New Federal Regulations in Opioid Treatment Programs

What does this mean for Massachusetts?

Session Reminders

Introduce yourself via the chat


What are you looking forward to this summer


Turn your camera on if you are able


Mute yourself when you are not speaking


Write your questions in the chat . . .


Please fill out your evaluation at the end of the session


IT Trouble? Contact Gretchen via chat or email

MA OTP TTA Team

Today's Presenters

Melissa Schoemmell

Jo Morrissey

Lili Njeim

Nadia Syed

Agenda

1. Welcome and Introductions
2. Background Information
3. Overview of the ***Waiver from Certain Regulatory Requirements and Guidance***
4. Evaluation Survey and Available Resources
5. Wrap Up and Upcoming Opportunities

Regulations At-a-Glance

Federal Regulations	DPH BSAS Regulations
42 CFR Part 8	105 CMR 164.000

Massachusetts Waiver from Certain Regulatory Requirements and Guidance

Today's Objectives

By the end of today's session, participants will be able to:

1. Describe the MA Waiver from Certain Regulatory Requirements and Guidance
2. State how the waivers and guidance apply within the OTP setting
3. Provide suggestions and feedback regarding what topics in the new regulations may require training and technical assistance

Temperature check

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Timeline: New Federal OTP Regulations

Released	Went into effect	Full compliance expected by
January 2024	April 2, 2024	October 2, 2024

A New Day in Opioid Treatment Programs

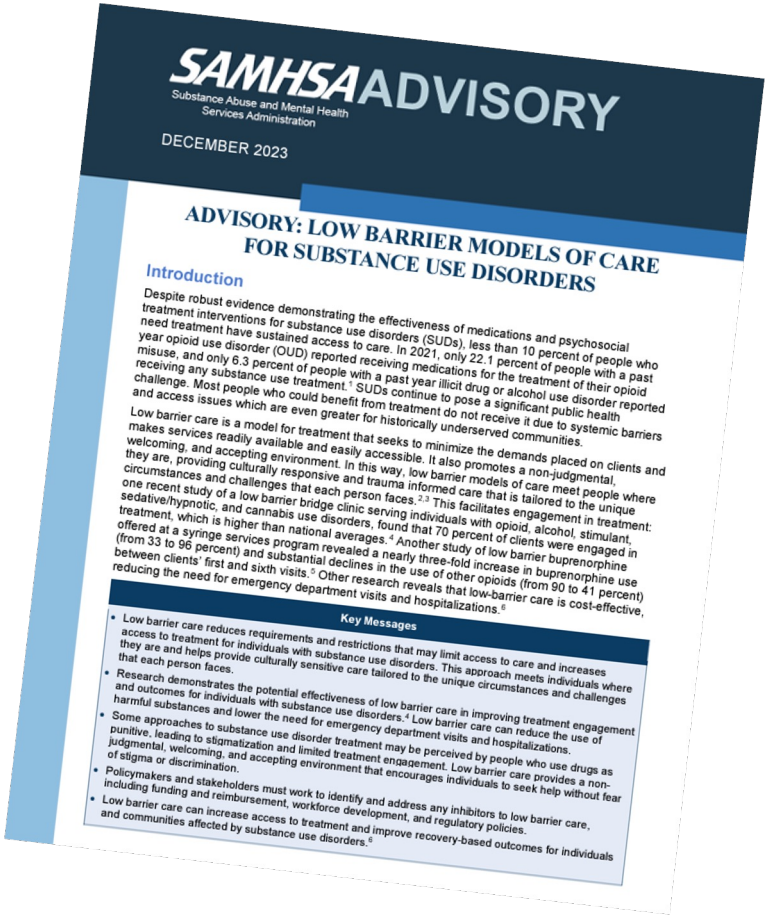
Underlying values and principles of SAMHSA's Revised Rule:

- Shared practitioner-patient decision-making
- Practitioners' clinical judgment
- Responsive, flexible OTP services
- Evidence-based practices
- Non-stigmatizing language

Low Barrier Care

Reduces requirements and restrictions that may limit access to care and **increases access to treatment** for people with SUD.

Meets individuals where they are and helps provide **culturally sensitive care tailored** to the challenges they face.



