Methadone: Update on Rules of Access, Dosing, Take-Homes, Etc.

Ari Greenberg, PA-C
Robert Sherrick, MD, DFASAM, Chief Science Officer

Community Medical Services

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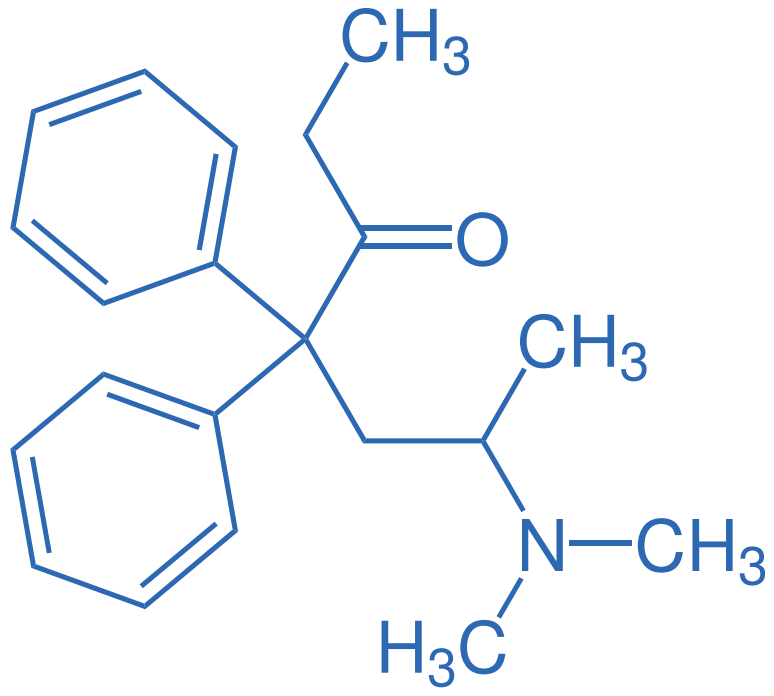
Outline

- Introduction to OTPs and methadone
- Review of regulatory oversight of OTPs
- History of 42 CFR part 8 and nature of the regulations in it
- What changes are in the Final Rule
  - Admission criteria
  - Take-home doses
  - Initial dosing
  - Telemedicine
  - Use of other drugs not affecting patient's risk
  - Split dosing
- How CMS has implemented these changes, esp. in MT
- Early results - retention, missed doses, discharges
- How to expand treatment to more people who need it



What is an OTP?

- Opioid Treatment Program
  - Licensed by SAMHSA and the DEA.
  - Inspected and certified by JCAHO, CARF or similar.
  - The only location outside of a hospital where methadone may be used to treat opioid use disorder or relieve withdrawal symptoms.
  - THE most regulated of any area of medicine in the US.

What does an OTP do?

- Dispenses methadone, buprenorphine, or naltrexone on the order of the medical provider.
- Observed window doses as well as take-home doses may be provided.
- On-site counseling, case management, and peer support.
- Regular urine drug screening required.
- Must comply with all state and federal regulations.

History and Regulation of OTPs

- Where do OTP regulations come from?
- When were they written?
- Who provides oversight to OTPs?

OTP Regulations - Who Regulates OTPs?

- 42 CFR Part 8 - SAMHSA/CSAT
- 42 CFR Part 2 - Confidentiality
- 21 CFR part 1306 - DEA
- State regulations
- State Opioid Treatment Authorities (SOTAs)

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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 was to prevent diversion of methadone
  - Not the primary goal: helping people who use opioids
- The most recent regulatory revision was 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

OTP Regulations - Who Regulates OTPs?

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

The Montana SOTA is Jacky Jandt.

Montana uses the federal guidelines and does not impose additional regulations on OTPs.

SAMHSA Regulations - Prior to the Final Rule

- 1 year of prior use OUD diagnosis required for admission.
- All patients started on daily dosing - coming to the clinic 6 or more days per week.
- Advancing TH levels required abstinence from all drugs and perfect clinic attendance over many months. 9 months of negative UDS results and perfect attendance are required to receive weekly TH level.
- Maximum initial methadone dose was 30 mg.
- Methadone intakes were not permitted via telemedicine (although buprenorphine was allowed, including audio-only).
- Split-dosing and exceptions all required approval from SAMHSA and the state SOTA.
- Testing for syphilis and TB required.
- Minimum of 8 UDS tests per year.

