Federal Update: Medications for Opioid Use Disorders

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CEO, Community Medical Services

11th Annual California Addiction Conference

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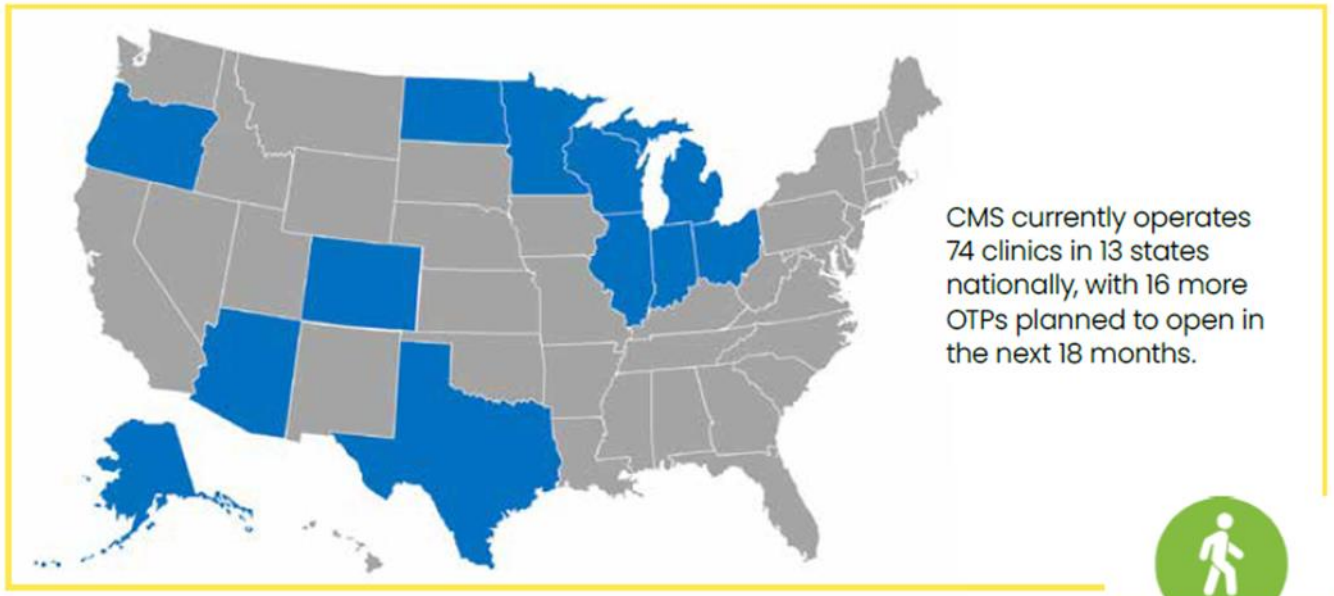
Connecting Recovery | Healing Communities

Company Intro: CMS



CMS currently operates 74 clinics in 13 states nationally, with 16 more OTPs planned to open in the next 18 months.

WALK-INS WELCOME

Whole Person Care (services vary by clinic)

- Hep-C Testing & Treatment
- HIV Testing & Treatment
- Peer Support Services
- Telehealth Behavioral Health
- Wound Care
- Psychiatric Services
- Group Therapy
- IOP
- Yoga
- Recovery Gym
- Mobile Methadone
- Prison, In-Patient Deliveries
- Prison Co-Locations
- Health-Home Care Coordination

Opioid Treatment on Demand (OTOD)

CMS believes in breaking down barriers to care. That's why we were the first in the nation to offer a 24/7 clinic, located in Phoenix, AZ.

Our Opioid Treatment on Demand (OTOD) model is uniquely positioned to provide community support by expanding hours beyond the traditional treatment model. Our clinics welcome walk-in intakes and offer extended operating hours allowing more convenient access for clients seeking care.

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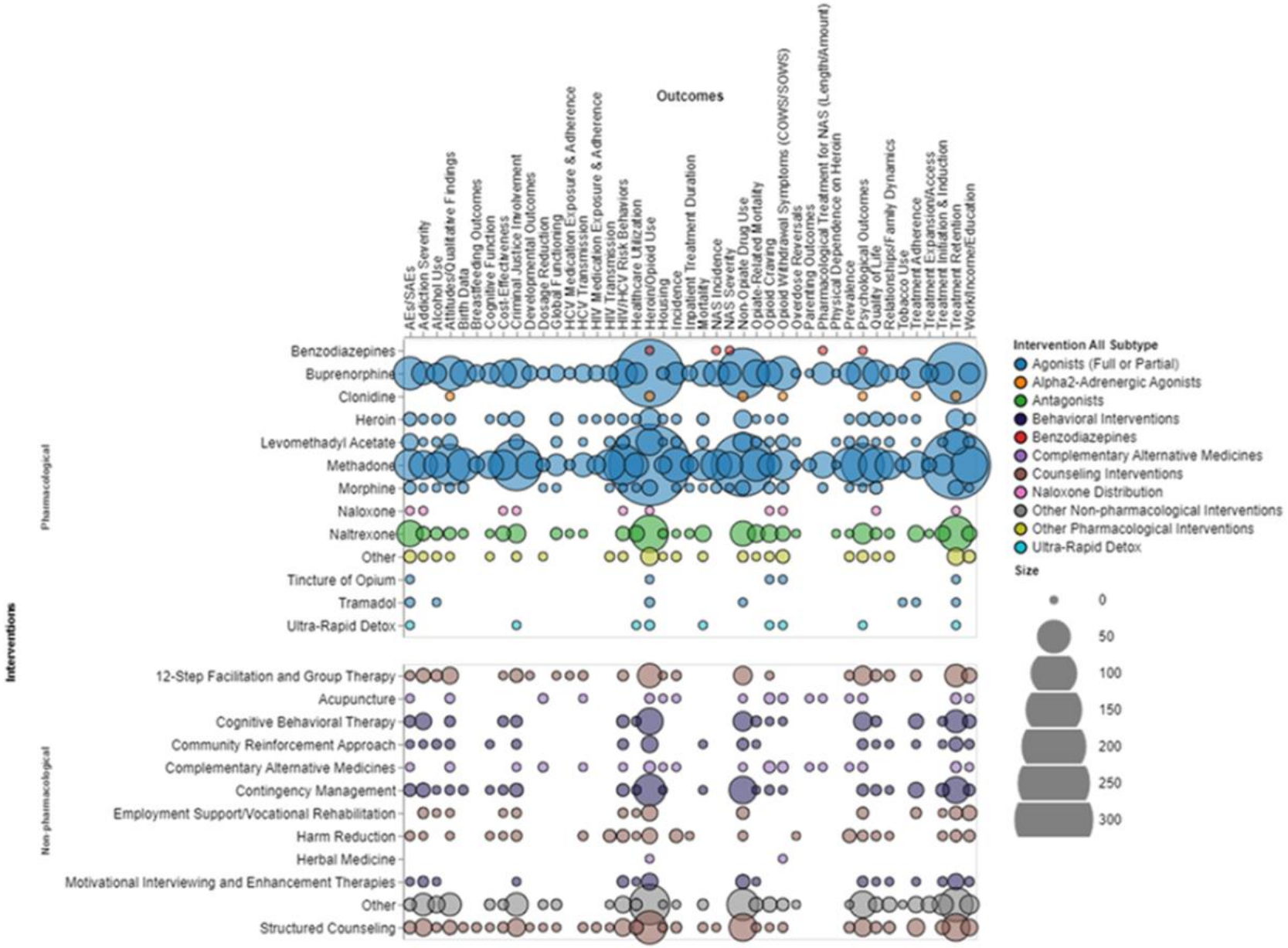
Intro to MOUD

