ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

How to Join:
https://iecho.org/public/program/PRGM1708646970665RHK0C7J5TR

For attendance, purposes please text the following code: GOBYOC to 608-260-7097

Session Date: Friday, January 17, 2025

Didactic Topic and Presenter:
Twenty Years Later: The Changing Landscape of Methadone Regulations

Hillary Tamar, MD, FASAM

Content Experts: Sheila Weix and Joe Galey

- 12:15 PM: Attendance text-in – Introductions
- 12:25 PM: Case Presentation
  - Presenter: Sarah Floden, MD - *Assistant Professor, CHS Track - Division of General Internal Medicine*
- 1 PM: Didactic Presentation
  - Presenter: Hillary Tamar, MD, FASAM
- 1:15 PM End of Session

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WISCONSIN DEPARTMENT of HEALTH SERVICES

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ECHO ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2025
Twenty Years Later: The Changing Landscape of Methadone Regulations
1/17/2025

Didactic Presenter: Hillary Tamar, MD, FASAM

Case Presenter: Sarah Floden, MD

Provided by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP)

Intended Audience:

Nurses, Nurse Practitioners, Pharmacists, Physicians, Physician Assistants, Pharmacy Technicians, Psychologists, Social Workers, Patient/Caregivers, Students

Objectives:

- Analyze the differences between the former OTP regulations and SAMHSA's Final Rule
- Discuss the implications of the Final Rule on current clinical practices in opioid treatment programs, both in Wisconsin and nationwide
- Compare Wisconsin OTP regulations to those found in other states, with an emphasis on opportunities to improve patient care

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Name	Role	Financial Relationship Disclosures	Discussion of Unlabeled/Unapproved uses of drugs/devices in presentation?	COI completion date
Randall Brown	RSS Chair	No relevant financial relationships to disclose	Yes	12/4/2024
Nada Rashid	RSS Coordinator	No relevant financial relationships to disclose	No	1/15/2025
Kathleen Maher	RSS Coordinator	No relevant financial relationships to disclose	No	12/9/2024
Ritu Bhatnagar	Planner	No relevant financial relationships to disclose	Yes	12/9/2024
Paul Hutson	Planner	usona (Independent Contractor - Consultant), Midwest Pharmacokinetic Consulting, LLC (Independent Contractor - Consultant), Otsuka America Pharmaceutical, Inc. (Independent Contractor - Consultant), Tryptamine Therapeutics (Independent Contractor - Consultant)	Yes	12/4/2024
Susan Mindock	Planner	No relevant financial relationships to disclose	No	12/7/2024
Sheila Weix	Planner	No relevant financial relationships to disclose	No	12/12/2024
Kellene Eagen	Planner	No relevant financial relationships to disclose	No	12/4/2024
Joseph Galey	Planner	No relevant financial relationships to disclose	No	12/12/2024
David Leinweber	Planner	No relevant financial relationships to disclose	Yes	12/4/2024

Hillary Tamar	Presenter	No relevant financial relationships to disclose	No	1/8/2025
Sarah Floden	Presenter	No relevant financial relationships to disclose	No	1/13/2025

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Case Presentation

Sarah Floden, MD
General Internal Medicine
Union Corners Clinic

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Case Introduction

- **One-liner (including age/sex):** 52M with traumatic asplenia, chronic shoulder pain, alcohol use disorder and opioid use disorder presenting to discuss treatment of diarrhea, anxiety, and insomnia after self discontinuing oral opioids 3 weeks ago.
- **Primary question for discussion:** Patient was concerned about how future employers could perform random drug testing and was hesitant to initiate vivitrol or other OUD treatment options as a result

Medical & Behavioral Health Diagnosis:	Current Medications:
• Alcohol use disorder • Opioid use disorder • Chronic shoulder pain s/p multiple rotator cuff procedures • GERD • Hyperlipidemia • Traumatic splenectomy 2/2 stab wound • Right temporal bone fracture after a fall	• Omeprazole 40 mg