SAMHSA Regulations - the Final Rule

- Fully revised 42 CFR Part 8
- Proposed update published December 2022
- Final Rule released January 31, 2024
- Took effect on April 2, 2024
- Full compliance required by October 2, 2024

Major Changes in the Final Rule

(All Subject to State Regulations)

- Non-stigmatizing and person-centered language
  - "withdrawal management" instead of "detox"
- Change in admission requirements
  - Removal of 1-year requirement
  - OUD in remission or "high risk of recurrence or overdose"
- Quantity of counseling and other services not specified
  - ". . . combination and frequency of services tailored to each individual patient"
- Lab testing not specified
  - "Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner"

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Major Changes in the Final Rule

(All Subject to State Regulations)

- Take-home level changes
  - Initial allowance of up to 7 TH doses
  - More rapid increases
- Methadone induction - first dose up to 50 mg (from 30 mg)
- Split dosing changes - no restrictions on split dosing
- Only other substance use that increases OD risk to the patient is necessary to consider in the take home determination
- Telemedicine admissions allowed
  - Must be live audiovisual for methadone
  - In-person exam required within 14 days
- Patients may opt out of counseling, labs, or other services

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Final Rule - new criteria for take-home doses

- 6 new criteria for TH doses replace the older list:
  - (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; and
  - (vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

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

More Take-Home Doses - Benefits and Risks

Benefits

- More patient autonomy
- Potential for increased treatment retention
- Fewer issues with transportation, childcare, employment
- Potential for increased access to medical, counseling
- 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.

Final Rule – CMS philosophy – Balancing Risks and Benefits

- **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 assessment should precede any dose increases. This mandates that all dose increases occur on clinic dosing days.

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.

The Problem of Diversion

- Diversion can not be prevented and 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.

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

There is little difference from daily up to triweekly, but a large increase when going above triweekly level.

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Take-home level - initial 2 weeks

- Initial take-home level determined by the medical provider at intake - daily, triweekly, or weekly.
  - Most patients qualify for initial triweekly TH level
  - Daily dosing only for those determined unable to safely handle TH doses
  - Weekly dosing for stable patients who will not require close induction monitoring.
- After 14 days may advance 1 level:
  - No more than 1 missed dosing day in the last 14 days
  - No behavioral issues for the last 14 days
  - Last UDS negative for opi, oxy, fent, BZ, and barb (amph, coc, and THC not considered)

Few patients will benefit from daily dosing - even patients with abnormal UDS results and inconsistent dosing may remain at triweekly level.

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Take-home level - after first 14 days

- Patients may be evaluated for advancement every 28 days
- Criteria for advancement:
  - No more than 2 missed dosing days in the last 28 days
  - No behavioral issues for the last 28 days
  - At least 1 valid UDS done since last dose increase and last UDS negative for opi, oxy, fent, BZ, barb (amph, coc, and THC not considered)
  - Up to date on medical follow-up visits
- Patients on >= 200 mg of methadone maximum TH level is bimonthly

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Reasons for daily TH level

- Proven diversion
- Failed medication call back
- Attempt to divert at the window
- Observed or reported sedation and concerns about patient safety (requires team discussion)
- Unable to store medication safely (e.g., pediatric poisoning)
- Lost 6 or more doses
- Concerns about patient's ability to safely self-administer TH doses (i.e., memory issues, SMI – requires team discussion and decision that daily dosing provides maximum benefit to pt)

- Patients are eligible to return to triweekly after 1 week on daily THs
  - Only if the original issue has resolved and no other incidents
- Treatment team must agree that the benefits outweigh the burden to the patient of daily dosing

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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.

Outside prescriptions

- UDS positive for prescribed medications are not considered abnormal
- Patients with prescriptions for benzodiazepines, Z-drugs, or other controlled sedatives are not eligible for TH level above bimonthly
- Short-term prescriptions for other opioids are allowed when clinically appropriate
- Chronic opioid prescriptions are not allowed and may be grounds for a Treatment Notification and/or suspension if continued after warning

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Methadone induction dosing

- First dose determined by the medical provider based on initial evaluation
  - Dose between 1 and 50 mg (where allowed)
  - If state regulations restrict the first day dose to 30 mg, the 2nd day dose may be increased up to 50 mg if ordered by the medical provider
  - Higher doses only for those with assessed tolerance
- Dose increases may be ordered over the first week
  - Dose increases only on clinic dosing days
  - Most patients will be admitted on triweekly dosing
  - Patients may come in on additional days if needed for dose adjustments
- Maximum dose at 7 days - 80 mg
  - This level only for those with established tolerance
  - Further dose increases require follow-up medical visit
- Dosing after the first week
  - After 7 days, prior dose increase guidelines apply (5-10 mg every 3-5 days)

