, accessed March 5, 2025

Final Rule - new allowances for take-home doses

Patients are now allowed to take home 7 doses on day 1 of treatment:

Days in Treatment	Maximum Number of Take-Home Doses
1–14	7
15–30	14
31 or more	28

SAMHSA has effectively turned over take-home determinations to the discretion of the OTP Medical Directors and their designees

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12, accessed March 5, 2025

Applying the FR criteria at admission

- (i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
  - All patients have an active OUD
- (ii) Regularity of attendance for supervised medication administration;
  - Can't be assessed
- (iii) Absence of serious behavioral problems that endanger the patient, the public or others;
  - Can't be assessed
- (iv) Absence of known recent diversion activity;
  - Can't be assessed
- (v) Whether take-home medication can be safely transported and stored;
  - Can't be accurately assessed and
- (vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health
  - Not specific enough to apply fairly to all patients.

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12, accessed March 5, 2025

Applying the Final Rule - Basic Principles

- **Patient Safety -** The primary arbiter of the correct take-home policy should be patient safety, which needs to be balanced with improved access and retention that is expected to occur with fewer required clinic doses.
- **Stability -** It is important to get each patient to a therapeutic dose as rapidly as can be safely accomplished.
- **Dose Increases -** For patient safety, a nursing or medical provider assessment should precede any dose increases. This mandates that all dose increases occur on clinic dosing days.

(Comments by author)

More Take-Home Doses - Benefits and Risks

Benefits

- More patient autonomy
- Potential for increased treatment retention
- Fewer issues with transportation, childcare, employment
- May be able treat more patients who need it

Risks

- Patient safety - risk of taking too much at once and overdosing
- How to titrate dose during induction
- Increased opportunity for diversion
- Fewer contacts with medical, counseling, peers, etc.
- Possible negative community perceptions

It is important to consider benefits and risks when determining take-home levels.

(Comments by author)

Maximum Number of Take-Home Doses by Level

Take Home Level	Maximum Take Home Doses
Daily	1
Weekends	2
Weekends + 1	2
Triweekly	2
Weekly	6
Bimonthly	13
Monthly	27

- From daily to triweekly TH levels, the maximum number of TH doses is 2.
- A maximum of 2 TH doses is equivalent to “weekends” TH level.
- Moving from triweekly to weekly increases the maximum THs to 6.

There is little difference in TH risk between daily and triweekly.

(Comments by author)

The Burden of Daily Clinic Dosing

- For any patient, it is rarely the case that the benefits of daily dosing outweigh the burden of coming to the clinic multiple days per week.

(Comment by author)

The Problem of Diversion

- Diversion can never be completely eliminated.
- It could be increased with more TH doses.
- Most diverted doses are used to prevent withdrawal or other drug use.
- Risk of overdose from diversion is unknown but unlikely to be anywhere near the risk from untreated OUD.

- We must be careful in balancing diversion vs. access.

Magdalena Harris, Tim Rhodes, Methadone diversion as a protective strategy: The harm reduction potential of 'generous constraints', International Journal of Drug Policy, Volume 24, Issue 6, 2013, Pages e43-e50, ISSN 0955-3959, https://doi.org/10.1016/j.drugpo.2012.10.003.

Initial Take-Home Level

- Determined by the Medical Provider at the intake assessment
  - Daily, Triweekly, or Weekly
- Most patients will not receive benefit from take-home levels below triweekly
- Some patients may be candidates to start on weekly dosing

Other Drug Use and TH Levels

- "(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;"

  - Benzodiazepines, barbiturates, and alcohol all can increase the acute respiratory depression caused by opioids.[1]
  - Stimulants, however, do not cause respiratory depression. [2]
  - Although data show increased OD risk when people use both stimulants and opioids, there is no clear physiologic mechanism.[3]
  - There is no evidence that restricting TH doses decreases risk of OD from combining opioids and stimulants.
  - The supposed benefits of restricting TH doses for those testing positive for stimulants do not outweigh the burden of frequent clinic visits.

[1]Bateman JT, Saunders SE, Levitt ES. Br J Pharmacol. 2023 Apr;180(7):813-828.
[2]Hassan SF, Wearne TA, et al. J Physiol. 2016 Feb 1;594(3):763-80.
[3]Palis H, Xavier C, Dobrer S, et al. BMC Public Health. 2022 Nov 15;22(1):2084.

Methadone Intakes Via Telemedicine

- Allowed with audiovisual real-time connection.
- This allows for increased access when a medical provider can not be present on site at the time the patient presents.
  - Especially in remote and rural areas.
- Not allowed in all states.
- In states that don't allow telemedicine intakes, patients must have had an in-person exam completed within a week prior to intake and the documentation must be available to be reviewed by the admitting provider.

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8/subpart-C/section-8.12, accessed March 5, 2025

Part 2b: Let's Take a Look at the Policies

Policy: Take-Homes

- TH Phases: daily, triweekly, weekly, biweekly, monthly
  - Daily: Only for those deemed incapable of handling doses safely. All daily clients are re-evaluated weekly for possible advancement to triweekly.
  - Triweekly: Routine for most clients. Allows dose titration during the first week of treatment.
  - Weekly: Only for clients who will remain on the same dose for the first week and not higher than 40 mg.
  - Dose increases only happen at the window, with a nursing evaluation.

- TH Advancement Interval: 14 days after intake and then every 28 days thereafter
  - Requires an interval UDS with results available for review at the 14-day mark

Internal policy from Community Medical Services

Policy: Take-Homes

- TH Advancement Criteria
  - Up to date with quarterly medical appointments
  - Have no more than two missed dosing days (whether consecutive or non-consecutive) in the last 28 days
  - Medication callback not required for take-home level advancement
  - At least one normal UDS in the last 28 days and the last UDS is normal

- UDS Evaluation
  - Drug screen results positive for unprescribed opioids, oxycodone, fentanyl, benzodiazepines, or barbiturates are considered abnormal
  - Amphetamines, stimulates, and cannabis are not considered as they do not increase the potential for overdose

Internal policy from Community Medical Services

Policy: Take-Homes

- TH Reduction
  - Reduction to daily: unsafe storage, failed medication callback, diversion, sedation, safety concerns, loss of 6 or more doses
    - **All lost doses result in a safety report**
  - Reduction by at least one level (not lower than triweekly unless determined necessary by an interdisciplinary team): repeatedly missing scheduled medical appointments, misuse of dose, presenting impaired, behavioral problems that endanger others or self, missing more than two dosing days consecutively, loss of 5 or less doses
    - Missing more than five dosing days consecutively results in demotion to triweekly
  - Reinstatement: clients are eligible to reinstate at triweekly after one week of daily dosing if the original issue, including a failed medication callback, has been resolved

Policy: Induction Dosing

- States with extended take-homes
  - Initial dose = maximum 50mg in patients with established opioid tolerance
  - Maximum 7-day dose = up to 80mg

- States without extended take-homes
  - Initial dose = maximum 30mg
  - May increase from 30mg to 50mg on day 2 of treatment

Internal policy from Community Medical Services

Policy: Split Dosing

- Diversion is always a concern when doses are taken outside of clinic

- A client must have some level of stability to initiate or continue split dosing
  - Unless taking both doses in clinic
  - Otherwise, must be at triweekly or above

- A peak and trough is required for all clients prior to initiating split dosing unless the client is pregnant
- Reasons to split: pregnancy, chronic pain, approaching 200mg with ongoing opioid withdrawal, subtherapeutic dose unable to be increased due to side effects (sedation, QTc), fast metabolizer, etc.

Internal policy from Community Medical Services

Part 3: Challenges in Implementing New Policies

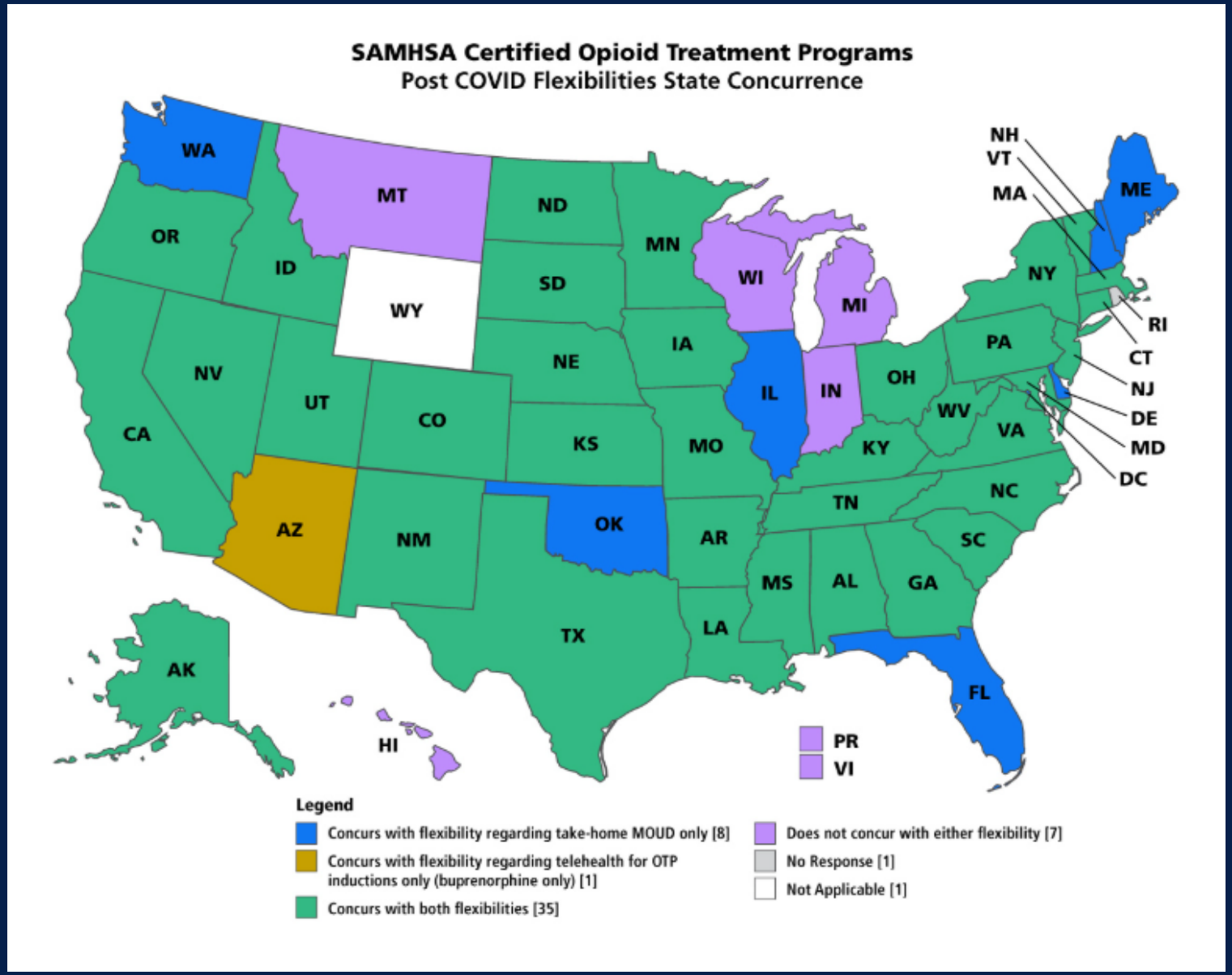
- Dealing with individual state regulations
- Once the policies have been determined, how do they get to the medical providers, counselors, nurses, and other staff?
- How do you deal with push back and reluctance to change long-term practices?