Substance Use

- History: Alcohol, marijuana, and opioid use. 10 years of oxycodone and/or hydrocodone use averaging 30-40 mg per day.
- Consequences of Substance Use:
  - Social/occupational/educational: patient without stable housing or employment, loss of job prompted visit
  - Physical (including evidence of tolerance/withdrawal): was intoxicated on admission for stab wound and head injury. Prior to most recent clinic appt reported diarrhea, abdominal cramping, insomnia, restless leg, anxiety after self discontinuing opioids.
- Past treatments: none

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Social History:	Family History:
• Social Factors/History: Previously worked as a cellular tower technician. • Education/Literacy: Graduated high school. Reported history of learning disability which warranted special education class enrollment throughout his education. • Income source: none currently, recently donated plasma (while he was withdrawing)	• Alcohol use disorder in father, mother, and 2 siblings • Heart disease in mother and paternal grandfather

Patient strengths & protective factors:	Risk factors:
• Goal to secure employment • Friends providing him with a place to stay while gets back on his feet • Reported sobriety from opioids for 3 weeks and wishes to continue • No prior history of complicated alcohol withdrawal • Frequent phone contact the weeks after his clinic appt	• Using alcohol to cope with opioid withdrawal symptoms • Without health insurance • Hesitant re treatment for OUD due to fear it will negatively impact employment • Family history of substance use disorder • Continued to use substances after hospitalizations for head injury and stab wound

Labs

- Normal CMP and A1c
- No substances detected on pain management profile

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Patient Goals & Motivations for Treatment

- ”I am looking for help with withdrawal symptoms”
- Wants to address recent escalation in opioid use (previously weekends only, transitioned to daily use)
- Finding stable housing and employment

Proposed Diagnoses

- Moderate opioid use disorder in early remission
- Opioid withdrawal

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Proposed Treatment Plan

- After discussing clonidine, gabapentin, buprenorphine, and naltrexone, he preferred to start with gabapentin to target anxiety and insomnia
- Discussed how HyVee contracts with Good Rx and has more affordable med prices
- Discussed how important it was to reach out with questions esp during this transition period
- Applauded him on his efforts in sobriety
- Call to Hotline: Recommended enrollment in BadgerCare and utilizing Compass program

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Discussion:

- **Primary question:**

what medication(s) would be most helpful to the patient in maintaining sobriety?

Would naltrexone or buprenorphine show up on an employer's random drug screening (and jeopardize patient's job prospects)?

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DSM-5 Substance Use Disorder ("Addiction")

- Tolerance
- Withdrawal

} Physical Dependence ≠ Use Disorder

- Larger amts/longer periods than intended
- Persistent desire/failed attempts to quit/control use
- Much time obtaining/using/recovering
- Important activities sacrificed
- Continued use despite known adverse effects
- Failure to fulfill major obligations
- Recurrent hazardous use
- Craving
- Ongoing use despite interpersonal problems

2-3 = mild
4-5 = moderate
≥ 6 = severe

By initialing here _______ you have acknowledged that Project ECHO case consultations do not create or otherwise establish a provider-patient relationship between any ECHO clinician and any patient whose case is being presented in a teleECHO clinic.

Twenty Years Later: the Changing Landscape of Methadone Regulations

Hillary Tamar, MD, FASAM

January 17th, 2025

Disclosure Information

No Financial Disclosures

Learning Objectives

- Analyze the differences between the former OTP regulations and SAMHSA's Final Rule
- Discuss the implications of the Final Rule on current clinical practices in opioid treatment programs, both in Wisconsin and nationwide
- Compare Wisconsin OTP regulations to those found in other states, with an emphasis on opportunities to improve patient care

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42 CFR Part 8: A Timeline

- **The regulations surrounding methadone treatment in the US were established from 1970-1974**
- **Until 2024, regulations were not largely different than the original text from the 1970's**
  - Primary goal of these regulations: prevent diversion of methadone
  - 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 Final Rule**
  - Proposed December 2022
  - Released February 2024
  - Effective April 2024
  - Compliance October 2024

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Key Point

While states can't choose to be less restrictive than the federal regulations, they can choose to be <u>MORE</u> restrictive (Wisconsin 👀).