Why MOUD: Evidence Map



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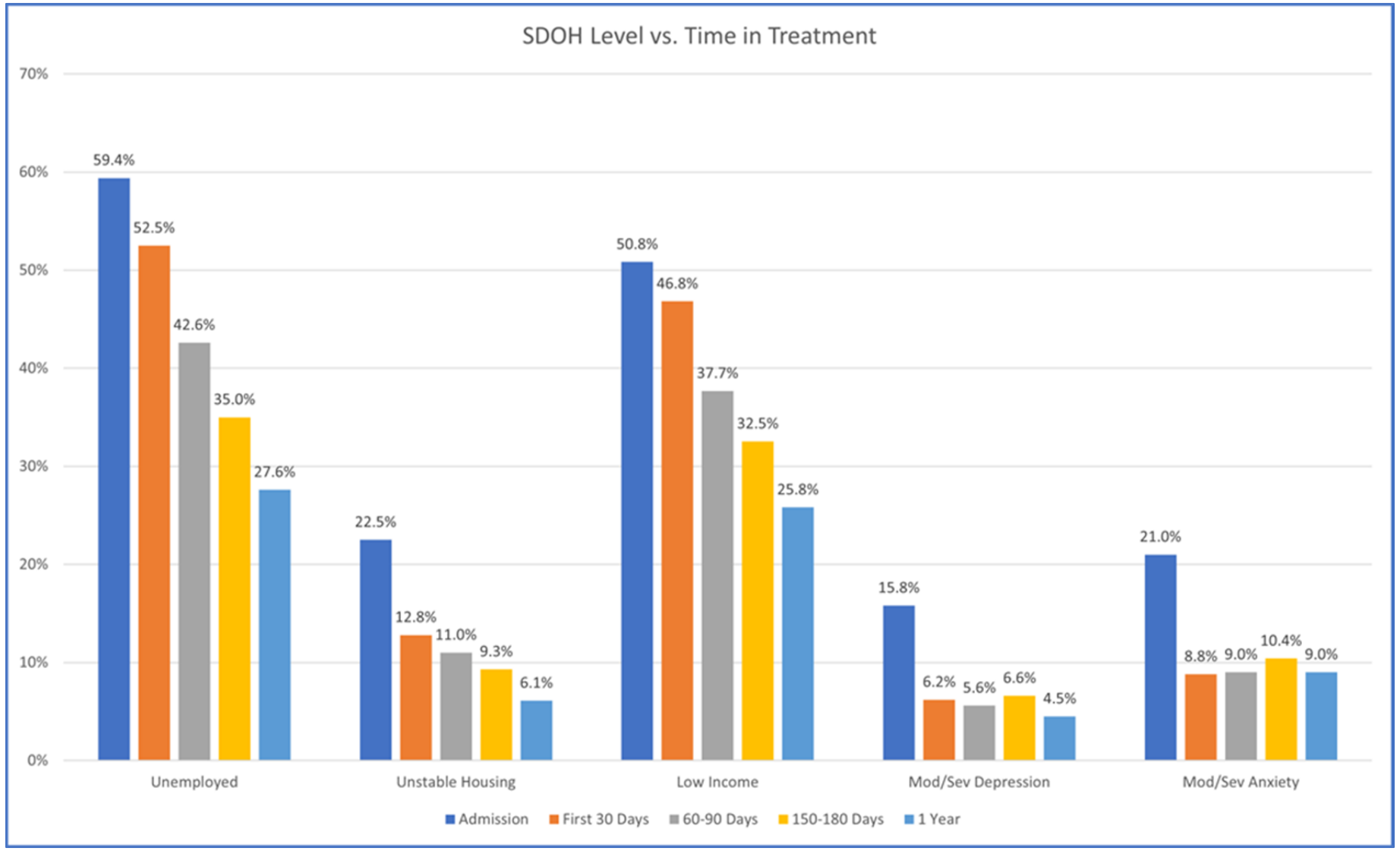
CMS SDOH Data



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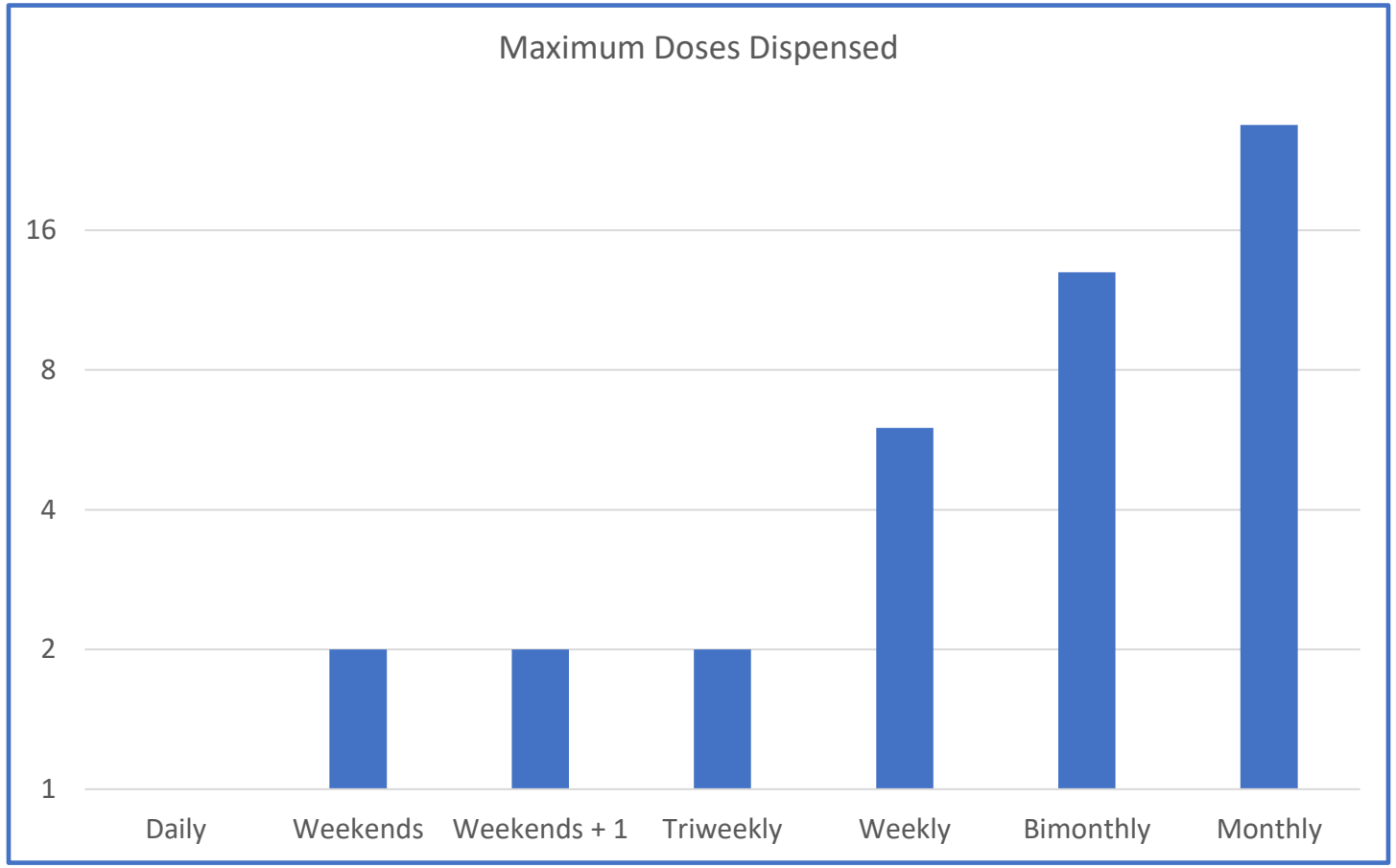
42 CFR 8.12 Changes

Final Rule - New Criteria for Take-Home Doses

- 6 new criteria for TH doses replace the older list of 9
  - "(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."
- Patients may receive 7 take home doses on day 1, 14 take home doses on day 15, and 28 doses on day 31
- CMS is not allowing the maximum THs under the Final Rule but will be changing our current policies

Why Triweekly Was Chosen for the “Floor”



Final Rule – CMS Philosophy

- Need to balance patient safety with lower barriers to care.
- Nursing assessment to precede any dose increases.
- Patients on weekends, weekends+1, or triweekly all take home up to 2 doses at once – there is little difference in patient safety among these levels, so they are combined into one level (triweekly).
- When patients go from triweekly to weekly level, they go from 2 to 6 take-home doses at once – a large increment.
- Transitioning from weekly to bimonthly to monthly likely has minimal risk difference, since the patient is taking home enough methadone at one time to be fatal if taken all at once.
- Patients are generally wanting more take-homes.