Dealing with Individual State Regulations

- Currently, it's difficult to pinpoint what each State is doing in regards to the rule adoption.
- For each State that we operate in, it has been vital to work with the State Opioid Treatment Authority and relevant department to develop and ensure our practices are aligned.
- The process included rule revisions, cross-departmental collaboration, review with the field, revisions, ad nauseum.

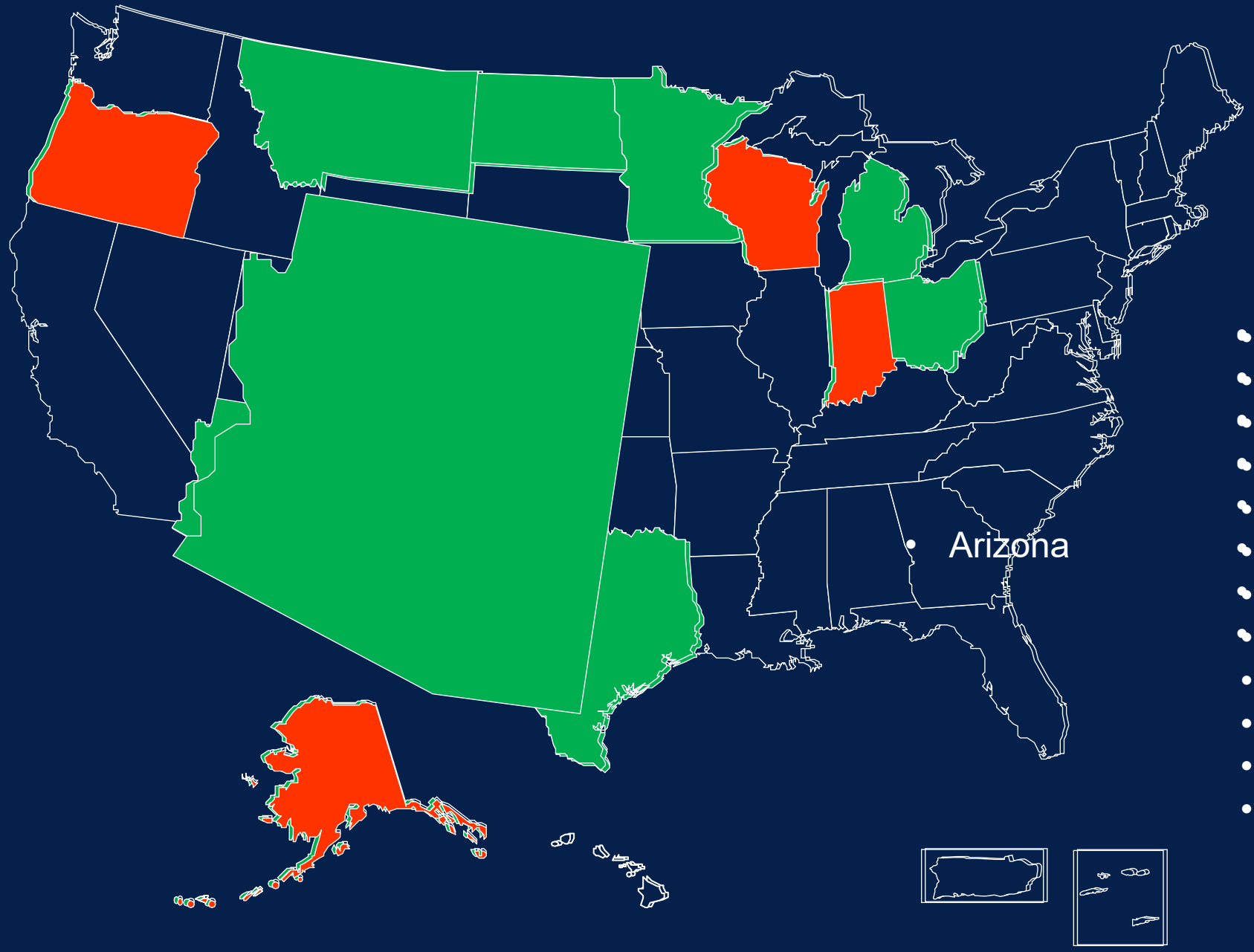
A few factors

- Interpretation of the rule revision by the State Opioid Treatment Authorities
- Current rules/laws/century code limitations
- Partial adoption vs “copy/paste” of revisions
- Requirements vs recommendations at the Opioid Treatment Program level



Post COVID Flexibilities State Concurrence

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/methadone-guidance, last accessed 3/6/2025

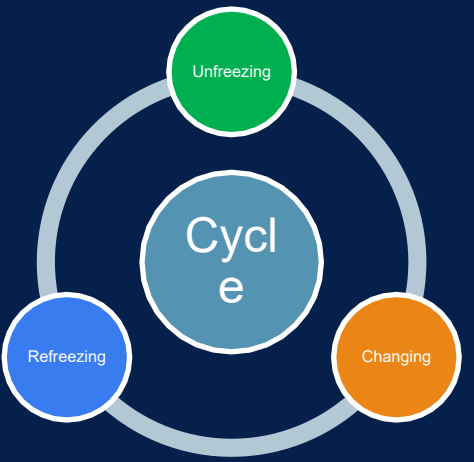


- Oregon
- Montana
- North Dakota
- Minnesota
- Michigan
- Ohio
- Wisconsin
- Colorado
- Arizona
- Texas
- Alaska

Implementation Process

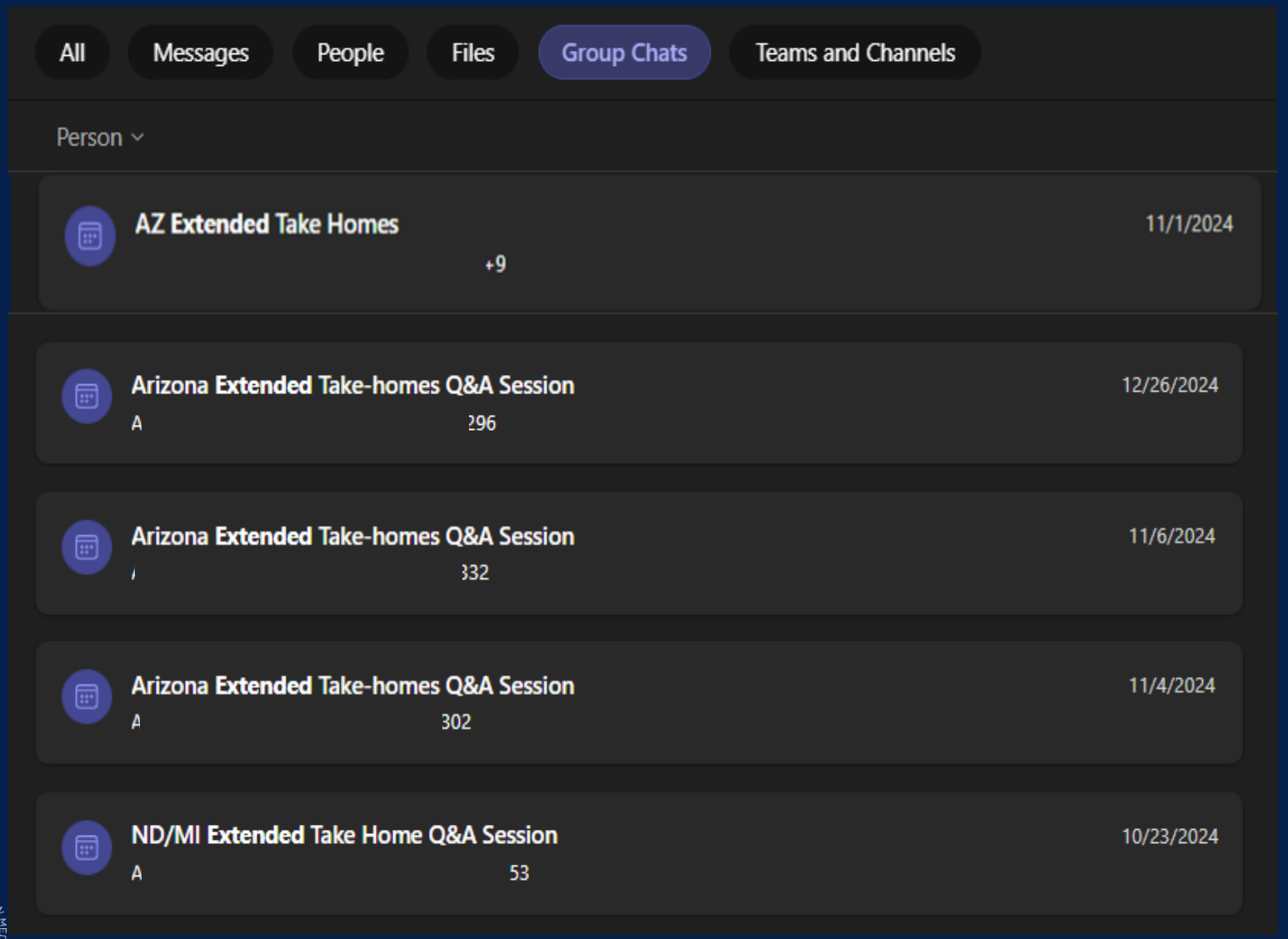
- Because of Concurrent adoption, we were able to pilot and learn even more from the COVID regulations
- What does this look like in one state?
- We will look at it through the lens of Organizational Change, with a purposeful, cyclical process.