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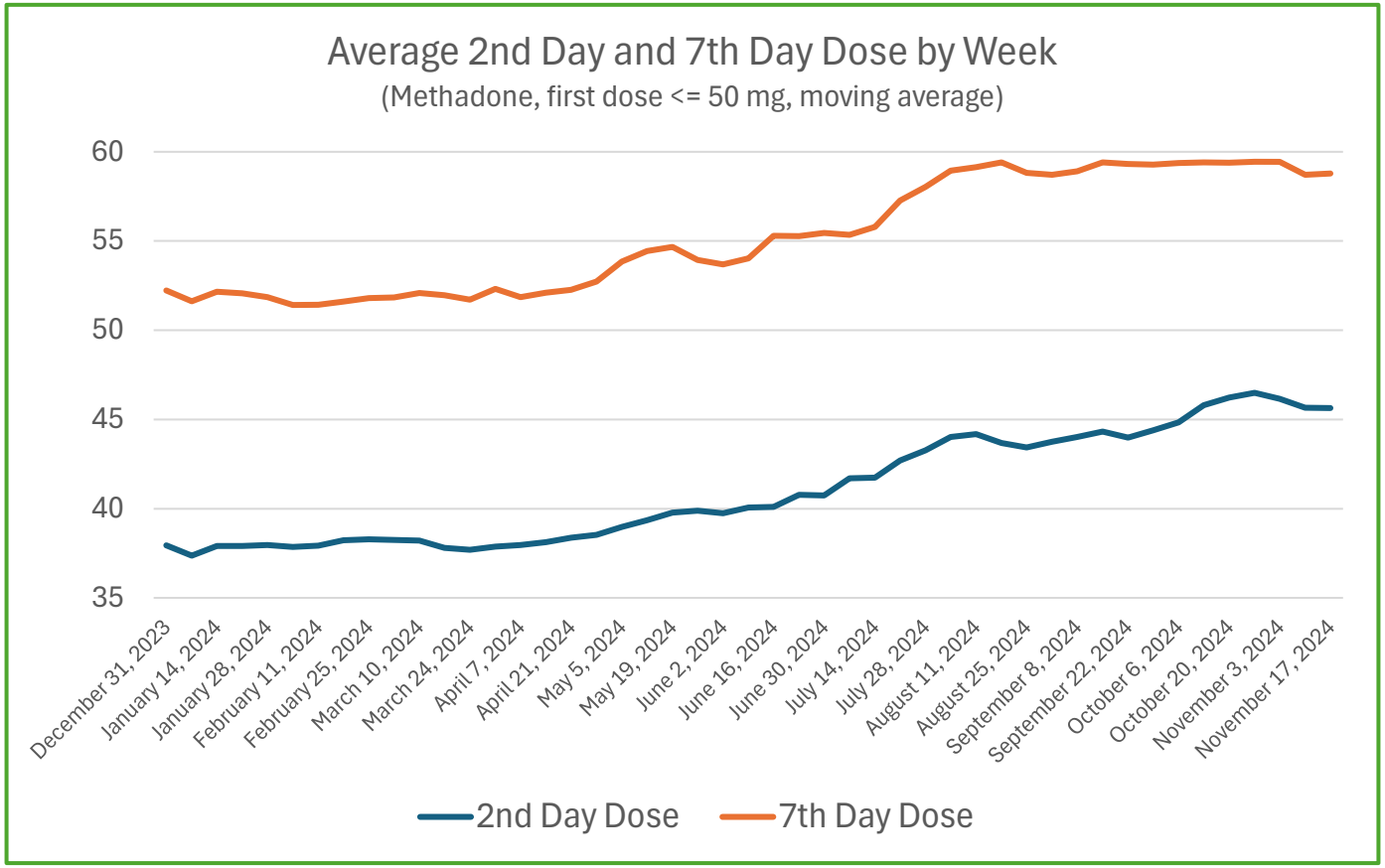
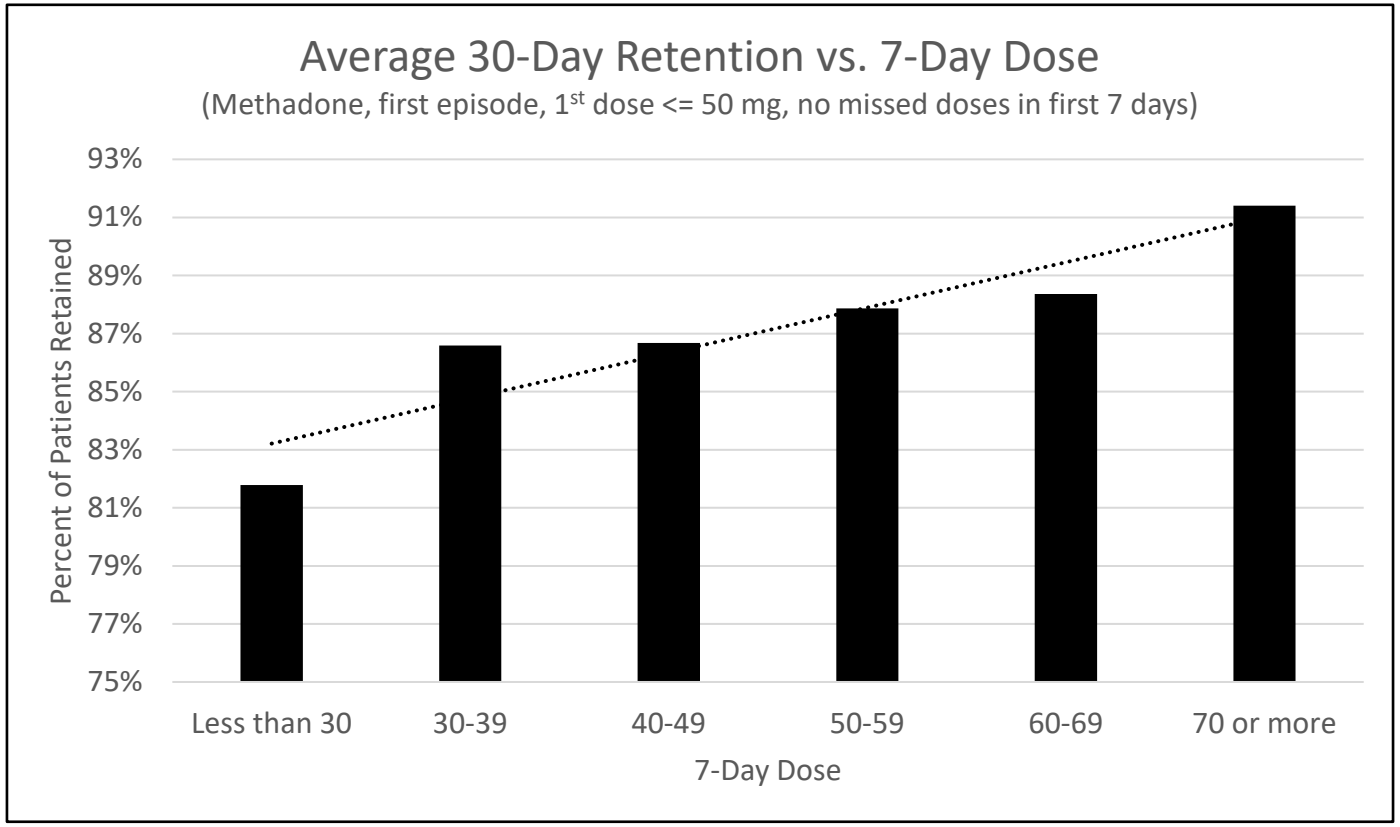
Average 2nd Day Dose 2024