Take-Home Level – Initial 4 Weeks

- All patients admitted to triweekly level or higher - M-W-F dosing
  - New “floor” of triweekly TH level
  - Daily dosing only for those determined unable to safely handle any TH doses
- 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)
- After 28 or more days may advance 1 level:
  - 28 days or more of treatment
  - 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 admission, within last 28 days, and last UDS negative for opi, oxy, fent, BZ, barb (amph, coc, and THC not considered)

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Take-Home Level – After First 28 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

- Missed dosing days
  - ❑ 1 day counted for each day the patient comes in on non-dosing day
  - ❑ If patient misses day, they are dosed in clinic and dispensed TH doses to last until the next scheduled clinic dosing day
  - ❑ If a patient misses more than 2 days in a row, decrease 1 level to a minimum of triweekly
  - ❑ During dose re-titration, TH doses may increase per protocol and TH triweekly until stable dose is attained
  - ❑ If patient misses 5 or more dosing days in a row, decrease to triweekly

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Patients Admitted on Weekly TH Level

- Patients may be started on weekly TH level per the discretion of the medical provider using shared decision-making with the patient
- Must stay on the same dose for the first week - the same as the first day
- Dosed in clinic and dispensed 6 TH doses
- Maximum dose 40 mg
- Medical provider follow-up visit required for any dose increases above initial amount

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Reduction in Take-Homes

- Reduction to 1 level, Minimum Triweekly:
  - ❑ Abnormal UDS for opi, oxy, fent, BZ or barb (amph, coc, and THC not considered)
  - ❑ Behavioral issues in the clinic
  - ❑ Missing more than 2 dosing days in a row (i.e., comes in 3 or more days late)
  - ❑ Lost doses up to 5 (replacement doses on triweekly dosing)

- Daily Take-Home Guidance:
  - ❑ 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)

- Additional Considerations:
  - ❑ Patients with abnormal UDS results / missing dose days will continue triweekly level
  - ❑ Exceptions for daily dosing only for specific cases and usually temporary
  - ❑ Patients are eligible to return to triweekly after 1 week on daily THs, only if the original issue has resolved and no other incidents

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Medication Call Backs

- MCBs will continue but only on a random basis
  - MCB not required to advance level
  - Failed MCB results in daily TH level
  - May go to triweekly after 1 week on daily
  - Further advances per usual policies
  - Buprenorphine patients will no longer have random MCB though MCBs may be ordered if diversion is suspected
  - Buprenorphine patients dispensed in the clinic will not be required to take a dose at the window

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Dose Changes

- All dose changes must happen on a clinic dosing day
  - ❑ Nursing evaluation at the window prior to dose increase
  - ❑ All take-home doses given must be the same amount
  - ❑ Take home doses must be the same amount as the last clinic dose
- Exception for those on clinic absence or administrative taper protocol
  - ❑ Take home doses may be increased per protocol
  - ❑ Maximum TH level triweekly during re-titration

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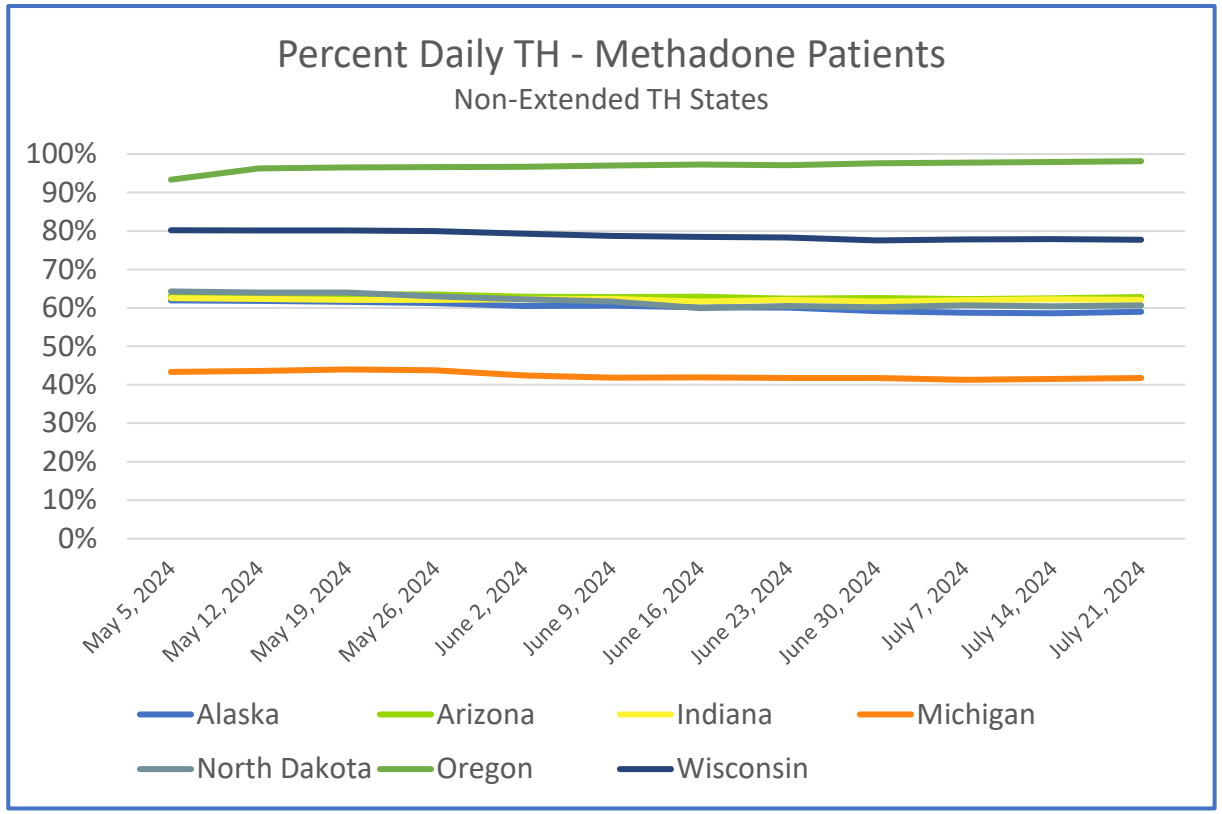
Preliminary Findings

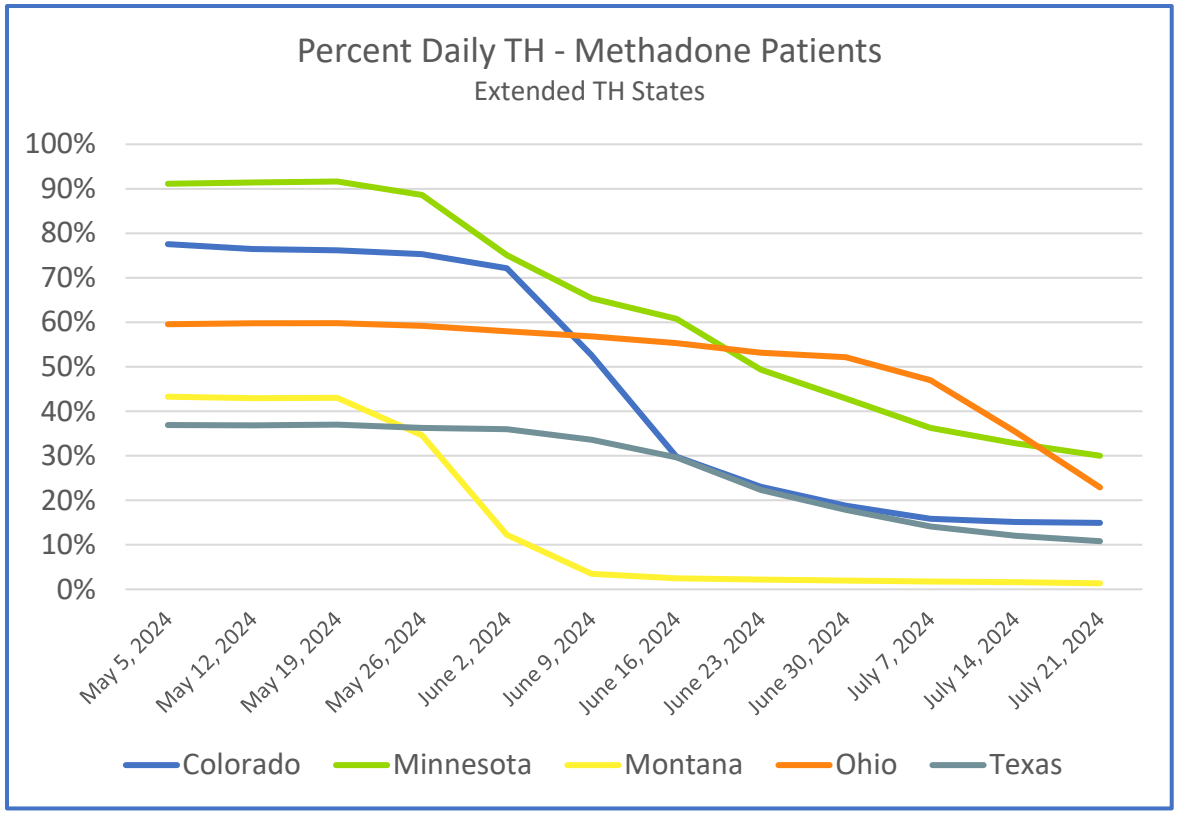
Federal Regulation Adoption by State

State	Telehealth Intakes (Methadone)	50mg Inductions	Extended Take-homes
AK	Yes	Yes	No
AZ	Hold-SOTA	Hold-SOTA	Hold-SOTA
CO	Yes	Yes	Yes
IN	Hold-SOTA	No	No
MI	Yes	Yes	No
MN	Yes	Yes	Yes
MT	Yes	Yes	Yes
ND	Yes	No	No
OH	Yes	Yes	Yes
OR	Yes	No	No
TX	No	No	Yes
WA	Yes	No	No
WI	Yes	No	No