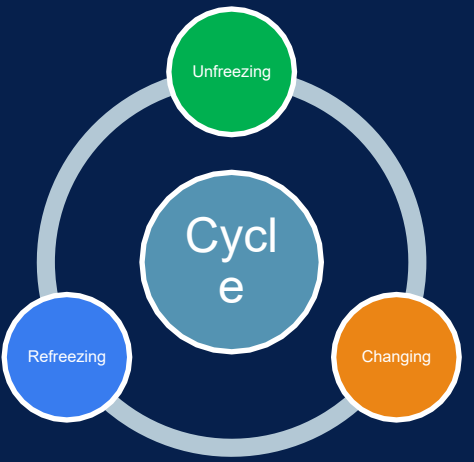
Snapshot of the Process



- Getting the rules developed and reviewed
- Shared understanding with leadership
- **Training with all staff (Unfreeze)**
- **Q&A Sessions (Unfreeze)**
- Implementation (Change)
- Individual discussions and Continued Q&A Sessions (Change)
- **Metrics and continued refinement (Refreeze)**

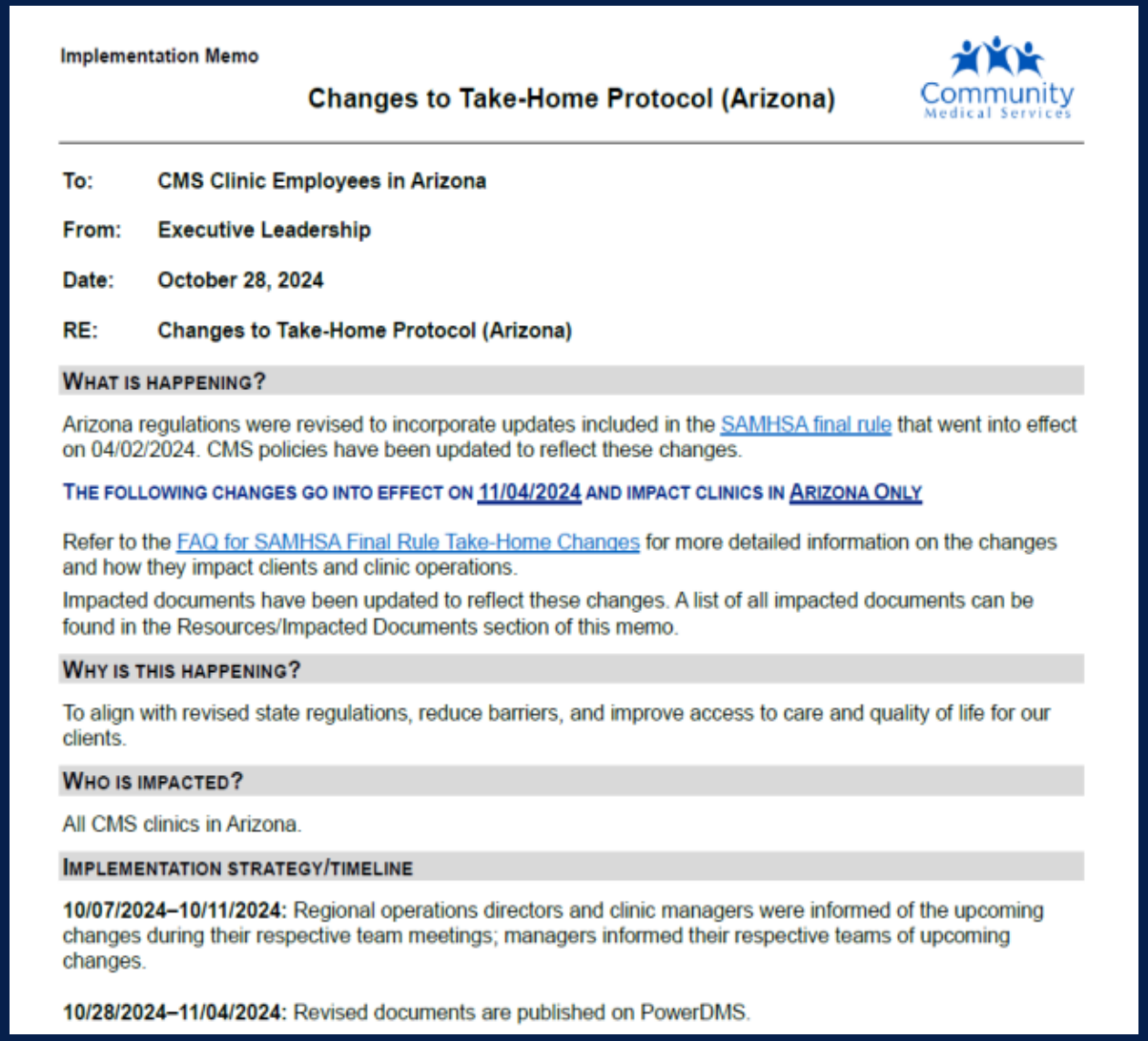
Rolling Q&A





- Developing and reviewing the new process
- Shared understanding with leadership

Unfreeze



Implementation Memo

Changes to Take-Home Protocol (Arizona)

Community Medical Services

To: CMS Clinic Employees in Arizona

From: Executive Leadership

Date: October 28, 2024

RE: Changes to Take-Home Protocol (Arizona)

WHAT IS HAPPENING?

Arizona regulations were revised to incorporate updates included in the SAMHSA final rule that went into effect on 04/02/2024. CMS policies have been updated to reflect these changes.

THE FOLLOWING CHANGES GO INTO EFFECT ON 11/04/2024 AND IMPACT CLINICS IN ARIZONA ONLY

Refer to the FAQ for SAMHSA Final Rule Take-Home Changes for more detailed information on the changes and how they impact clients and clinic operations.

Impacted documents have been updated to reflect these changes. A list of all impacted documents can be found in the Resources/Impacted Documents section of this memo.

WHY IS THIS HAPPENING?

To align with revised state regulations, reduce barriers, and improve access to care and quality of life for our clients.

WHO IS IMPACTED?

All CMS clinics in Arizona.

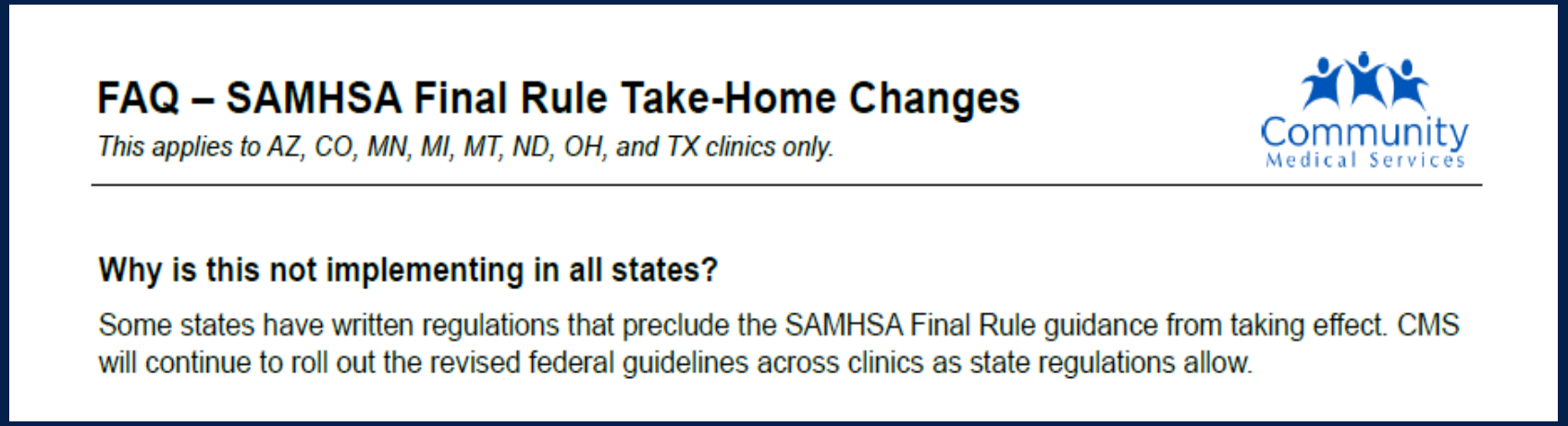
IMPLEMENTATION STRATEGY/TIMELINE

10/07/2024–10/11/2024: Regional operations directors and clinic managers were informed of the upcoming changes during their respective team meetings; managers informed their respective teams of upcoming changes.

10/28/2024–11/04/2024: Revised documents are published on PowerDMS.

- Training with all staff (Unfreeze)

Unfreeze



FAQ – SAMHSA Final Rule Take-Home Changes

This applies to AZ, CO, MN, MI, MT, ND, OH, and TX clinics only.

Community Medical Services

Why is this not implementing in all states?

Some states have written regulations that preclude the SAMHSA Final Rule guidance from taking effect. CMS will continue to roll out the revised federal guidelines across clinics as state regulations allow.

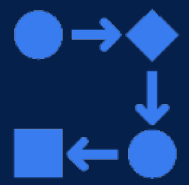
- Training with all staff (Unfreeze)

Unfreeze

- Q&A Sessions (Unfreeze)

Unfreeze

- “When can a patient increase to weekly take-homes?”
- “Does this apply to new and existing patients?”
- “What would cause a patient to have their take-home levels reduced?”
- “Are patients who are overdue for a medical appointment on daily until they see the medical provider?”
- “If a patient is weekly and they miss or are absent, what does that do for their take-homes?”