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Key Point

- Do states have to respond to the new regulations?
- <u>No, they don't.</u>

- When the Final Rule refers to "compliance date," that's for accrediting bodies, not states.

Global Change: Language

Old Rule

- Medication-assisted treatment (MAT)
- Maintenance treatment
- Detoxification treatment
- Drug abuse (verbiage removed, not replaced)

VS

New Rule

- Medication for opioid use disorder (MOUD)
- Comprehensive treatment
- Withdrawal management

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."

Global Change: Addition of Harm Reduction

Example

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

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Change: Admission Criteria

Comprehensive Treatment, General

Old Rule

- Patient must have 1 year history of OUD except...
  - Exceptions: pregnancy, previously treated patients, released from a correctional facility in the last 6 months

VS

New Rule

- Elimination of 1 year admission requirement
- "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."

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What Does Wisconsin Say About Admission Criteria?

- "The person is currently addicted to an opioid drug, and that the person became addicted at least one year before admission for treatment."

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Change: Admission Exams

Comprehensive Treatment, General

Old Rule

- "OTPs shall require each patient to undergo a complete, fully documented physical evaluation... before admission to the OTP... the results of serology must be completed within 14 days following admission."

VS

New Rule

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

Key Point

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

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Where Does Wisconsin Stand on Labs?

- "The comprehensive physical examination... shall include a complete blood count and liver function testing. The service shall test for Hepatitis A, B, C and HIV... If the patient declines permission to test shall be documented in the patient's record.

- An updated comprehensive physical examination including lab work shall be completed annually."

Change: Admission Platform

Comprehensive Treatment, General

Old Rule

- **Methadone intakes must be completed in-person**

VS

New Rule

- **All examinations may be completed by telehealth**
  - Methadone admissions must use an audiovisual platform
  - Audio only may be used for buprenorphine and naltrexone

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Key Point

- The ability to complete methadone admissions via telehealth has been enormously impactful.

Change: Admission Dosage

Comprehensive Treatment, General

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"

Key Point

- An intake dose of methadone 50mg is uncharted territory and is probably best for patients with high tolerance, not all patients.

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What Does Wisconsin Say About Intake Dosing?

- "For each new patient enrolled in a service, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams..."

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Key Point

- **Wisconsin is not the only state that copied and pasted 30mg into their law.**

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Key Point

- The regulations never dictated what the second day's dose could be.

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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? exactly how regular?)**

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

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

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

(vi) Length of time in comprehensive maintenance treatment **(but 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)**

Change: Take-Home Criteria

New Criteria – Use These to Determine Stability

(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

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Key Point

- How can we use these six criteria on admission to determine stability/safety?
- We can't.

Key Point

- **Cocaine, methamphetamine, and cannabis should not affect take-home eligibility because they do not increase overdose risk.**