SAMHSA ADVISORY

Substance Abuse and Mental Health Services Administration

DECEMBER 2023

ADVISORY: LOW BARRIER MODELS OF CARE FOR SUBSTANCE USE DISORDERS

Introduction

Despite robust evidence demonstrating the effectiveness of medications and psychosocial treatment interventions for substance use disorders (SUDs), less than 10 percent of people who need treatment have sustained access to care. In 2021, only 22.1 percent of people with a past year opioid use disorder (OUD) reported receiving medications for the treatment of their opioid misuse, and only 6.3 percent of people with a past year illicit drug or alcohol use disorder reported receiving any substance use treatment.[1] SUDs continue to pose a significant public health challenge. Most people who could benefit from treatment do not receive it due to systemic barriers and access issues which are even greater for historically underserved communities.

Low barrier care is a model for treatment that seeks to minimize the demands placed on clients and makes services readily available and easily accessible. It also promotes a non-judgmental, welcoming, and accepting environment. In this way, low barrier models of care meet people where they are, providing culturally responsive and trauma informed care that is tailored to the unique circumstances and challenges that each person faces.[2,3] This facilitates engagement in treatment: one recent study of a low barrier bridge clinic serving individuals with opioid, alcohol, stimulant, sedative/hypnotic, and cannabis use disorders, found that 70 percent of clients were engaged in treatment, which is higher than national averages.[4] Another study of low barrier buprenorphine offered at a syringe services program revealed a nearly three-fold increase in buprenorphine use (from 33 to 96 percent) and substantial declines in the use of other opioids (from 90 to 41 percent) between clients' first and sixth visits.[5] Other research reveals that low-barrier care is cost-effective, reducing the need for emergency department visits and hospitalizations.[6]

Key Messages

- Low barrier care reduces requirements and restrictions that may limit access to care and increases access to treatment for individuals with substance use disorders. This approach meets individuals where they are and helps provide culturally sensitive care tailored to the unique circumstances and challenges that each person faces.
- Research demonstrates the potential effectiveness of low barrier care in improving treatment engagement and outcomes for individuals with substance use disorders.[4] Low barrier care can reduce the use of harmful substances and lower the need for emergency department visits and hospitalizations.
- Some approaches to substance use disorder treatment may be perceived by people who use drugs as punitive, leading to stigmatization and limited treatment engagement. Low barrier care provides a non-judgmental, welcoming, and accepting environment that encourages individuals to seek help without fear of stigma or discrimination.
- Policymakers and stakeholders must work to identify and address any inhibitors to low barrier care, including funding and reimbursement, workforce development, and regulatory policies.
- Low barrier care can increase access to treatment and improve recovery-based outcomes for individuals and communities affected by substance use disorders.[6]

So what does this mean for your OTP?

Let's get into it!

01.
Guidelines for Licensed and/or Approved Providers

02.
Waivers from Certain Regulatory Requirements

New Regulations by Topic Area

Definitions, Roles, and Responsibilities

Assessments and Examinations

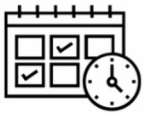
Medication, Dosing, and Supervised Withdrawal

Telehealth

Take-home Medication

Pregnant Women

Consent to Treatment



Interim Treatment

Required Services

Provide adequate:

medical, counseling, vocational, educational, and other screening, assessment, and treatment services

Meet patient needs with:

combination and frequency of services tailored to each patient based on an individualized assessment.

Definitions, Roles, and Responsibilities

Medical Directors

- Must be a physician
- Responsible for all medical and behavioral health services
- Can now delegate specific responsibilities to mid-level practitioners

Practitioners

- Physicians, Physician Assistant, or Advanced Practice Registered Nurse acting within the scope of service pursuant to state and federal law
- Can initiate and make all MOUD dosing decisions and review laboratory results

Assessments and Examinations

1. **A screening examination**
    - Ensures that the patient meets the **criteria** for admission
    - Ensures no contraindications to treatment with MOUD

2. **A full history and examination**
    - Full in-person physical and behavioral health assessment within 14 days of admission