Implementation (Change)

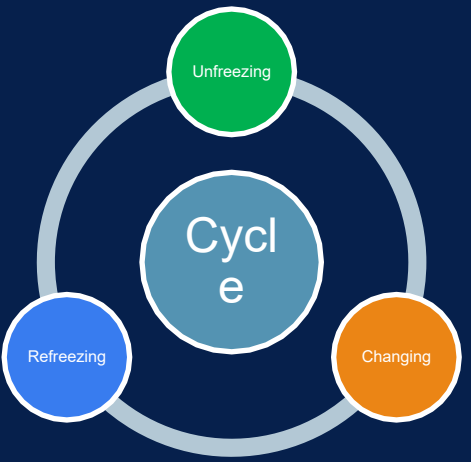
- Coaching, training, encouragement, recognition, and empathy

Individual and Continued Q&A Sessions (Change)

- Help and guidance, regular feedback and providing adequate resources

Metrics and continued refinement (Refreeze)

- Monitor and evaluate (part 4), period of relative stability



Ongoing Q&A in chats
Metrics on adoption
Outcome Data shared

Addressing Reluctance to change

- What is the experience for patients?
- What is the experience for professionals?
- Organizational Culture:
  - A culture of Change
  - A culture of Respect
  - A culture of using Evidence Based decision Making
  - Walking alongside staff and patients.
- Patient Advisory Groups

The Provider Experience

"As a chorus of physicians and advocates calls for loosening methadone restrictions, states have been slower to adopt new relaxed federal rules."

“At least 10 states have “stability criteria for take-home doses that were stricter than federal rules as of June 2021.”

“Some won’t allow take-home doses for patients who drink alcohol or use cannabis.”

"The first big update to U.S. methadone regulations in 20 years is poised to expand access... but experts say the addiction treatment changes could fall flat if state governments and methadone clinics fail to act."

“Even individual clinicians might have their own views about what patients must do before being allowed take-home doses.”

"New federal regulations have the potential to transform OTP care... However, without changes at the state level, methadone access won’t improve."

The Patient Experience

Many clients report difficulties in affording treatment, impeding their ability to comply with program requirements

"I never in a million years could have gone back to school, got my Ph.D., done research, or taught- any of that stuff-if I had to go to a clinic every day. It's night and day in terms of your ability to live a stable, happy, quality life."

Transportation barriers have long been associated with poorer health outcomes; this burden is especially acute for individuals with opioid use disorder, a chronic disease often associated with low socioeconomic status.

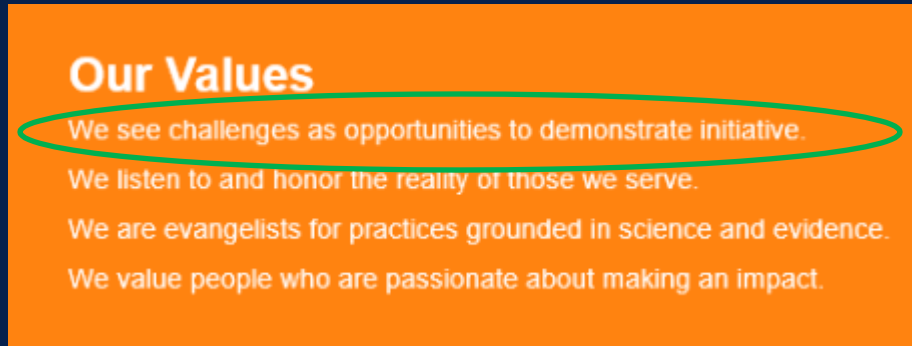
"I don't like methadone because I don't like showing up every day. I just don't."

"I lived in Town A, then had to drive to Town B every day before turning around and working in Town C. In my day, it added an hour. Nobody likes to add an hour to the morning."

"The last time I did it, and I actually just hopped off the program, and I got high again; because I was sick of going in every day. Then, if you miss a day, or don't wake up early enough, or I can't go anywhere, that's just frustrating to me."

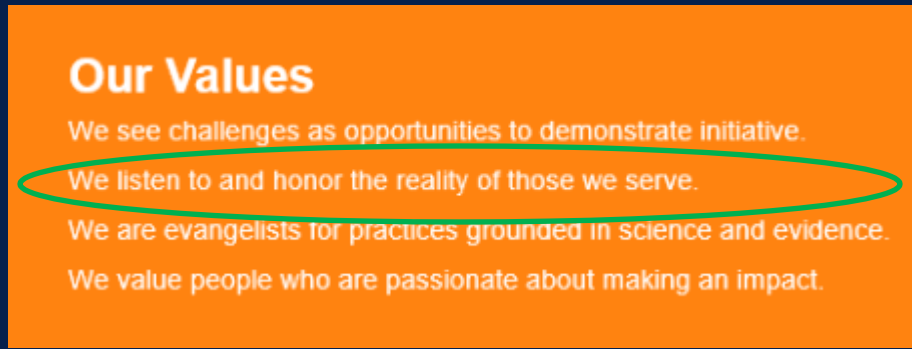
A culture of Change

- Providing education to staff and patients
  - Implementation Memorandums
  - FAQ's based on actual questions
  - Q&A Sessions
  - On-going team "chats"



A culture of Respect

- Addressing resistance to change with an understanding of the "why" and how it impacts patients
  - Addressing the most common "resistance"
    - We often want people to be "fixed" the way we want them to be "fixed"
    - Earning versus rights
    - Using medication as a lever to get people into counseling/compliance
    - "…but they are using a stimulant"
  - What is the ultimate goal for this person's recovery?



A culture of Evidence Based Decision Making

- Providing the evidence; including our own pilots and national research
  - Starts with the evidence
  - Data/Outcomes provided throughout the process
  - Adoption rate consistently reviewed
  - “Don’t fix what’s not broken” vs Here is why it was not working

Our Values

We see challenges as opportunities to demonstrate initiative.

We listen to and honor the reality of those we serve.

We are evangelists for practices grounded in science and evidence.

We value people who are passionate about making an impact.

Walking Along, not pushing, nor pulling

- Treating staff resistance, concerns, and apprehension with the same level of passion and compassion that we are asking them to demonstrate with patients
  - Seeking first to understand
  - Utilizing the evidence from the field, the data from the implementation, and the outcomes for patients
  - The process included sessions that integrated feedback from the field which was then considered for revisions
  - We are never done; we can always improve

Our Values

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What we learn from Patients

Help me understand why you are doing this?

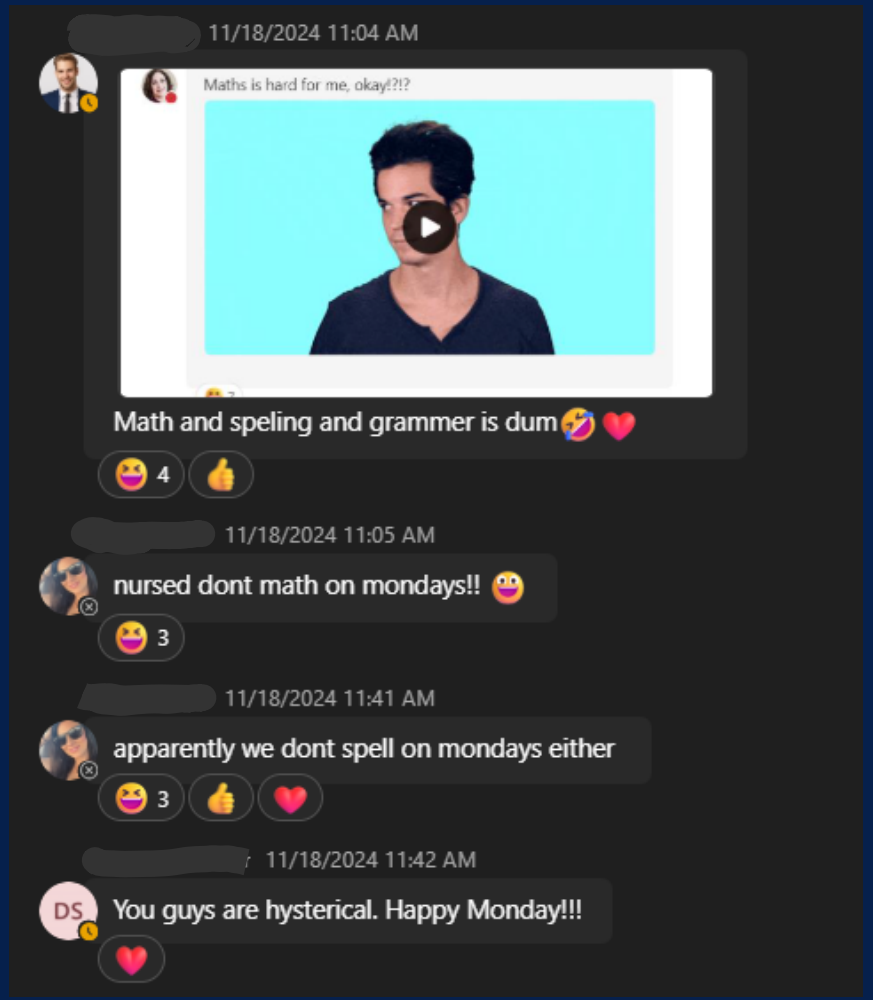
But, what about people who are still using some substances?

When can I increase my take-homes?

Aren't you worried about people abusing this?

How do you know if it's working?