Arizona is on temporary hold until 10/1 per SOTA
Indiana SOTA citing "physical" in-person for tele-methadone induction
Texas is the only state with face-to-face requirements for methadone induction

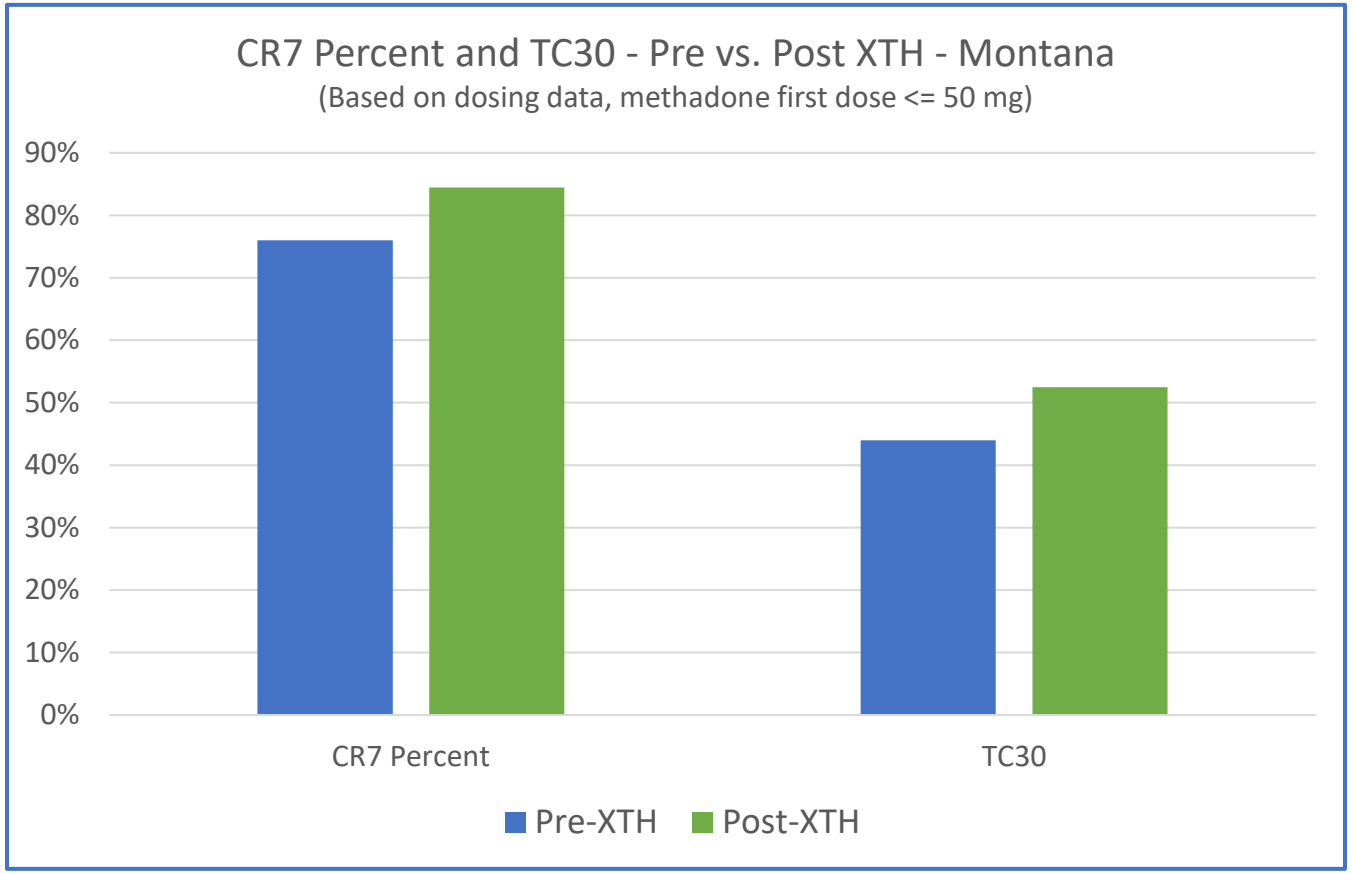
Implementation of Extended Take Home Levels





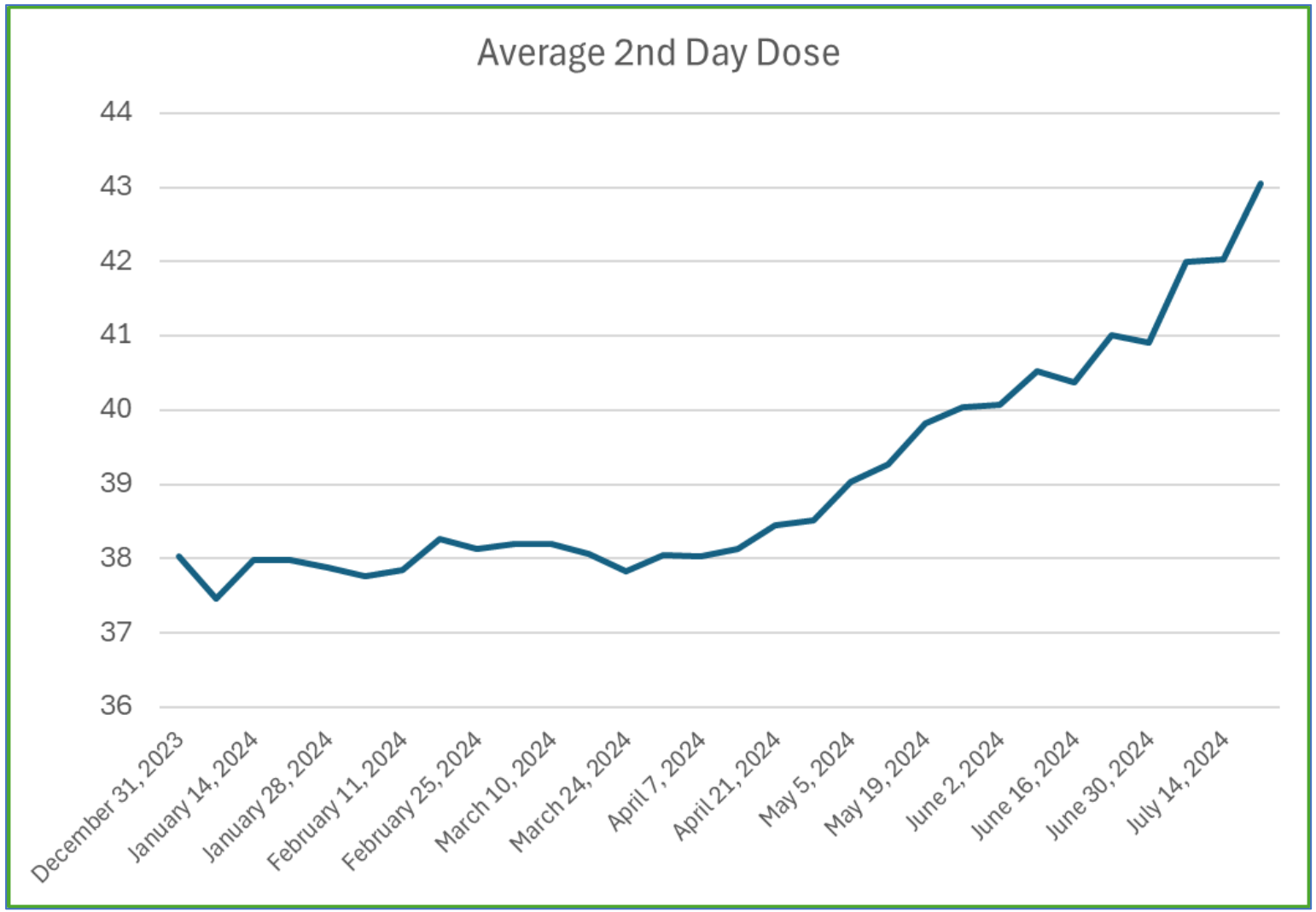
Key Points: Extended take-home policies have had a large effect in most states where they have been implemented.

