

# OPIOID TREATMENT PROGRAMS- WHERE WE ARE IN 2025

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OTP FEDERAL  
REGULATORY CHANGES

42 CFR PART 8 FINAL RULE



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First “major” revision to the regulations surrounding the provision of methadone for withdrawal management and maintenance since 2001.

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There was a goal to reframe the treatment experience, increase access, individualized care (“not one size fits all”)

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Focus is on a culture shift in care and service delivery

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Themes include “shared decision making”, flexibility, trust, attempts to decrease stigma (language) and practitioner judgement

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Substance Abuse and Mental Health Services Administration (SAMSHA) released with effective date of 4-2-24

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Awareness that State regulations may be more stringent, and States may need to explore components that will be adopted/implemented

# OVERVIEW

# INITIAL DOSE

## Old Language:

For each new patient enrolled in a program, the initial dose shall not exceed 30 mg and the total for the first day shall not exceed 40 mg (this typically required individual waiting for the second dose of 10 mg after a period of assessment)



## New Language:

For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type of opioid involved in the patients OUD, other medication or substances being taken, medical history, severity of withdrawal symptoms. **The total dose for the first day shall not exceed 50 mg**

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### Old Language:

Maintenance treatment: An OTP shall maintain current procedures designed to ensure that patients are admitted...That a person is currently addicted to an opioid drug and that the person became addicted at least 1 year before admission to treatment.

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### New Language:

Comprehensive treatment: An OTP shall maintain current procedures to ensure that patients are admitted to treatment. Meets the diagnostic criteria for moderate/severe Opioid Use Disorder (OUD) or is at high risk for overdose. **No longer need 1-year verification.**

# ADMISSION CRITERIA

# INITIAL MEDICAL EXAMINATION



- **New Language:** Initial medical examination: OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts: 1. screening exam to ensure individual meets medical necessity 2. a full history and physical.
- **New Language:**.. Patient may commence treatment with MOUD after the screening examination has been completed.
- **New Language:** “Where the examination is performed outside of the OTP, the screening examination must be completed 7 days prior to OTP admission.”
- **New Language:** “A full in-person physical examination... must be completed within 14 calendar days following a patient’s admission to the OTP.”



There is also language stating the **“medical screening”** can be performed via telehealth



Collaborating with DPH regarding medical screen vs H&P and the use of telehealth



Additional language mentions the need for periodic physical exam once per year conducted by an OTP practitioner

## INITIAL MEDICAL EXAM ADDITIONAL CONSIDERATIONS

# UNSUPERVISED DOSING

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Formally known as take home bottles (THBs)

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Historically, there was a perspective of “earning” THBs based on the 8-point criteria at set increments.

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Shift in philosophy from earning to individualized perspective based upon “therapeutic” benefit vs risk.

Absence of active substance use *or* health conditions that increase risk of overdose *or* ability to remain safe

Consistent attendance for supervised dosing

Absence of significant behavioral health concerns with a focus of safety of self/others

Absence of recent diversion activity

Ability to safely store unsupervised doses

Additional criteria as determined by OTP Medical Director

# UNSUPERVISED DOSES



Initial 14 days of treatment = up to 7 unsupervised doses can be dispensed



14-30 days of treatment = up to 14 unsupervised doses can be dispensed at one time



After 30 days in treatment = up to 28 unsupervised doses can be dispensed



Specific language included: "it remains within the OTP practitioner's discretion to determine the number of THBs.... but this determination must be based on the criteria (outlined in previous slide)."

# UNSUPERVISED DOSING CONTINUED

# MID-LEVEL PRACTITIONERS

- - "A health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for OUD and as a result, is authorized to practice within an OTP"
- - "...practitioners must continue to adhere to State requirements that may apply to the provision of methadone and scope of practice."
- - Within mid-level scope of practice within CT.
- - Mid-level practitioners include Physician Assistant(PA), Advanced Practice Registered Nurse .
- - Mid-level exemption is no longer required for prescribing.
- - Mid-level exemption would be required for PA/APRN to assume role as medical director.