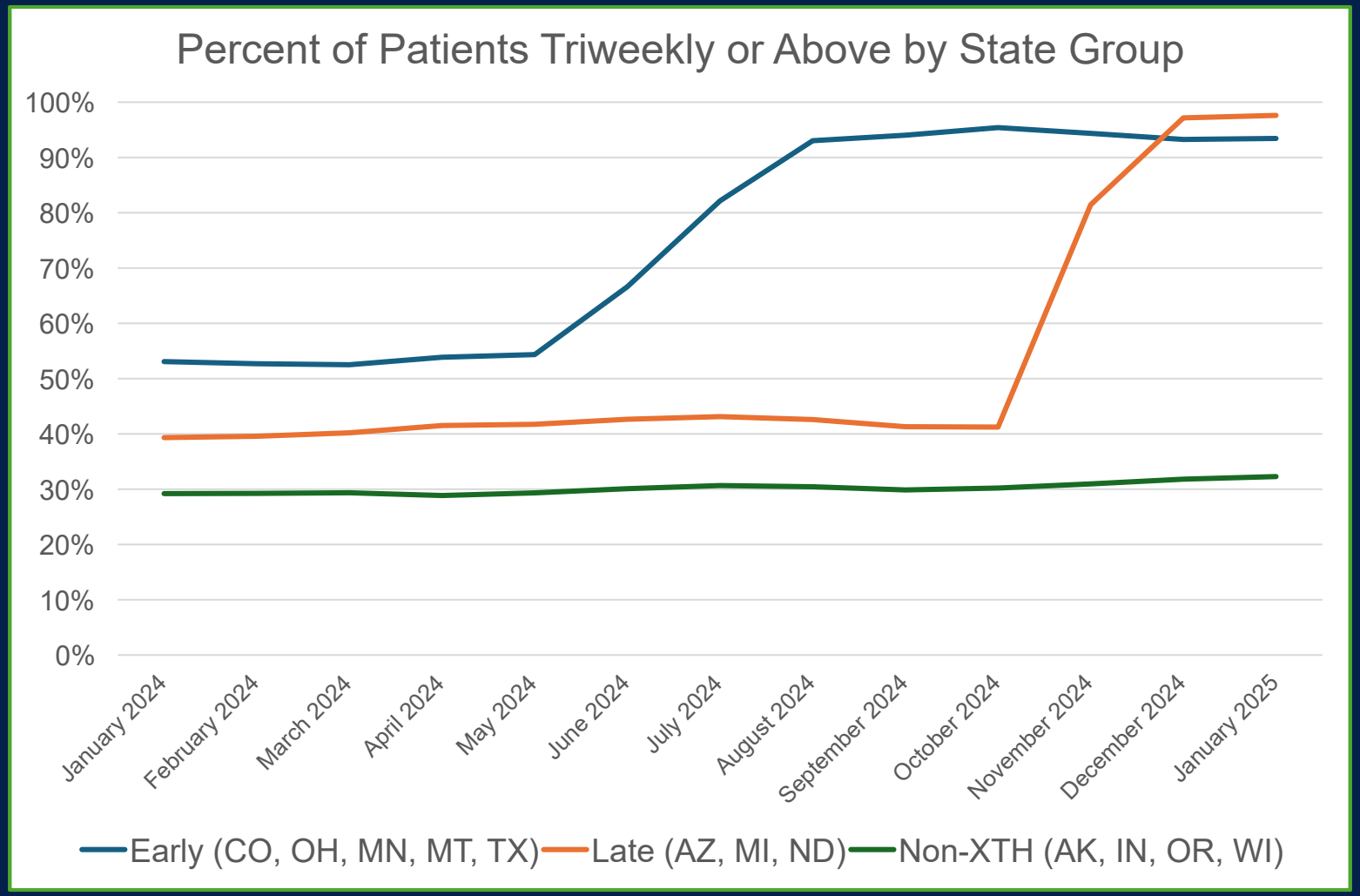
- **Metrics**
- Continued conversations
- **Metrics**
- Questions keep coming
- Meeting with patients
- **Metrics**
- Talking with staff
- And…..**Metrics**



Part 4: Implementation and Outcome Data

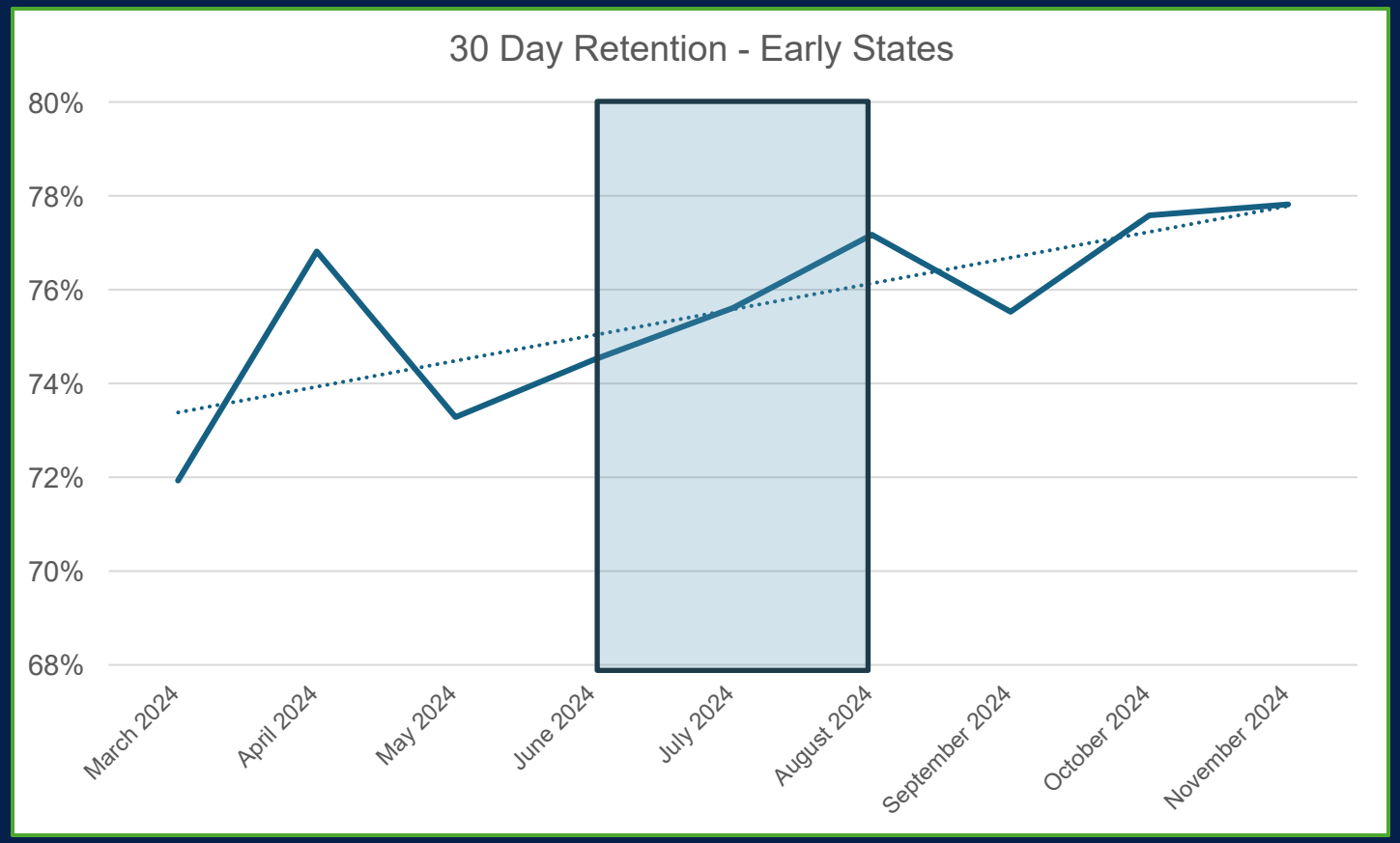
- How complete was the implementation?
- How did the changes affect patient outcomes?

Percent of Doses Triweekly or Higher Take-Home Level



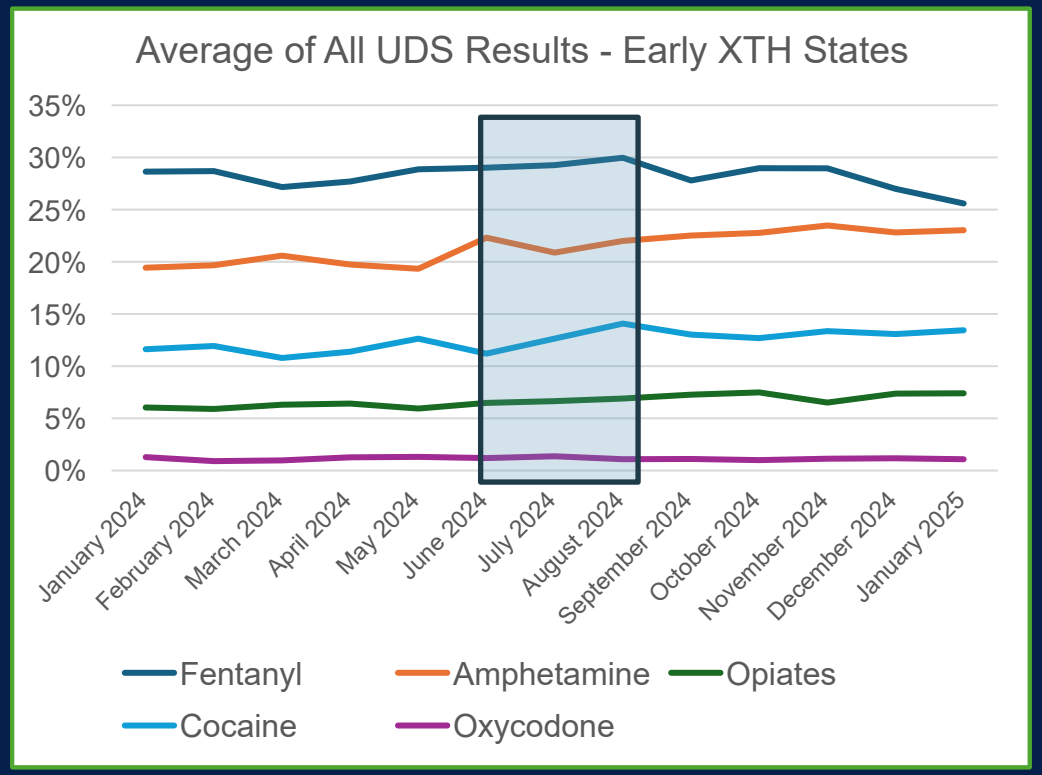
(Internal data from author)