Average CR7 and TC30 – Pre vs. Post XTH - Montana



Key Points: Early retention improves with more initial take-home doses

Average 2nd Day Dose



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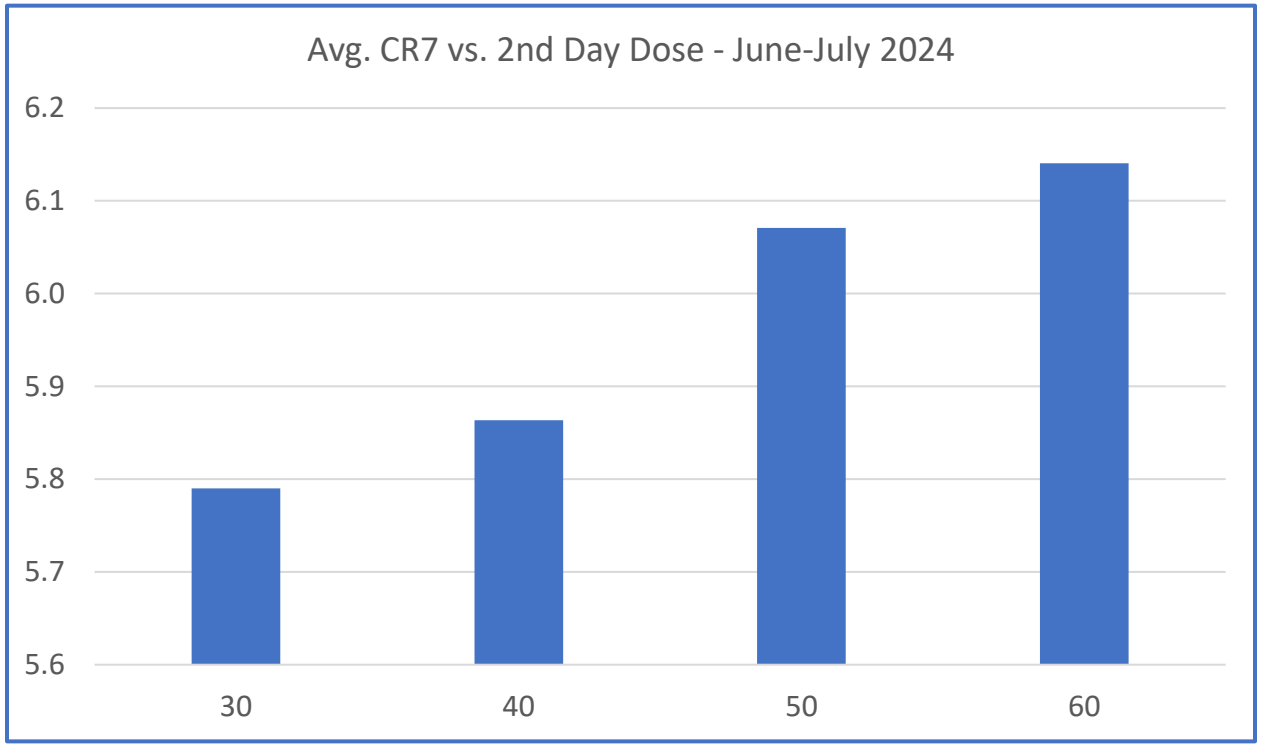
Average CR7 vs. 2nd Day Dose



Key Points: Early retention improves with higher initial dosing

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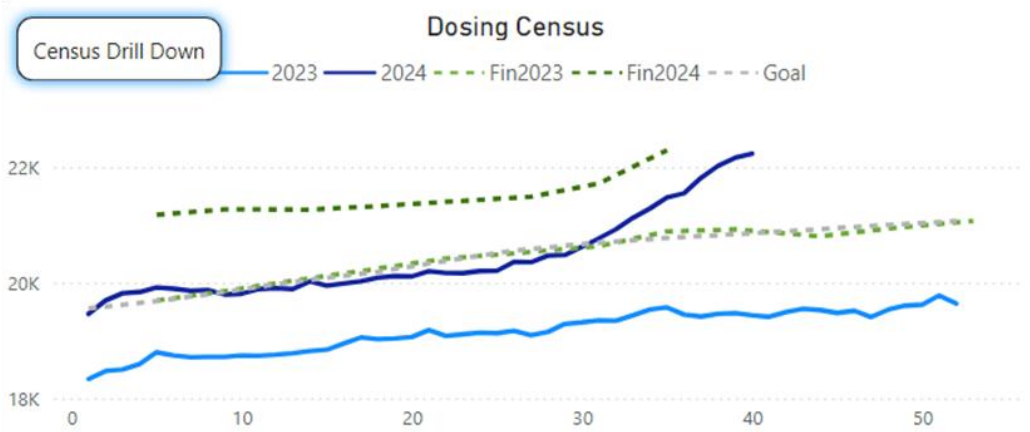
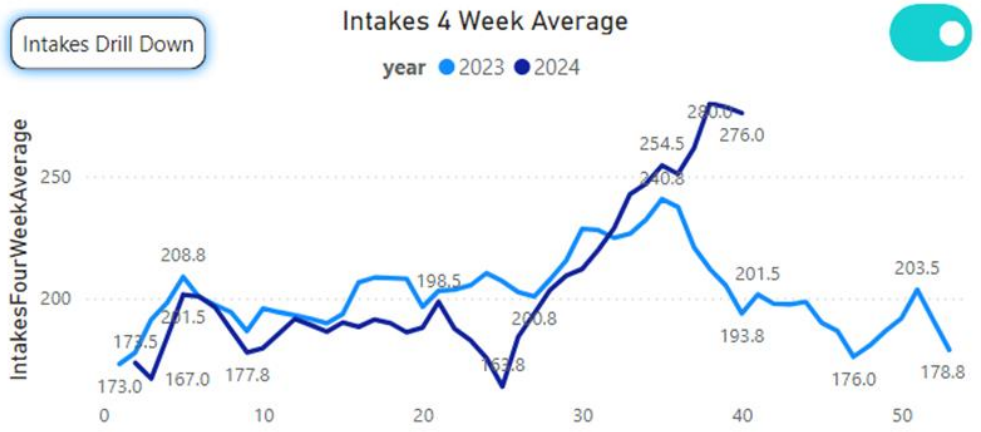
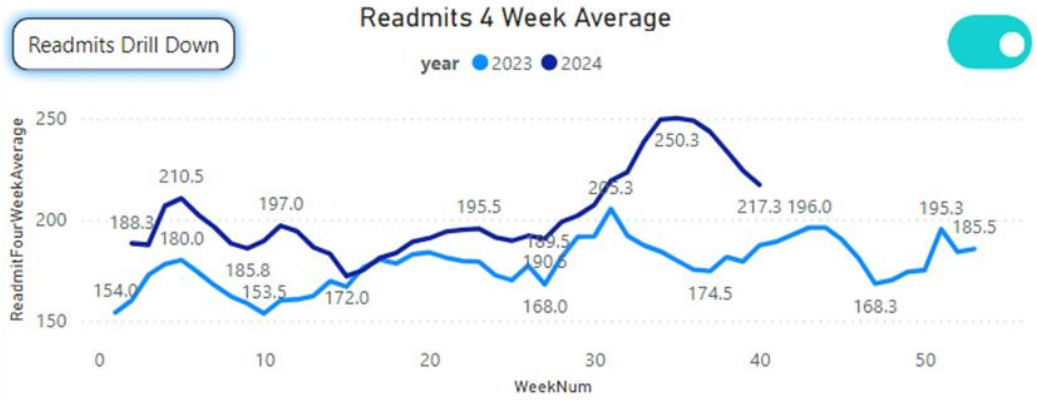
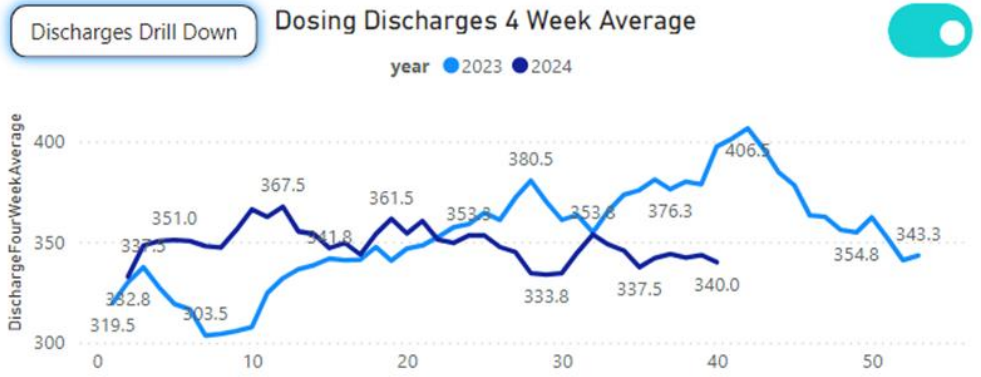
Additional Data Trends

Patient Census Trends









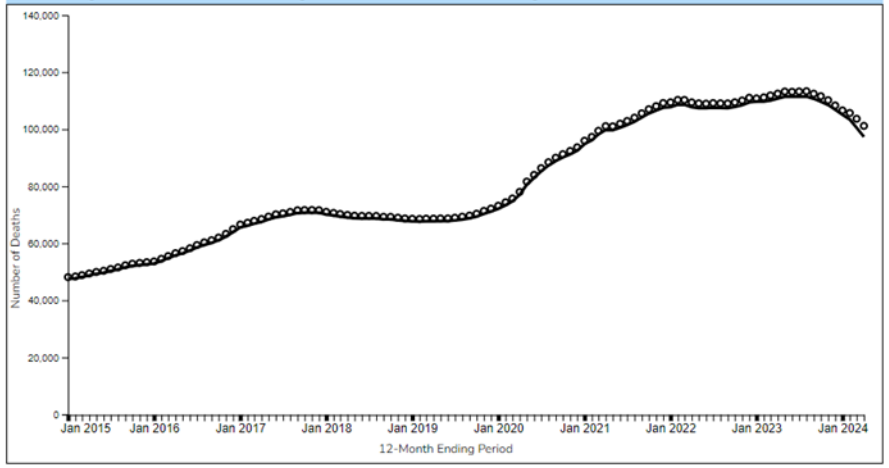
Key Points: Census is increasing as a result of Intake Rates increasing and discharge rates decreasing

What is going on?