The average 2nd day and 7th day dose have been increasing across all clinics

Average 7th Day Dose 2024

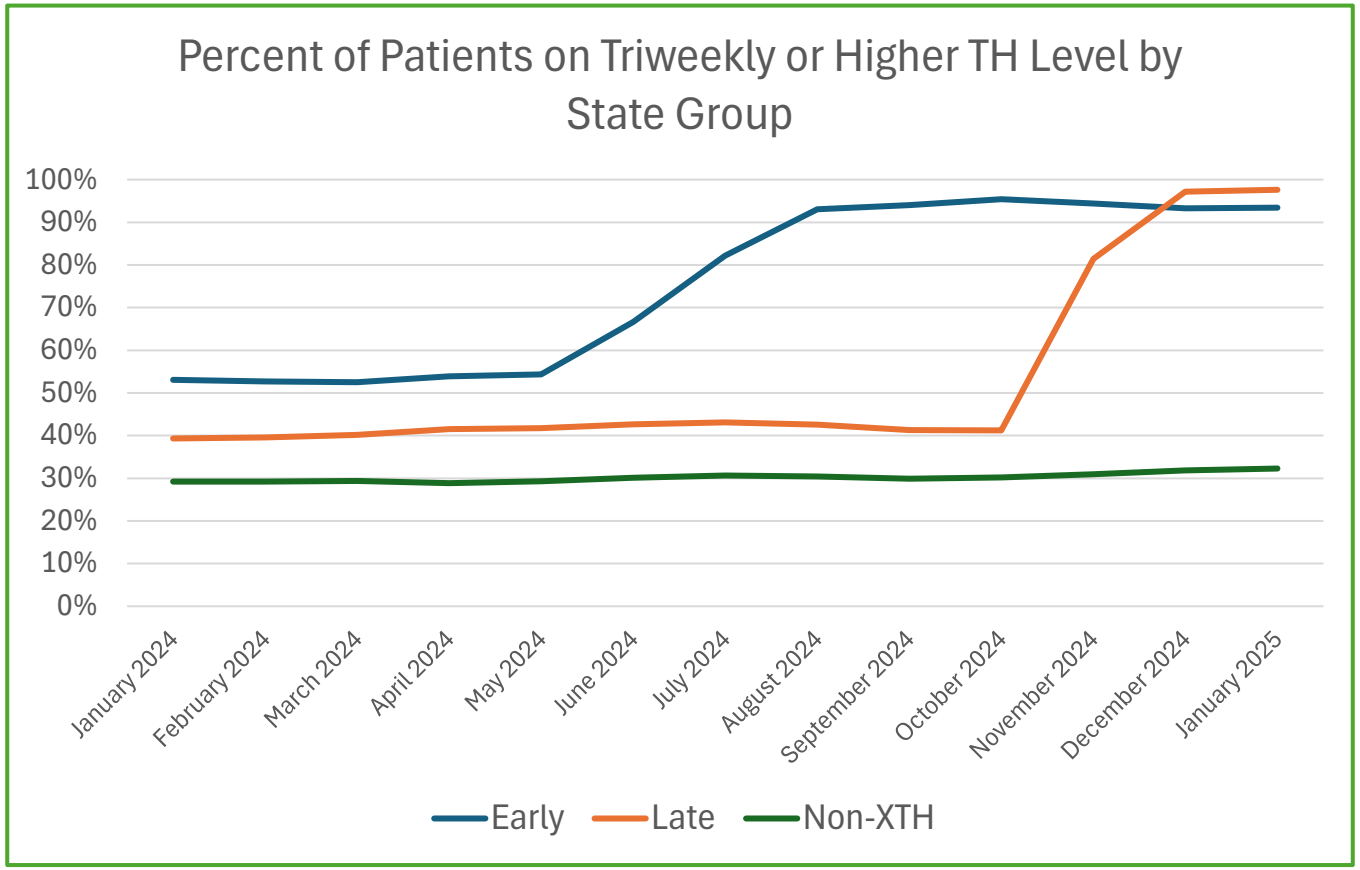


The 30-day retention is higher with higher 7-day doses

Implementing the Final Rule – Extended Take-Home Doses

- Implementation by state – due to differences in state regulations
  - Early phase – June-July 2024 – 5 states (CO, OH, MN, MT, TX)
  - Late phase – October 2024 – 3 states (AZ, MI, ND)
  - XTH not yet allowed – 4 states (AK, IN, OR, WI)
- Policies and Work Instructions revised and published
- Multiple training sessions scheduled for counselors, nurses, medical providers
- The largest change is in patients below triweekly level – most were increased to triweekly
- Individual change forms filled in during counseling sessions