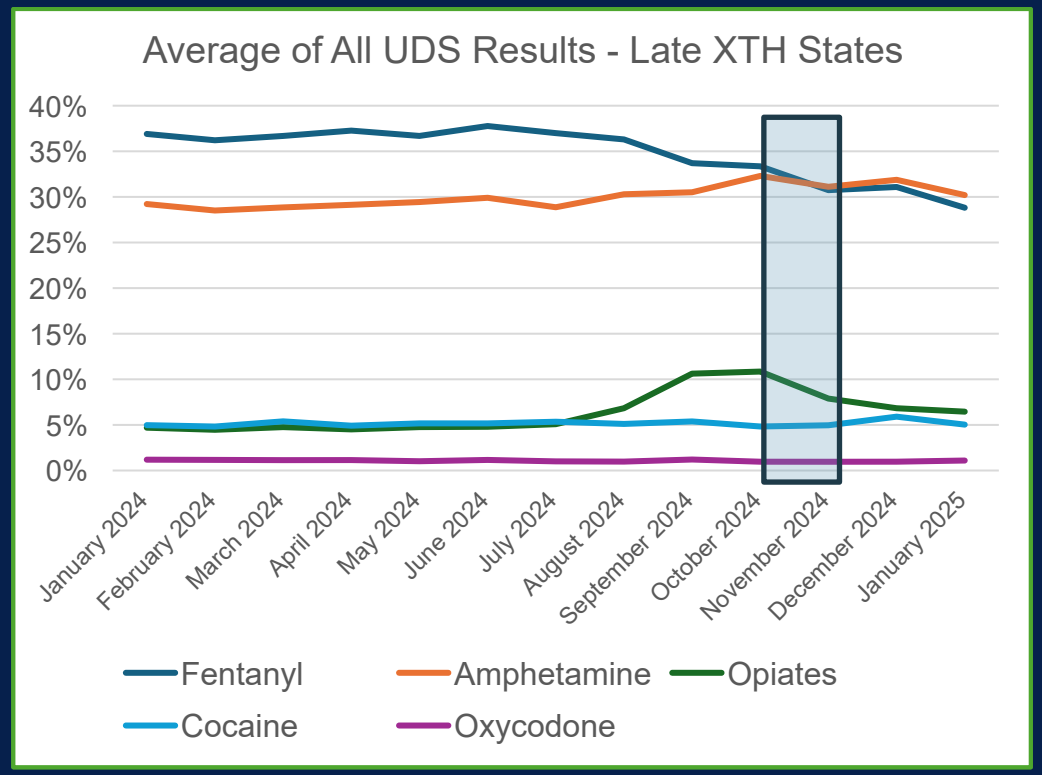
30-Day Retention - Early States



(Internal data from author. P-value = 0.02 for trend)

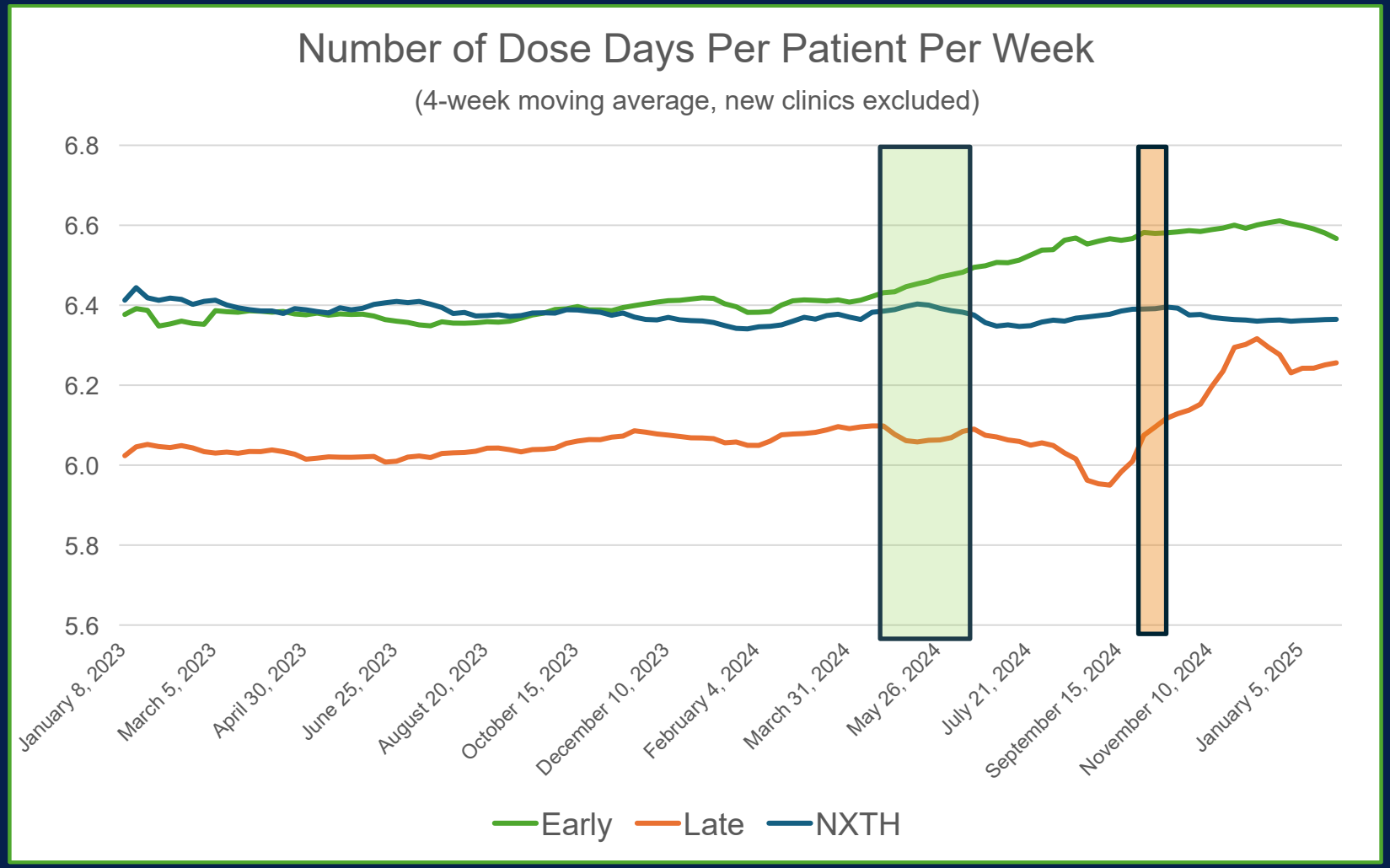
Urine Drug Screen Results





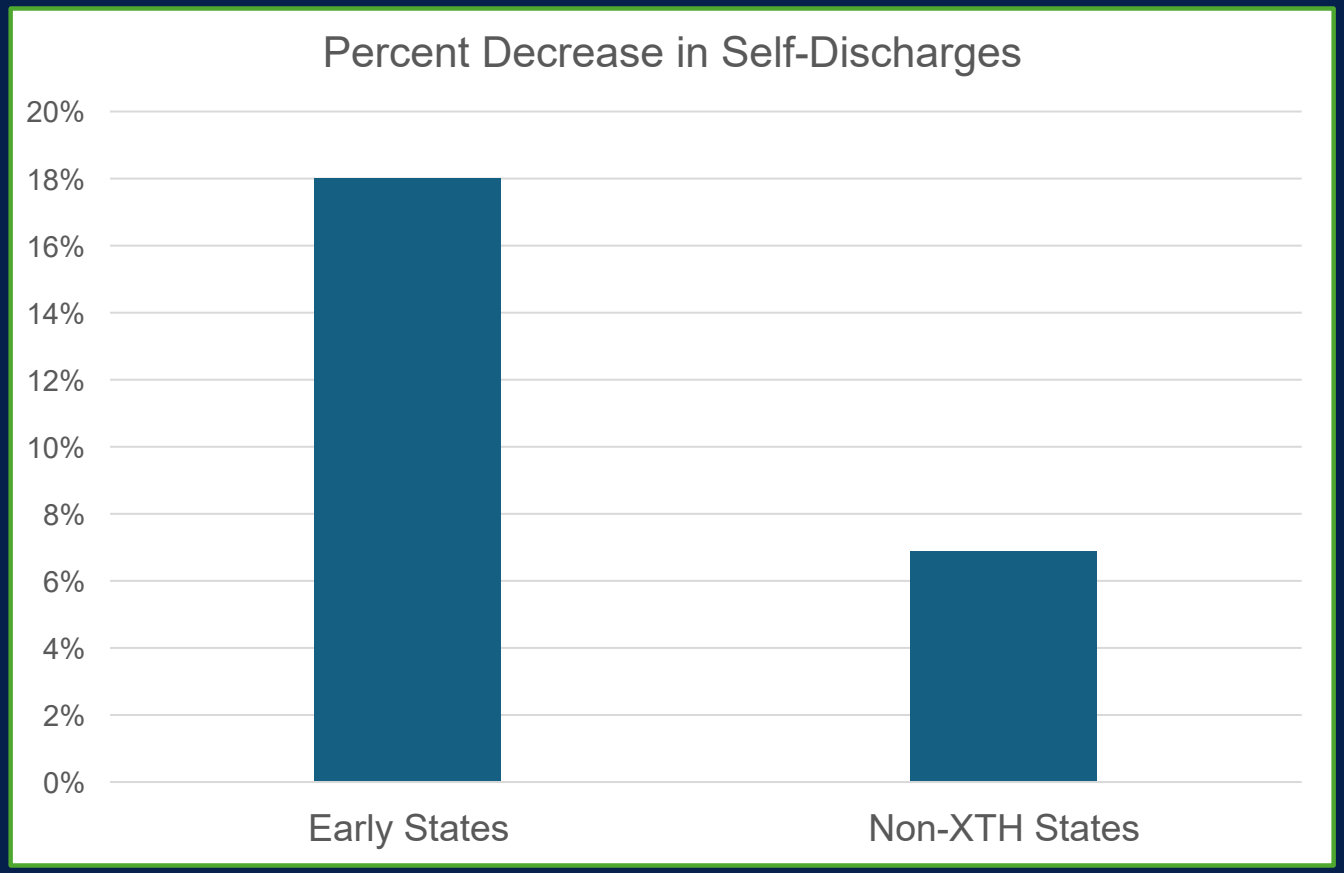
(Internal data from author)

Average Dose Days Per Week



(Internal data from author)