12 Month-ending Provisional Number and Percent Change of Drug Overdose Deaths

Based on data available for analysis on: September 1, 2024

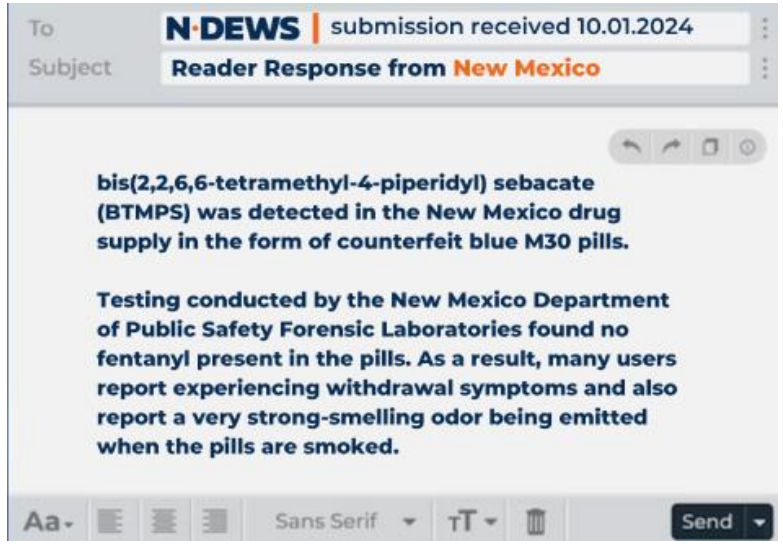
Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: United States



Are Mexican drug cartels and their Chinese partners finally feeling pressure?

Jen Daskal (center), a deputy assistant to President Biden on the National Security Council who focuses on fentanyl policy, walks next to Xu Datong (right), director of China's Narcotic Control Bureau, after a launch ceremony of the U.S.-China Counternarcotics Working Group in Beijing on Jan. 30.

