

# Making a Transformation (MAT) Conference 2024

# Breakout A: Modernizing Opioid Treatment Regulations to Increase Access to Care

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# Disclosures

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# Course Overview

- » This session will provide an overview of key changes in federal regulations approved on February 2, 2024 to increase and improve access to treatment for opioid addiction in Opioid Treatment Programs.
- » The course will allow for a discussion about how OTPs can take steps for implementation.
- » **\*\*California state laws, regulations, and program guidance are in the process of being updated. Up and until that process is completed, OTPs and practitioners must adhere to existing CA regulatory requirements.**

# Regulation Overview

- » Population disparities amplify the importance of promoting patient-centered care that is appropriate and responsive to patient needs while also fostering a treatment environment that supports and sustains patient engagement.
- » The final rule facilitates the practitioner-patient relationship while also expanding the reach of OTPs to engage communities with unmet comprehensive treatment intervention options.
- » Allows for OTPs to develop treatment plans with the flexibility to be more responsive to their patient's individualized needs.
- » The goal is to improve patient outcomes by meeting the patients where they are in their lives.

# Patient Admission – Improved Access to Care

- » Patient admission criteria is now allows for clinical determination rather than documented opioid misuse of one-year.
- » \*\*Qualified Practitioner under federal rule changed the definition of practitioner to a health care professional licensed by a state to prescribe medications and authorized to work in an OTPs.
  - *Practitioner*, for purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

# Initial Medical Examination

- » § 8.12(f)(2)(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner.
- » *If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission.*
- » Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, *must be transmitted*, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

# Patient Admission: Telehealth Improves Access

- » OTPs can now use telehealth when admitting patient
- » This change provides flexibility to address staffing issues when the practitioner that meets the requirements to conduct and evaluation is unavailable.



# Medication and Mobile Units

- » § 8.11(h) *Medication units, long-term care facilities and hospitals.*
- » (1) Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary by submitting form SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations. *Medication units include both mobile and brick and mortar facilities.*
- » (2) *Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.*

# Medication and Mobile Units

- » Medication and Mobile Units can now provide the full array of OTP services.
- » Prior to this change, medication units services were limited to dispensing medications and were not allowed to provide the necessary counseling services OTP patients rely on as part of their treatment.
- » \*This change is intended to improve access in rural and urban areas where patients may have difficulties accessing treatment at a “fixed” OTP location. It is also an opportunity for OTPs to physically engage in marginalized communities that need intervention.

# Medication – First Dose

- » The Final Rule allows for a higher first doses. The increase in the allowable milligrams recognizes the higher dosing levels associated with fentanyl misuse and will assist NTP programs to stabilize patients withdrawal symptoms.
- » (ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and ***severity of opioid withdrawal***.
- » The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

# Medication – First Dose

- » The increase of the standard first dose reflects the current rise in Fentanyl overdoses and deaths.
- » OTP's experience with patients misusing Fentanyl is that higher doses of Methadone are necessary to meet the severity of the withdrawal.
- » The regulation includes clarification of allowance for higher doses if clinically indicated, enhancing the OTP's ability to address a patient's need of starting at the medically indicated dose level.

# NTP Services Summary

- » Modernized Admission Requirements
  - Now based on diagnosis of severe or moderate opioid misuse
  - New definition of practitioner
- » Increased Utilization of Telehealth
  - Transmittal of patient history
- » New Take-Home Allowances
  - Recognize patients life activities and constraints
- » Higher first dose levels
  - Help to stabilize patients with higher opioid tolerance
- » Mobile Units and Medication Units (MUs)
  - Expand access to all NTP services in underserved communities
- » All of the combined changes help to improve access to patients in underserved areas and allow for more patient centered care.

# Questions for Discussion

- » Which of these changes are priorities for your organization?
  
- » For OTPs, how will you plan to implement these changes?
  - What steps will you take to prepare for implementation?
  - What systems will you need to put in place? How will you start?
  
- » Which of these changes will be most challenging?

# Questions