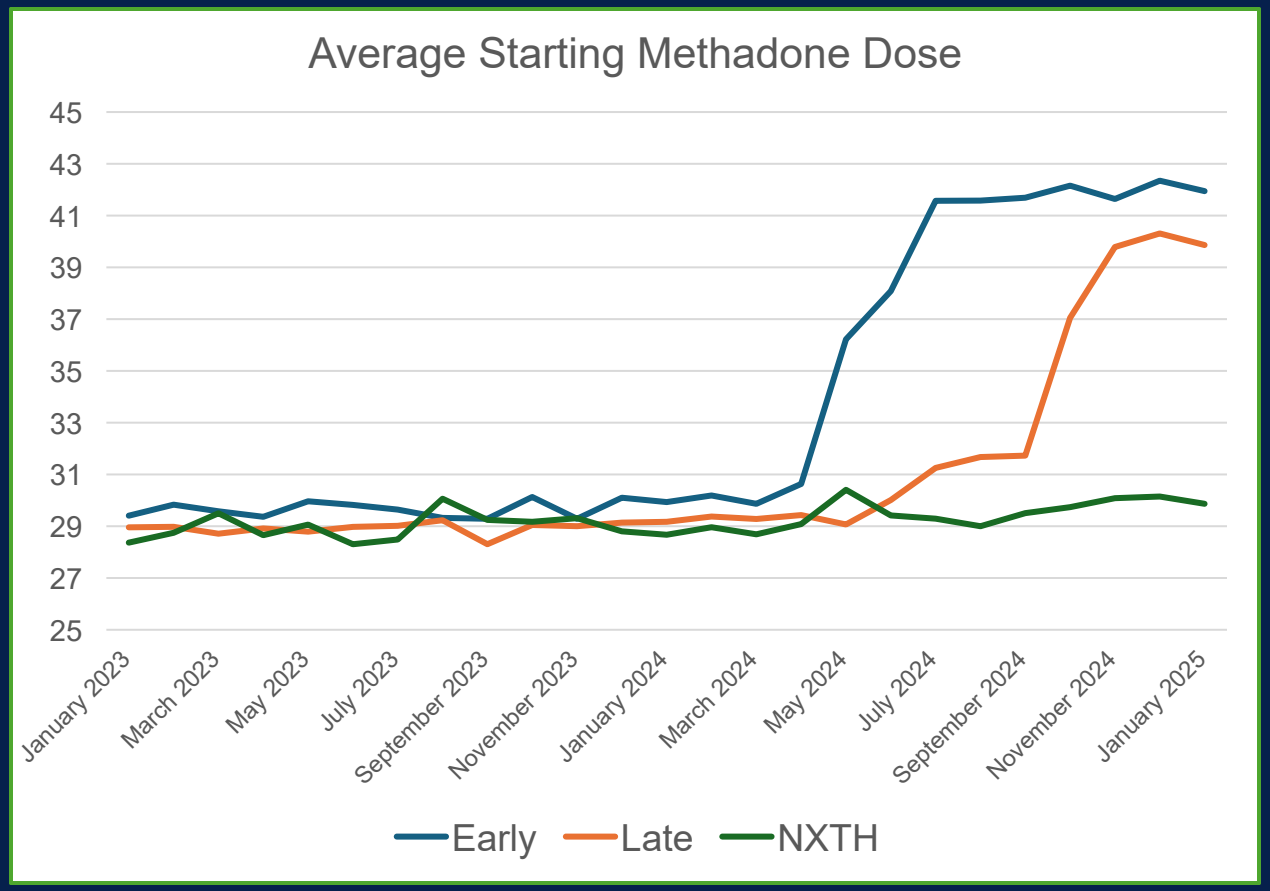
Self-Discharges



Percent change in self discharges from before XTH implementation (January - May 2024) compared to after implementation (August - December 2024).

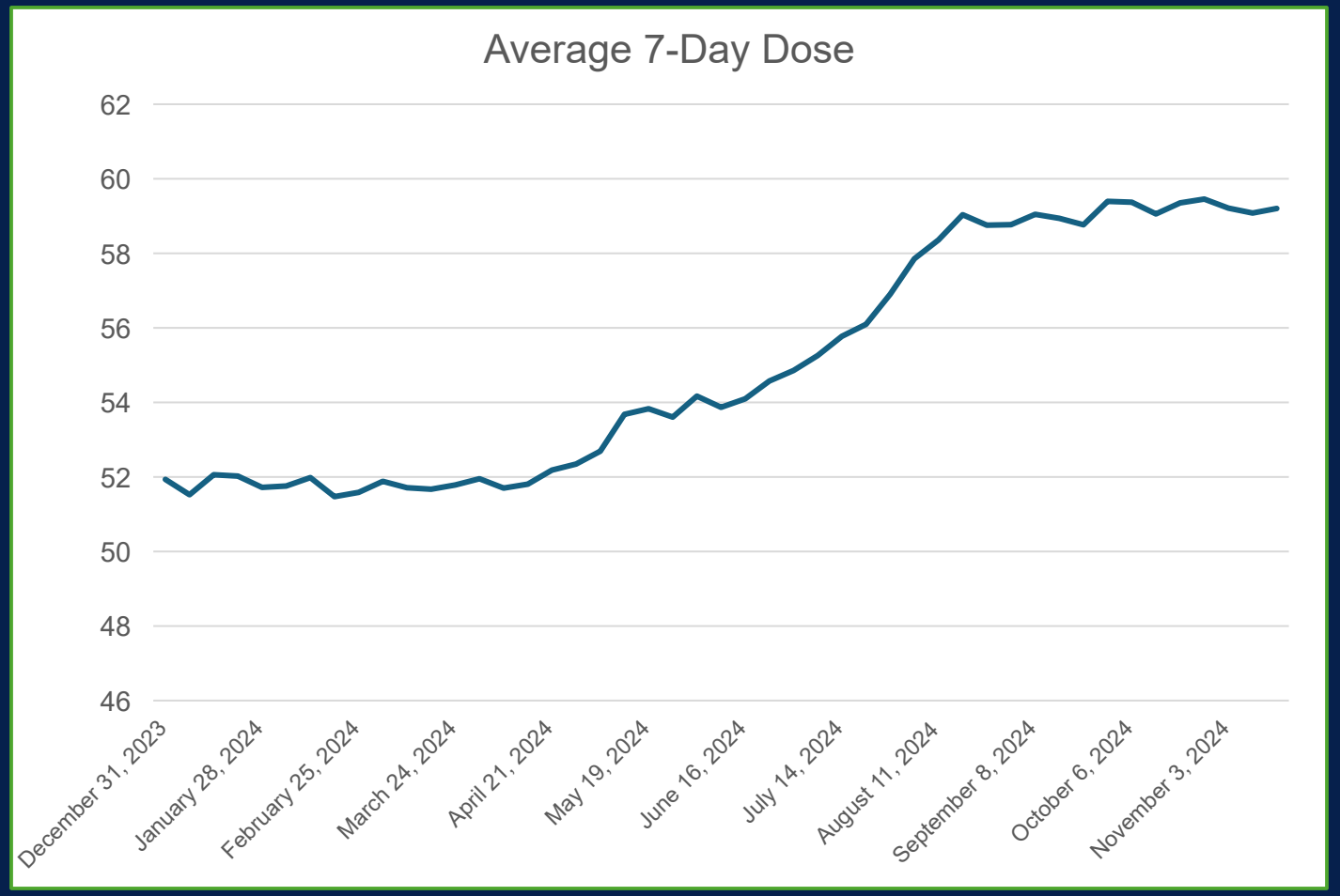
(Internal data from author. P=value for Early State trend < 0.04)

Starting Methadone Dose by State Group



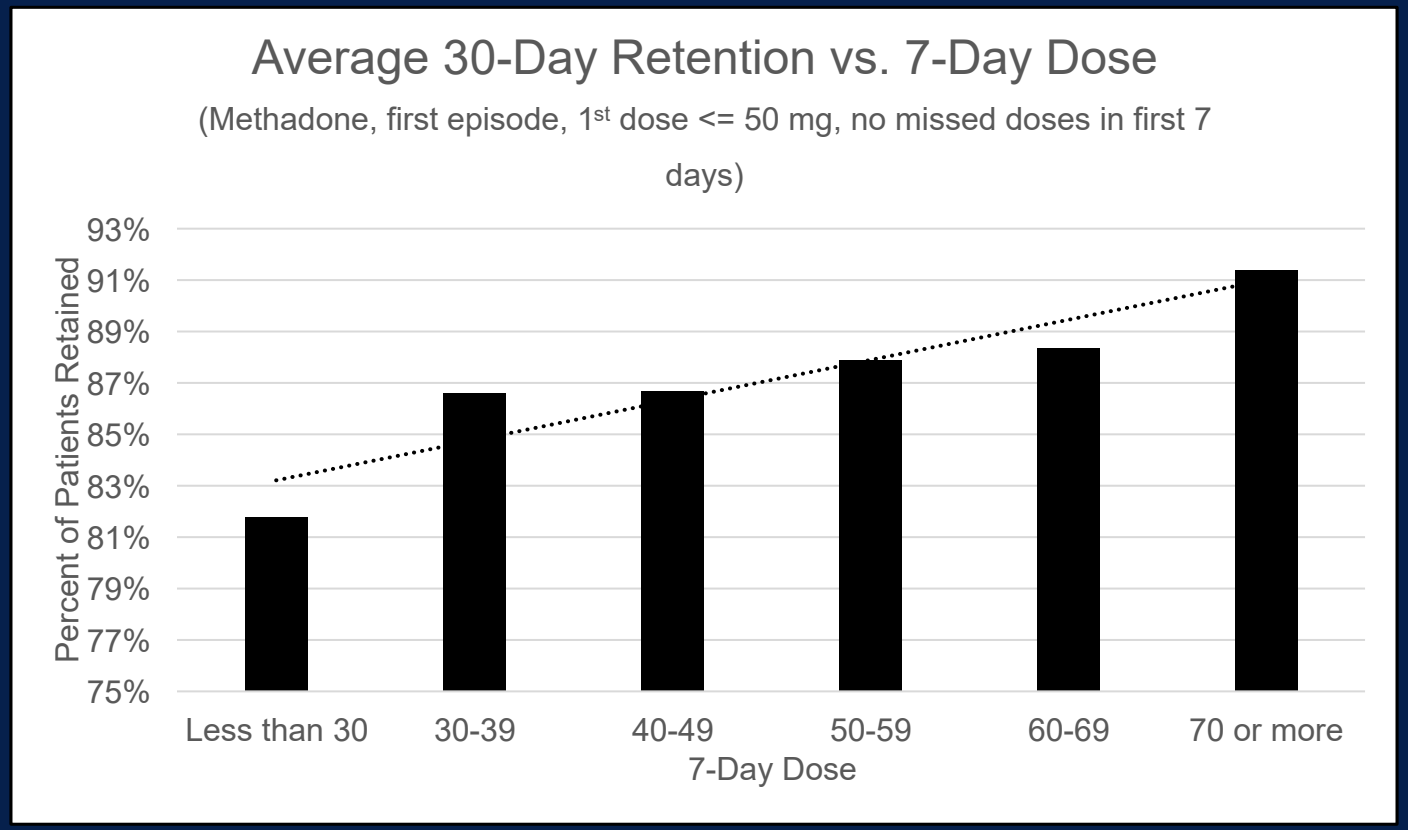
(Internal data from author)