Percent of Doses Triweekly or Higher Level

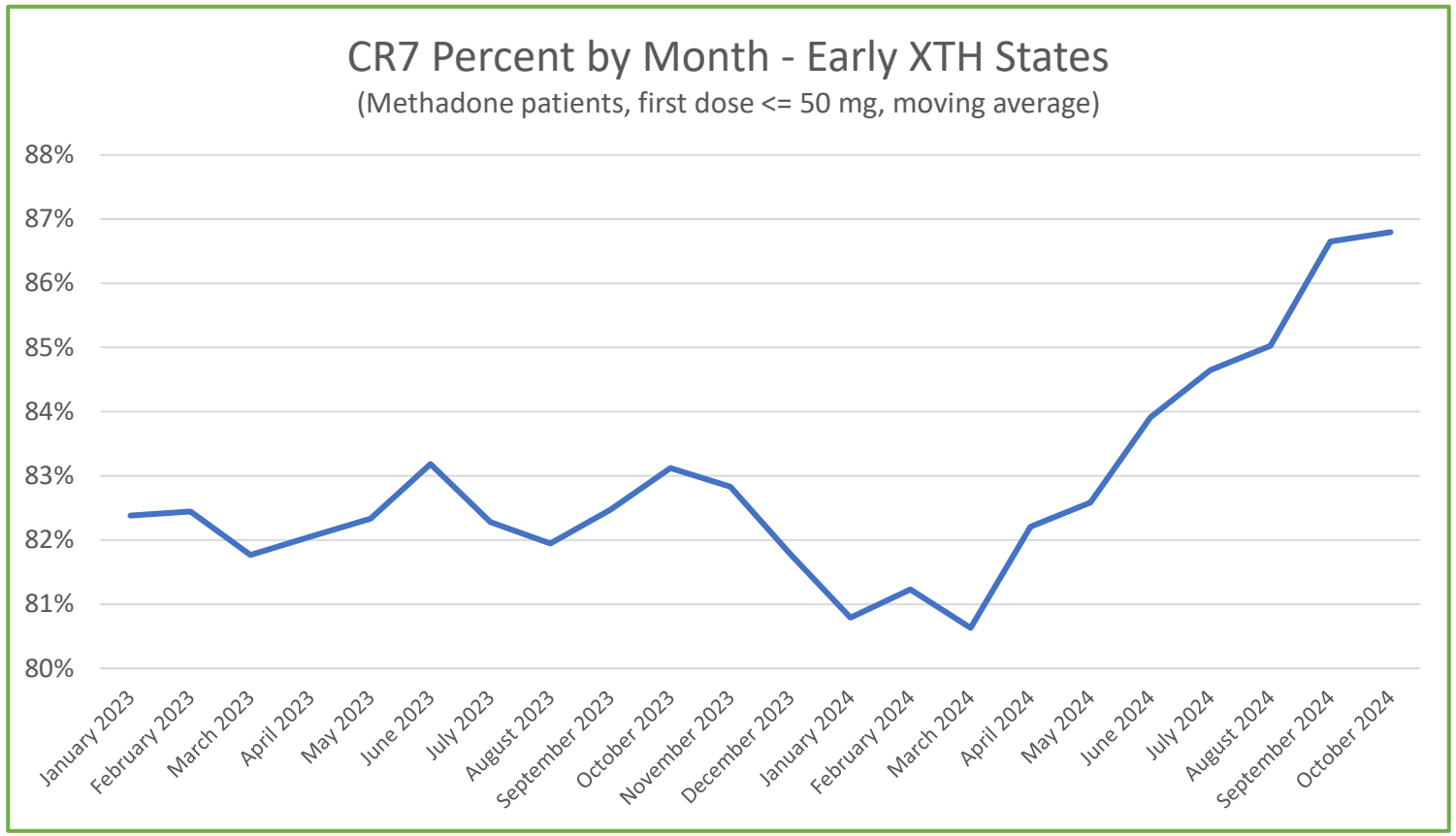


The percentage of doses at triweekly level or higher increased to over 90% within a few months of implementation in states where allowed.

Extended Take-Home Doses – Initial Responses

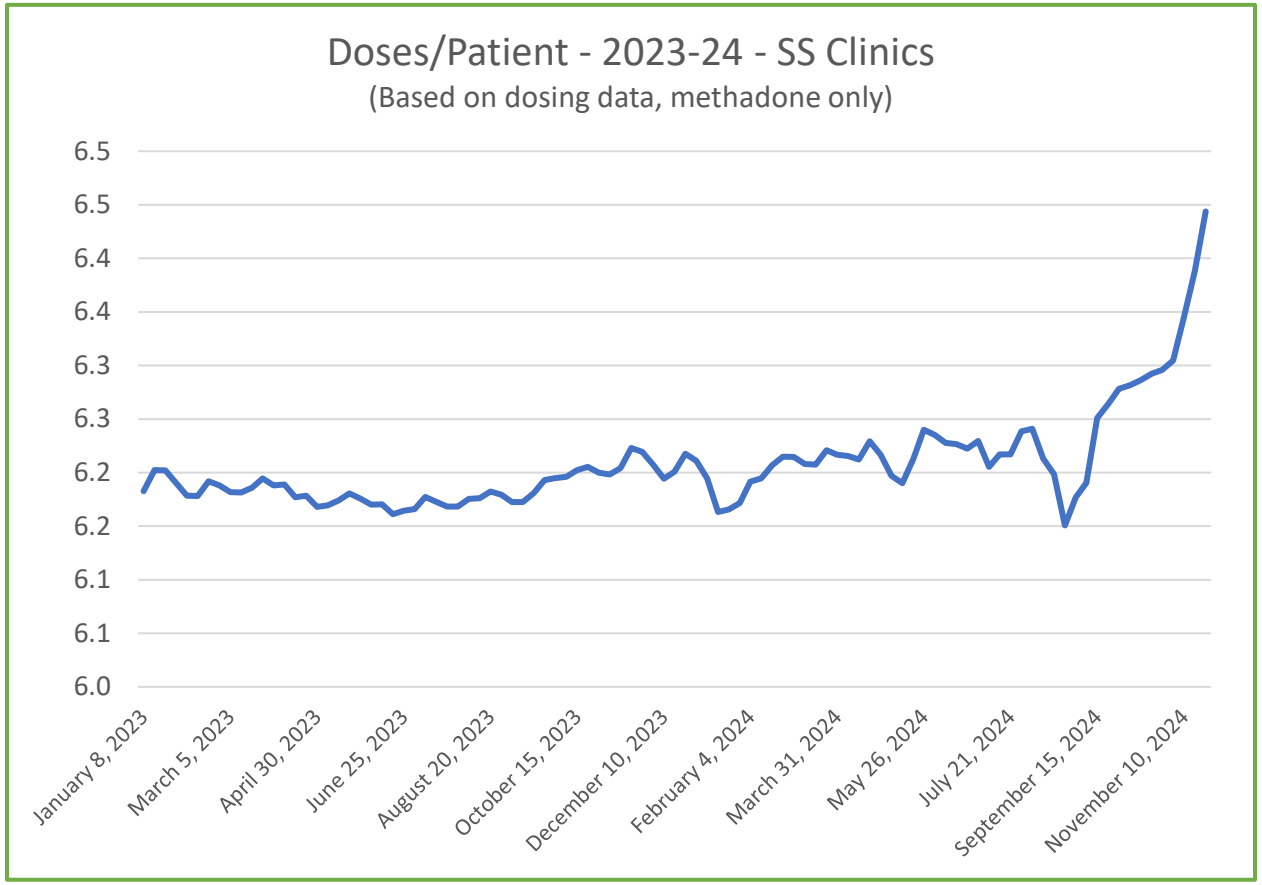
- Some initial concerns from counselors and medical providers
  - Concerns about certain patients getting take homes who had been on daily dosing for a long time
  - Concerns about possible increase in diversion, illicit drug use
  - Changing policies that have been in place for years can be difficult
- Overall response strongly positive
  - Staff felt that with few exceptions, patients did much better with XTHs
  - Patients were very pleased to have more take home doses
- No significant change in average clinic UDS results
- No reported adverse outcomes