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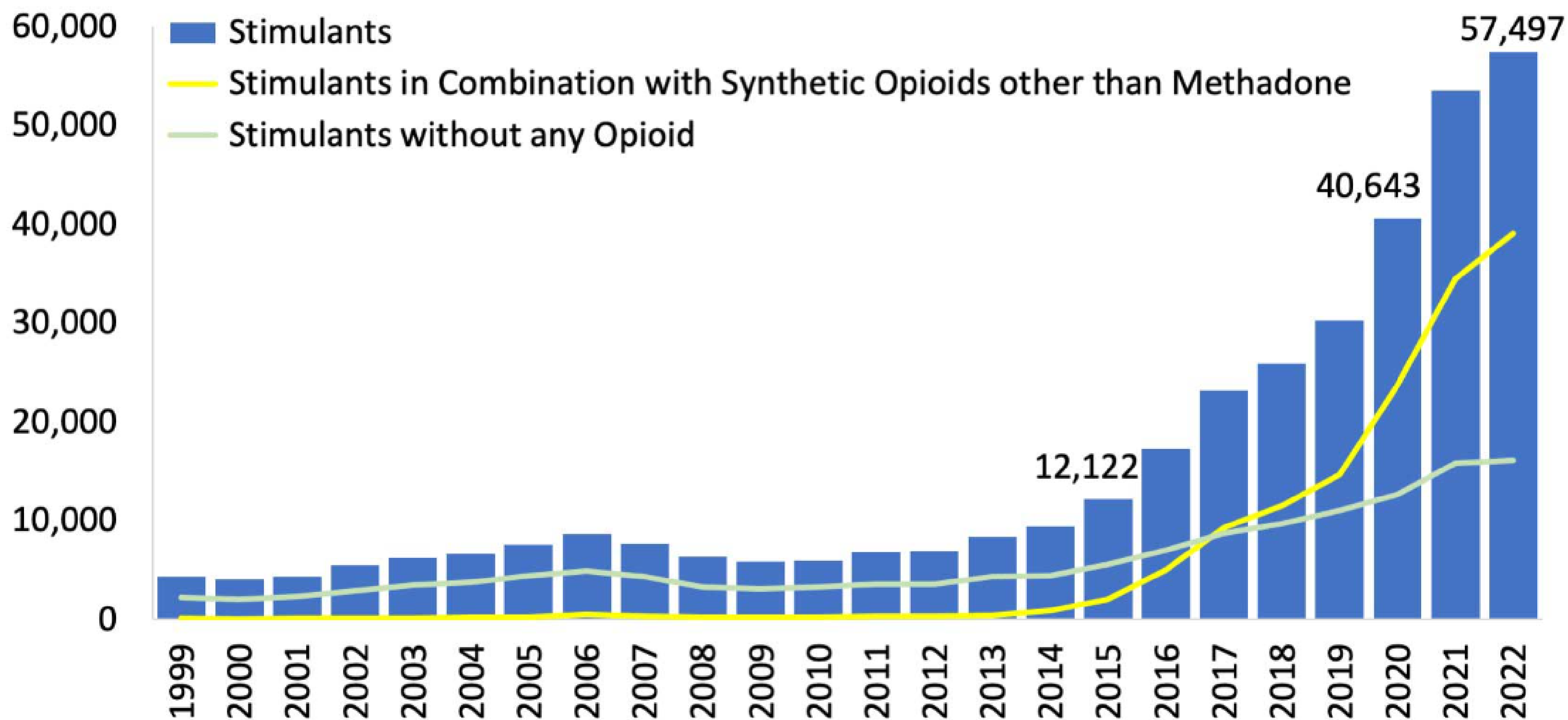
Figure 6. U.S. Overdose Deaths Involving Stimulants* (cocaine and psychostimulants with abuse potential), by Opioid Involvement, 1999-2022



Key Point

- **While we know that overdose deaths involving both stimulants and opioids are increasing, we have no evidence of a physiologic mechanism.**

Key Point

- **We also have no evidence that giving patients less take-homes makes them any less likely to overdose.**

In other states, we don't test for cannabis.

In Wisconsin, we are required to by state law.

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Change: Take-Home Amount
Old Rule

Time In Treatment	Amount of Take-Home's 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

Change: Take-Home Amount

New Rule

Time In Treatment	Amount of Take-Home's Allowed
1-14 days	7 Take-Homes
15-30 days	14 Take-Homes
31+ days	28 Take-Homes