Average Day-7 Methadone Dose - All Clinics



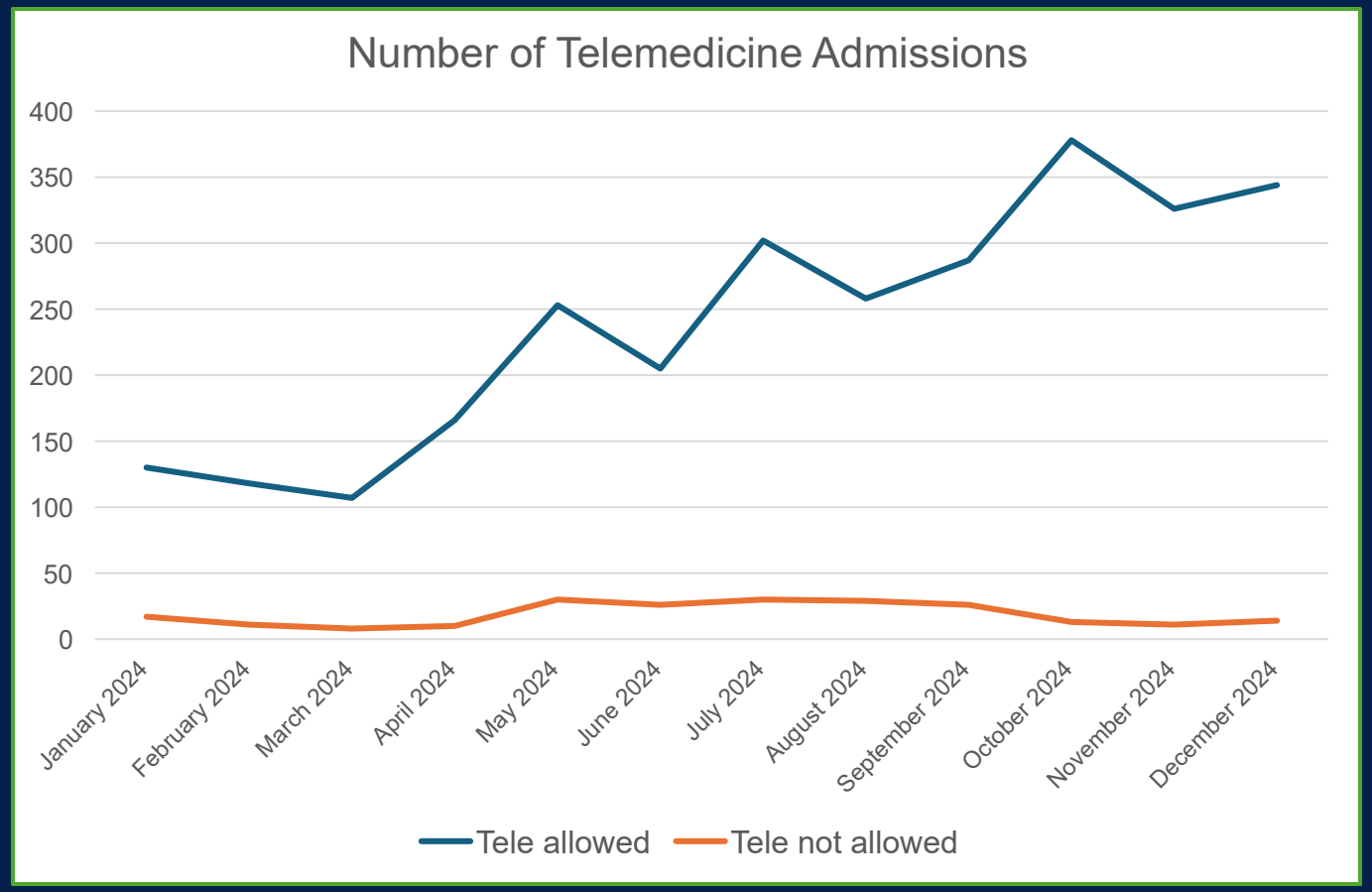
(Internal data from author)

7-Day Dose vs. 30-Day Retention



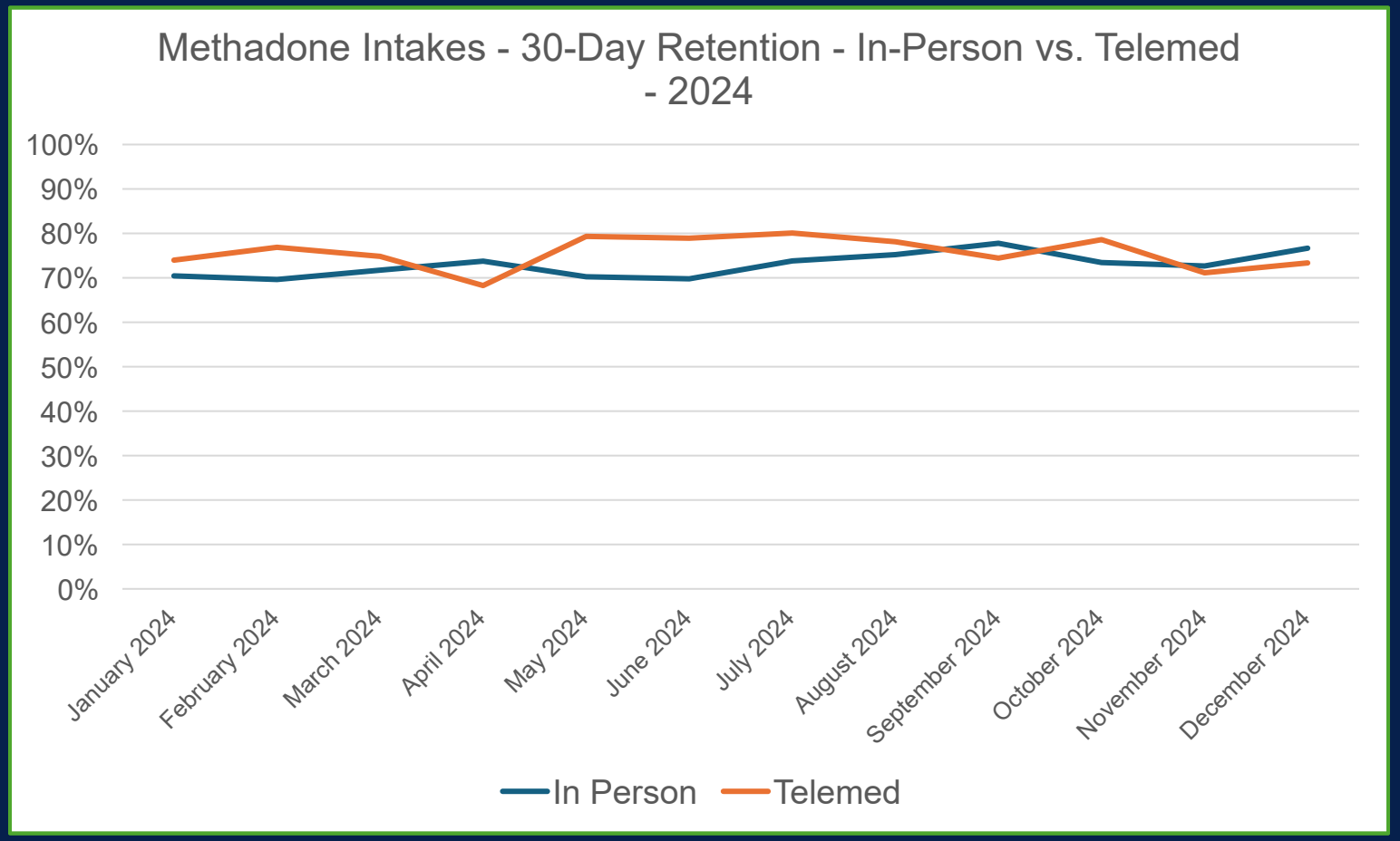
(Sherrick, R, Relationship Between Methadone Induction Dosing and Retention in Treatment in Opioid Treatment Programs, Journal of Addiction Medicine, publication in progress).

Number of Methadone Telemed Intakes by State Group - 2024



(Internal data from author)

Methadone Intakes - 30-Day Retention - In-Person vs. Telemed - 2024



(Internal data from author)

Summary of Outcome Analysis

- Full implementation of extended take-homes can be accomplished in a few weeks.
- Extended take-homes are associated with improved 30-day retention.
- Improvement also shown for long-term patients.
  - More doses per patient per week.
  - Fewer self-discharges.
- No significant increase in abnormal UDS results.
- Telemed intakes can be increased and retention is similar to in-person intakes.
- Initial experience indicates that first day doses can be safely increased above 30 mg.

Impact

"This makes me feel normal, not like a criminal having to 'check in' even when I was doing good."

"I finally got the job I wanted because I don't have to come in here every day now!"

"I tried so many times to make this work, and I couldn't get here every day. This made it so I can succeed."

"Can I just say…Thank you!! You don't know what this has done for my life."

(Quotes from Community Medical Services Patient Advisory Groups)