Retention Before vs. After XTHs – Early Implementation States



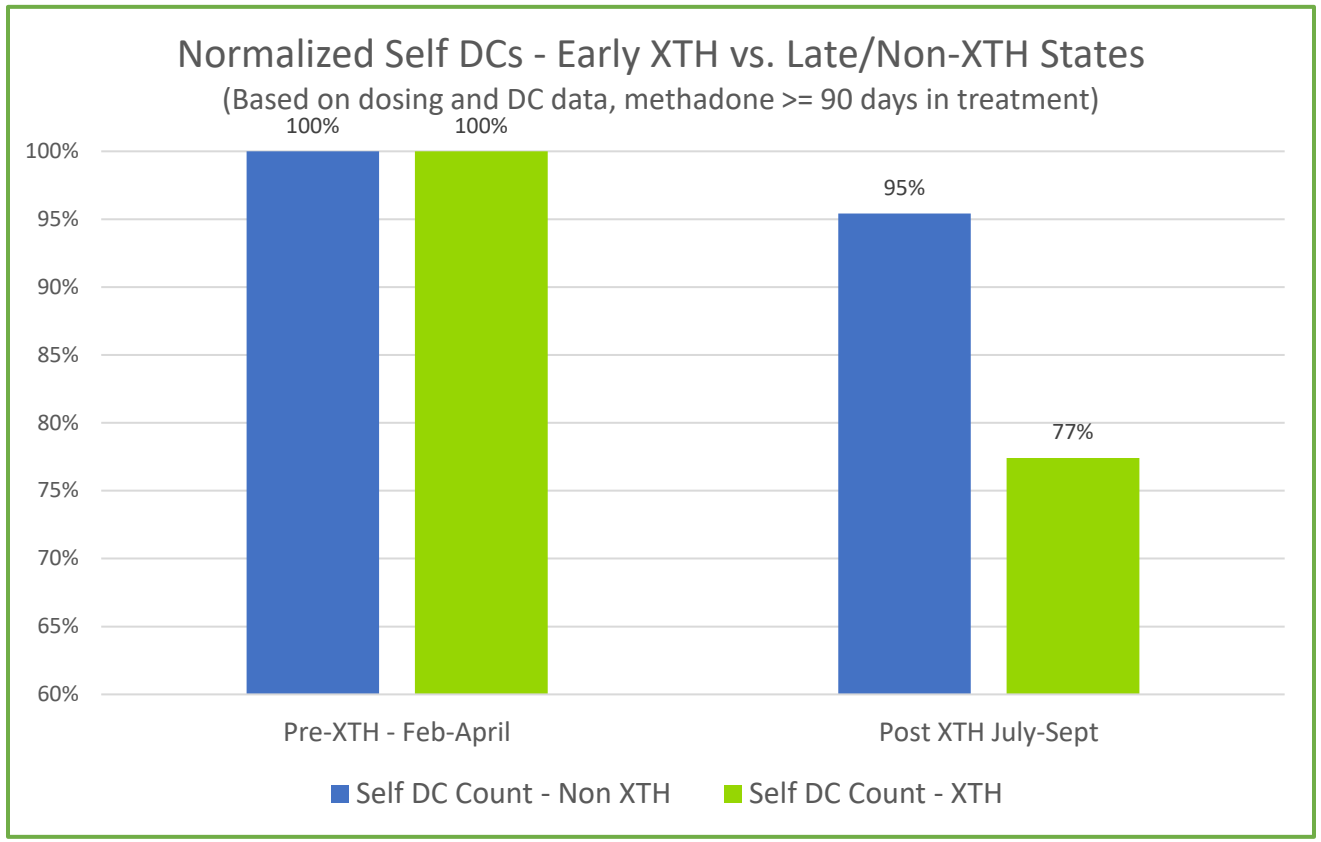
The CR7 Percent (% of doses taken during first week of treatment) improved after XTH implementation

Average Doses/Patient per Week



The change in average doses/week per patient is remarkable when compared to the long-term stability of this measure

Self-Discharges per Week



AWOL discharges decreased by 23% in XTH states, compared with 5% in other states

Final Rule Implementation – Outcomes Summary

- No significant change in average clinic UDS results
- No reported adverse outcomes
- Improved retention in treatment for admissions/readmissions
- Improvement also shown for long-term patients
  - More doses per patient per week
  - Fewer self-discharges