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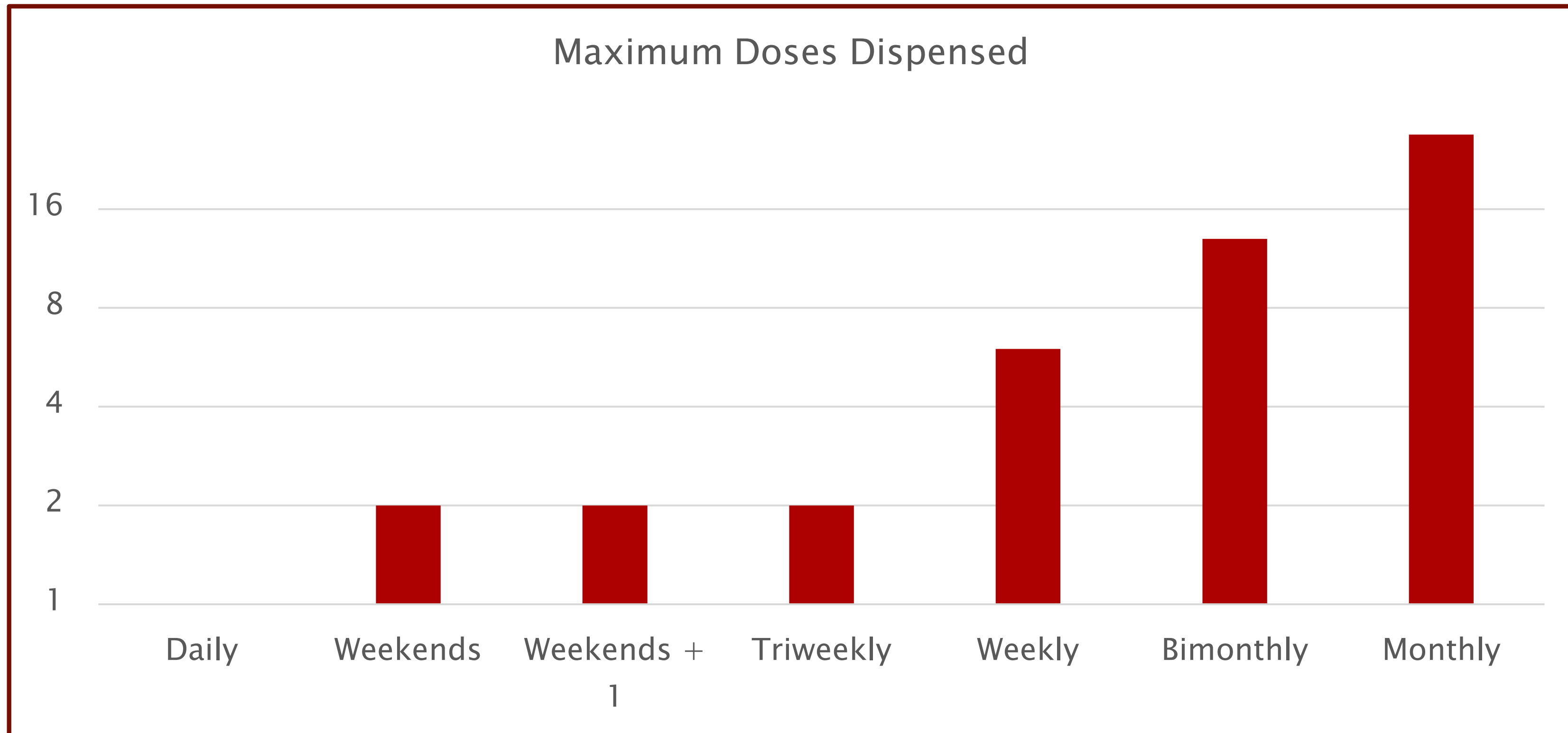
Visualizing Take-Homes



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This visualization is not true of Wisconsin.

Unlike most states, OTPs in Wisconsin are required to dose 7 days per week.

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Key Point

- Time in treatment requirements have been drastically reduced.

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Questions?

Thank you!

Resources

- https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes
- https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder
- https://docs.legis.wisconsin.gov/code/admin_code/dhs/030/75/vii/59/6/a/2
- https://www.govinfo.gov/content/pkg/FR-2001-01-17/pdf/01-723.pdf
- https://www.sciencedirect.com/science/article/abs/pii/S0376871621002611
- https://www.vitalstrategies.org/resources/information-about-new-federal-regulations-for-opioid-treatment-programs-otps/
- https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig7

References

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- Opioid drugs in maintenance and detoxification treatment of opiate addiction; Substance Abuse and Mental Health Services Administration, HHS. Final rule. Fed Regist. 2001 Jan 17;66(11):4076-102. PMID: 11503765.
- Pelletier LR, Hoffman JA. New Federal Regulations for Improving Quality in Opioid Treatment Programs. J Healthc Qual. 2001;23(6):29-34. PMID: 16758002; PMCID: PMC1474812.
- https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs

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