Ng Han Guan/Pool/AFP via Getty Images/AFP



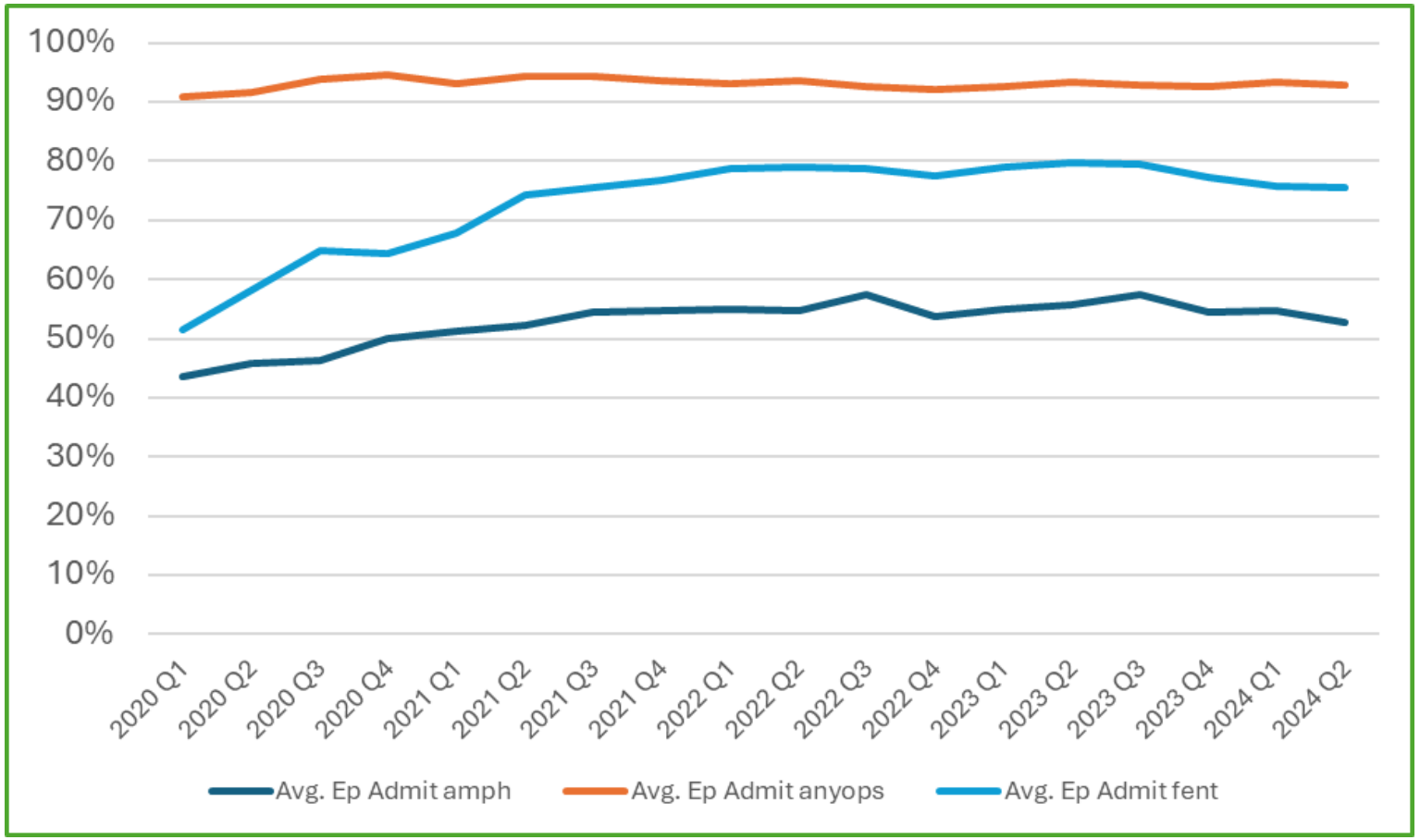
HEALTH

The pipeline of deadly fentanyl into the U.S. may be drying up, experts say

UPDATED OCTOBER 1, 2024 · 6:03 PM ET

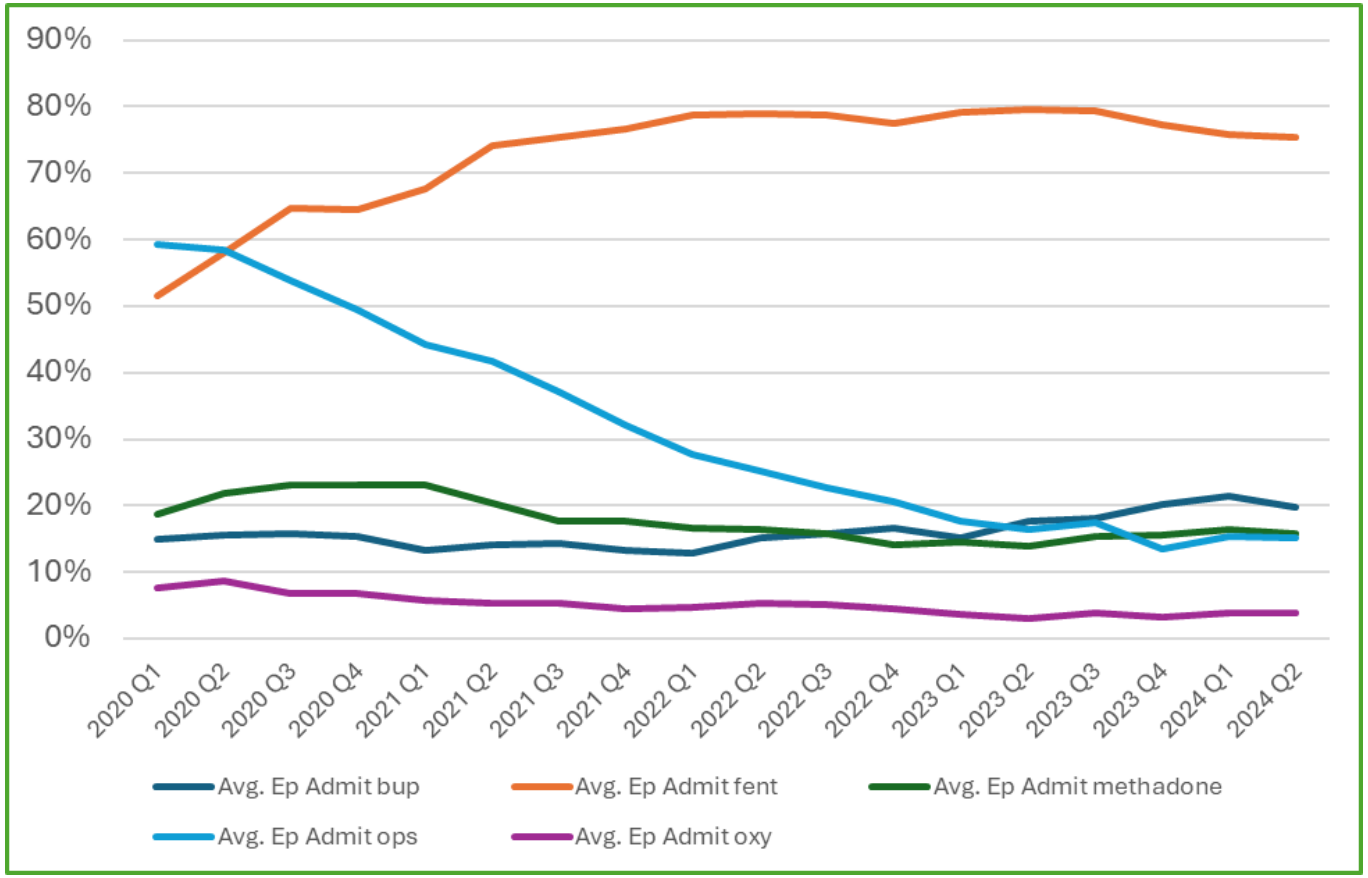
HEARD ON MORNING EDITION

Admission UDS Trends - 2020-2024



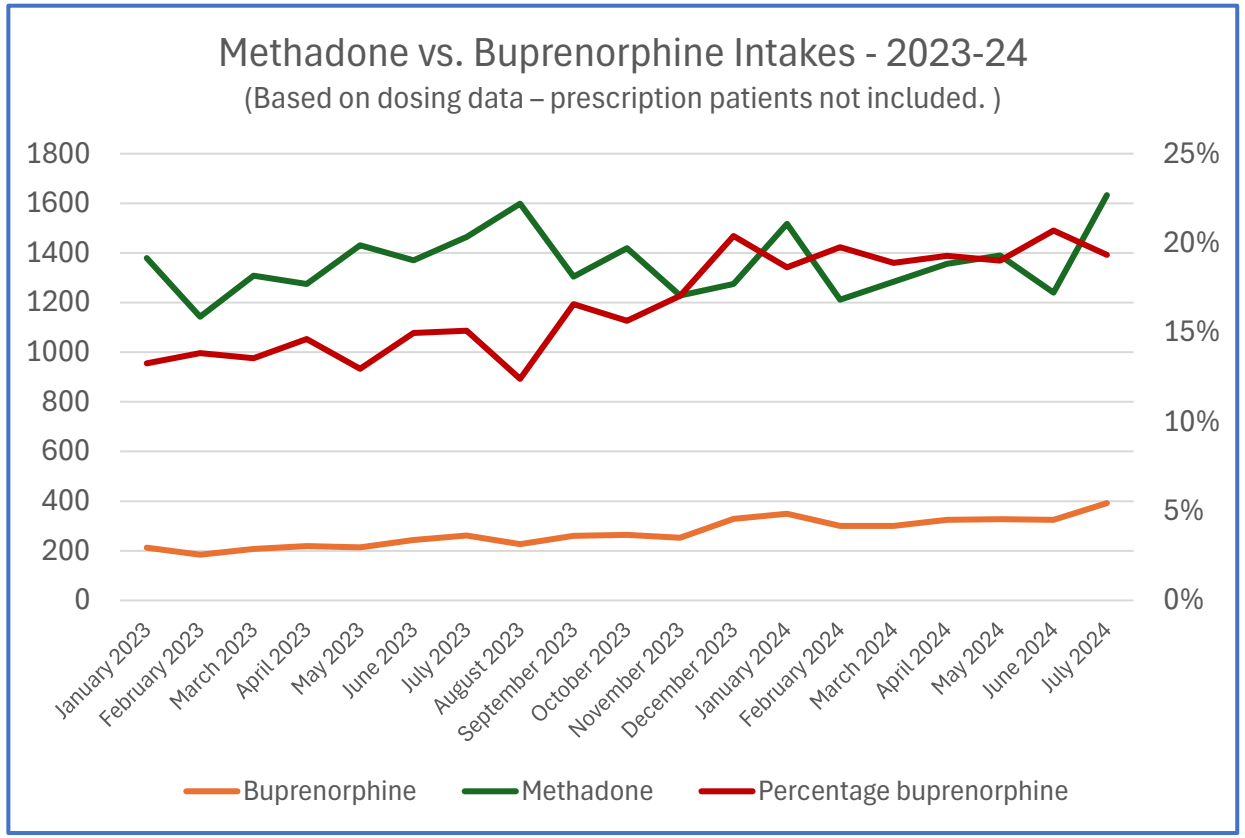
Key Points: The percentage of patients positive for fentanyl and/or amphetamines has been declining recently

Admission Opioid Percentage Trends - 2020-2024



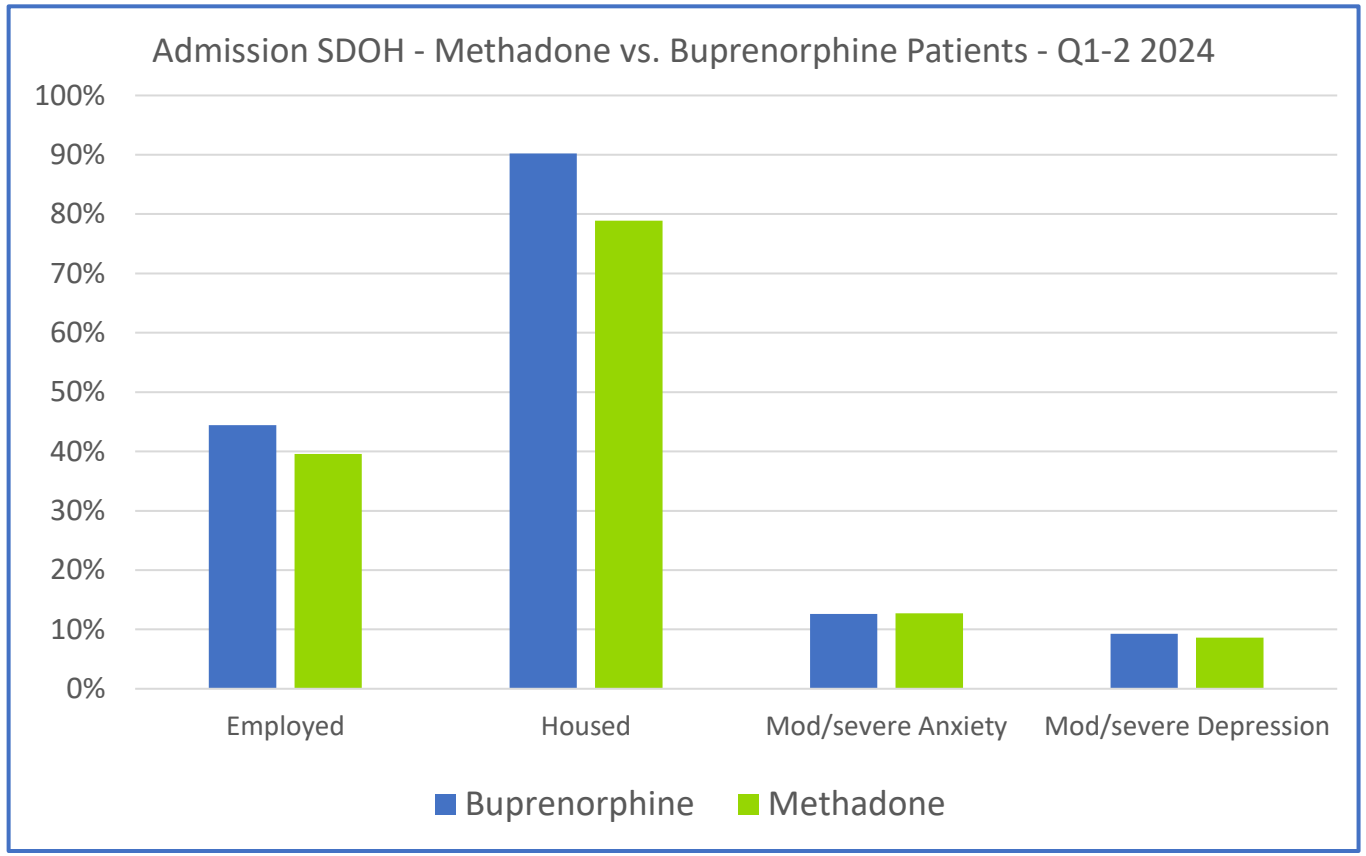
Key Points: Rates of positivity for fentanyl upon intake are decreasing, however positive for methadone & buprenorphine or increasing