# COUNSELING SERVICES

“OTPs must provide adequate substance disorder counseling and psychoeducation .. as clinically necessary and mutually agreed upon...”



“...promote a person-centered approach to care that does not make medication contingent upon involvement in counseling services but fosters shared decision making”



Providers have questioned the monthly clinical contact requirement in CT which is currently tied to Medicaid billing and is a component of the OTP 1115 standards.

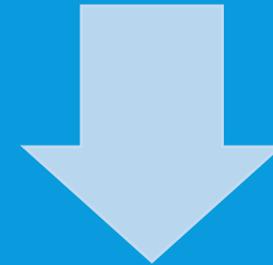


How will an individual’s progress towards treatment goals and objectives be monitored without counseling services?

# WITHDRAWAL MANAGEMENT

The final rule removes the requirement that those seeking withdrawal management cannot initiate methadone treatment more than twice a year. Providers were required to submit a CSAT exception request to admit an individual with more than two withdrawal management protocols per year.

**New Language:** There is nothing stated in the Federal regulations or statutes that limits the number of times a person can initiate treatment with methadone or any other medication.



# WHERE WE ARE TODAY:

- Focus on the SAMHSA definition of recovery  
*"a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential"*
- Working with OTPs to embrace the overarching themes of individualized care, shared decision making and harm reduction.
- Embracing a model of treatment, services and the provision of medication that is devoid of punitive policies and procedures.



## WHERE WE ARE TODAY

- For each new patient enrolled in the OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type of opioids involved in the patient's opioid use disorder (OUD), other medications or substances used, medical history and severity of withdrawal symptoms. The total first dose shall not exceed 50 mg.
- An OTP shall maintain current procedures to ensure that patients admitted to treatment meet diagnostic criteria for moderate/severe OUD or is at high risk for an overdose. Verification of one year history of use is no longer required.
- A healthcare professional who is appropriately licensed by the State to prescribe and/or dispense medications for OUD is authorized to practice within an OTP. Midlevel practitioners no longer require CSAT exemption to prescribe methadone within the OTP as long as they adhere to scope of practice as defined by the State.
- Withdrawal management (updated terminology from detoxification) admissions limitation of no more than two admissions per year has been removed.

# IMPORTANCE OF PARTNERSHIPS

- Collaborations with state partners including DPH, DCP and DSS
- Initial meetings with state partners to review changes, discuss embracing the revisions, identifying areas for continued discussion
- Work continues with DPH to identify ...
- Collaboration with federal partners including SAMHSA
- Meeting on 12-9-24 with SAMHSA to review revisions to 42 CFR part 8 with CT OTPs at CVH (Middletown, CT), DPH in attendance
- Meeting with SAMHSA, DPH and DMHAS on 1-29-25 to discussion the revisions, impact on CT regulations, implementation



# MOBILE OTPS



# OVERVIEW

- Basically, an arm of the OTP that is “on wheels”
- Any registered OTP can apply to operate a mobile OTP under the registration of a brick-and-mortar location
- The mobile OTP must return to the “home” location daily
- Mobile OTPs must operate within the borders of the State
- The goal is to increase access to methadone as well as all formulations of medication for opioid use disorders (MOUD) for maintenance and withdrawal management
- Outlines specifics regarding diversion control and contingency planning

# WHERE WE ARE TODAY

- RFP released on 7-11-24 to fund 2 mobile OTPs in CT using Opioid Settlement funds
- Proposals were due 10-3-24
- Targeted for 4 areas of the state (Central, Northeast, Northwest and Southeast)
- Also, planning to focus on access for individual at long term care facilities and residential treatment
- Goal was to expand access to medication for opioid use disorder in remote areas
- Contracts issued to providers effective 1-1-25
  - \*APT Foundation
  - \*Community Health Resources (CHR)

# FOR QUESTIONS OR MORE INFORMATION

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