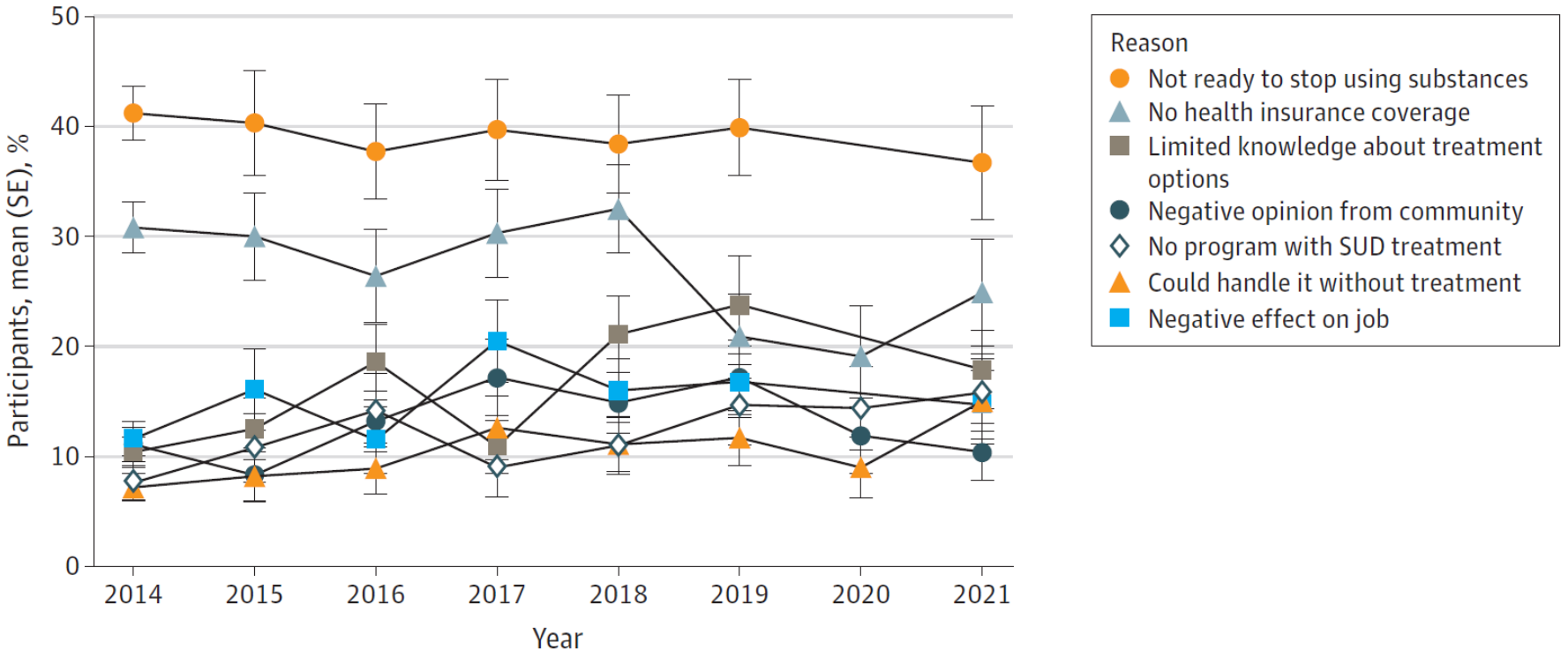
Most people who need OUD treatment do not get it

- For all SUDs, prevalence increased from 8.2% to 17.1% from 2013 to 2023.
  - OUD prevalence more than doubled from 0.8% to 2.0%
  - AUD from 6.6% to 10.2%
  - DUD from 2.6% to 9.6%
- Only 18.3% of PWOUD received treatment in 2022.
  - AUD treatment rate was 7.6% and DUD was 13.1% in 2022.
- Of those who did not receive treatment, only 5.7% perceived a need for it.
  - Of these less than half made efforts to seek treatment

Liu L, Zhang C, Nahata MC. Trends in Treatment Need and Receipt for Substance Use Disorders in the US. JAMA Netw Open. 2025;8(1):e2453317. doi:10.1001/jamanetworkopen.2024.53317

Why do people who need SUD treatment not ask for it?

Figure 2. Reasons for Not Receiving Treatment



Most of these issues can be addressed by education and outreach.

Liu L, Zhang C, Nahata MC. Trends in Treatment Need and Receipt for Substance Use Disorders in the US. JAMA Netw Open. 2025;8(1):e2453317. doi:10.1001/jamanetworkopen.2024.53317

What people need to know about methadone treatment

- While abstinence may be a final goal, it is not required, and everyone is welcome whether they are ready to stop using or not.
  - We do not discharge patients on the basis of UDS results
- Most patients only need to come to the clinic 3 days a week to start out.
  - Patients can move to weekly clinic visits after 2 weeks if doing well
  - Clinic hours are designed to allow people to continue with work and other normal activities
  - Wait times for dosing are usually < 5 minutes
- Financial issues should not be a barrier
  - Many patients on or eligible for Medicaid (note: Medicaid expansion critical to maintain access)
  - Treatment can be started with no initial payment
  - Out-of-pocket cost is much less than obtaining street drugs
- MOUD is still not widely understood and remains stigmatized - even among PWOUDs.
  - Much more public outreach and education needed

Why Should Providers Be Involved?

- We are the front line in the fight against overdoses.
- Providers, patients, and their families need more correct information about SUDs and their treatment.
- Not being ready for treatment is not a barrier to education.
- We need to help more people access life-saving treatment for OUD.