Methadone and Buprenorphine Admission/Readmissions



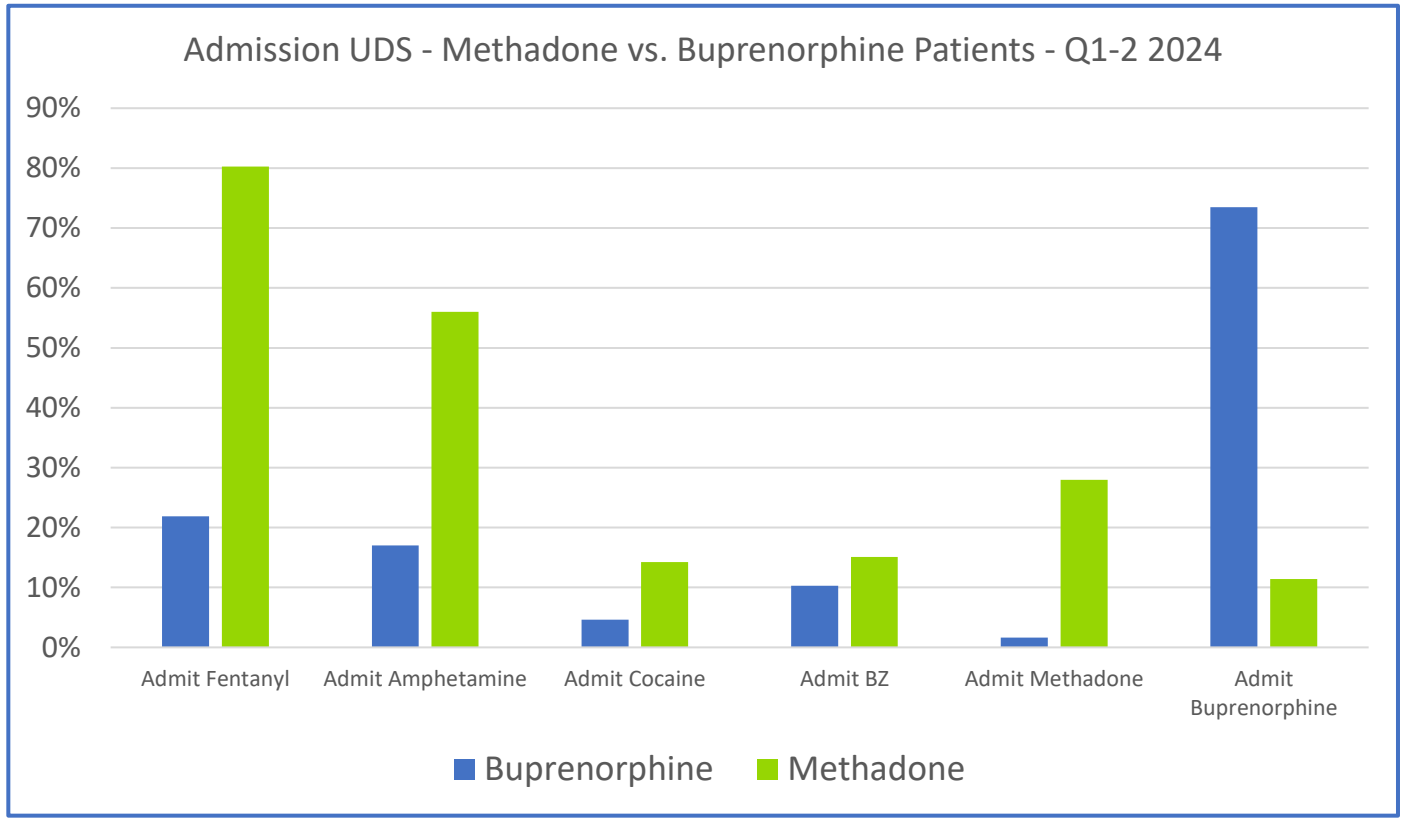
Key Points: Methadone intakes have been largely stable since 2023, however, buprenorphine admissions have increased, now up to 20% of all intakes.

SDOH - Methadone vs, Buprenorphine Admission/Readmissions – Q1-2 2024



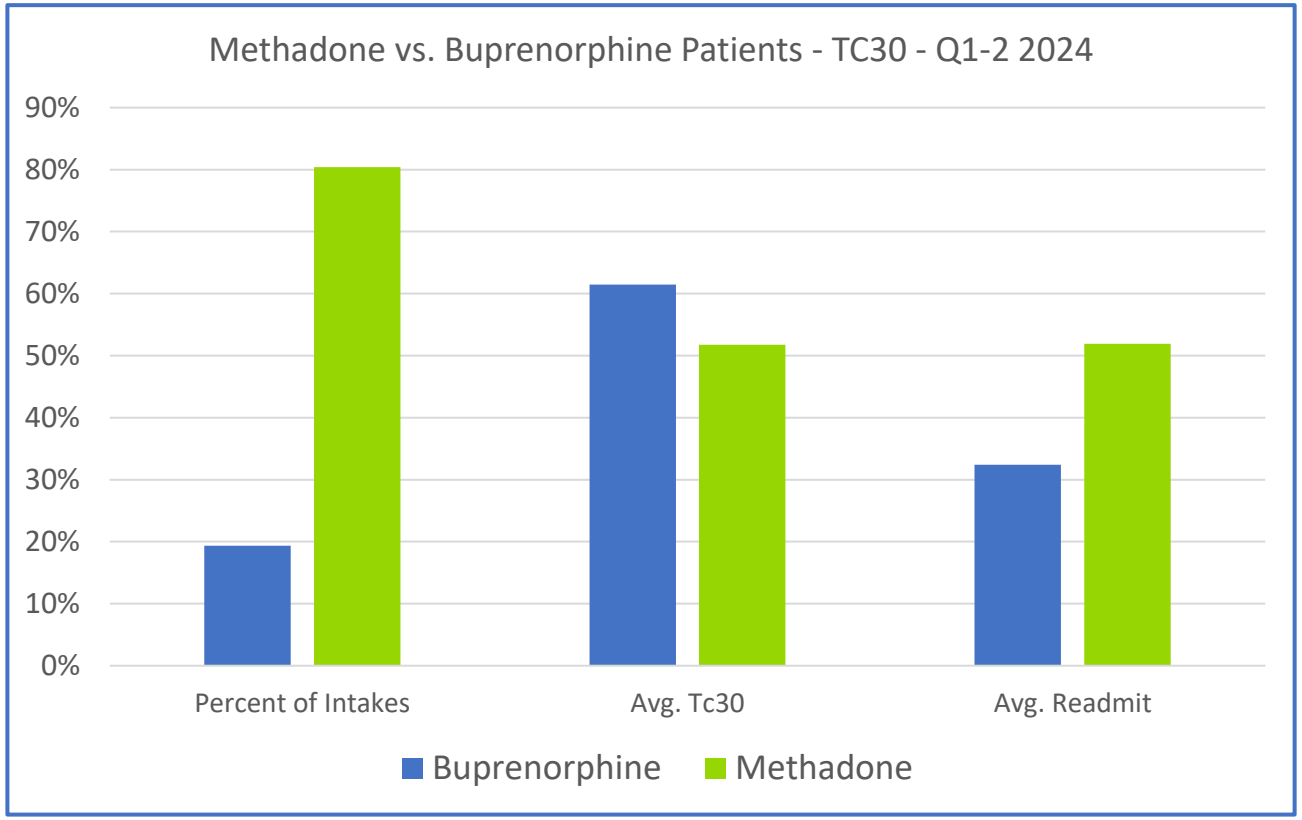
Key Points: Buprenorphine patients are more likely to be employed and housed than methadone patients. The mental health measures on admission are the same for both groups.

UDS Results - Methadone vs, Buprenorphine Admission/Readmissions – Q1-2 2024



Key Points: Methadone patients are more likely to be positive for fentanyl, amphetamine, cocaine, and BZs than buprenorphine patients. Three quarters of buprenorphine patients test positive for buprenorphine on admission.

TC30 - Methadone vs, Buprenorphine Admission/Readmissions – Q1-2 2024



Key Points: Methadone patients have a lower average TC30 and higher percentage of readmissions. Buprenorphine patients are now around 20% of all intakes.