Assessments and Examinations

What if the licensed practitioner is <u>not an OTP practitioner?</u>
The screening examination must be completed **no more than seven days prior** to OTP admission

What if the examination is <u>performed outside of the OTP</u>?
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

Assessments and Examinations

OTHER ASSESSMENTS

Annual Medical Exam – Completed by an OTP Practitioner

Periodic Behavioral Health Assessment Services

Minimum of 8 random drug screens per year*

Assessments and Examinations

Requirements removed for admission:

- Determining that the patient has a current physiological dependence on opioid for at least a 12-month duration
- Adult patients with two or more unsuccessful episodes of supervised withdrawal within a 12-month period
- Patients under 18 have two documented unsuccessful attempts at short-term withdrawal or drug-free treatment within a 12-month period

Assessments and Examinations

Care Planning

Treatment plans are referred to as **care plans** within the Final Rule.

Shared decision-making is emphasized.

clinical judgment + **patient-centered care** = **shared decision-making**

between practitioners and patients in creating individualized care plans

Medication, Dosing, and Supervised Withdrawal

- In addition to Physicians, **Practitioners can now initiate and make dosing decisions in OTPs.**
- Choice of medication and the initial dose of medication should be individually determined
- Total dose is at the discretion of the practitioner

Medically Supervised Withdrawal

- The Department waived the requirement that a waiting period of at least one week is required between withdrawal attempts.
- Practitioners are expected to determine the rate of decrease for each patient
- The Department waived the requirement for monthly drug screens if the withdrawal period extends beyond 30 days
- The Department waived the requirement prohibiting take-home medication for withdrawal management

Questions

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Telehealth

- Audio/Visual telehealth platforms are allowable for screening
  - *Acceptable to use audio-only devices for methadone* ***only*** *if the patient is in the presence of a licensed practitioner registered to prescribe & dispense controlled medications*
- If the patient is appropriate for MOUD via the screening, the physical exam needs to be performed in person

Take-Home Medication

NEW: Revised Criteria for dispensing MOUD to patients for unsupervised use - Risk/Benefit Analysis

- Risk of overdose or ability to function safely.
- Attendance at supervised medication administration.
- Absence of serious behavioral problems that endanger the patient, the public or others.
- No known recent diversion activity.
- Medication can be safely transported and stored.
- Any other criteria relevant to the patient's safety and the public's health.

Take-Home Medication

and time in treatment

Take-Home Medication

Eligibility assessments must be completed regularly, at minimum:

1. Upon admission
2. Monthly following admission dependent on each patient's schedule and need

Documentation must include:

1. Why the patient is deemed ineligible (if need be)
2. Why the patient's number of take-home doses has increased or decreased
3. The individualized education, guidance, and support provided to the patient to be eligible for initial or increases in take-homes
4. Evidence that the patient was educated on the safekeeping of take-home medication

Take-Home Medication

OTPs are expected to:

- Create opportunities for touchpoints with patients
- Support discussions on treatment progress
- Educate patients on what is needed to advance in their care
- Revise take-home policies
- Educate the patient on safekeeping of take-home medication

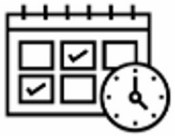
Pregnant Women

- Prioritize admission
- Pregnancy should be confirmed
- Evidence-based treatment protocols for pregnant patients, such as split dosing regimens, may be instituted
- Prenatal and other sex-specific services, including reproductive health services for pregnant and postpartum patients, must be provided (directly or through a referral)

Consent to Treat Policies

Program policies must ensure:

- **Patients** are informed of their consent options and relevant facts concerning the use of MOUD
- **Program staff** clearly record when consent is given either verbally or electronically



Interim Treatment

Interim treatment: *Interim treatment* means that on a temporary basis, a patient may receive some services from an OTP, while awaiting access to more comprehensive treatment services. The duration of interim treatment is limited to 180 days.

- Maximum time for interim treatment increased from **120 days** to **180 days and allows for profit OTPs to utilize interim maintenance**

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Evaluation Survey

Your feedback will…

- Inform future session topics and discussion
- Be used to develop new trainings and technical assistance resources
- Refine our delivery of information to best suit your needs

Register Today!

Roundtable discussion, Session 1

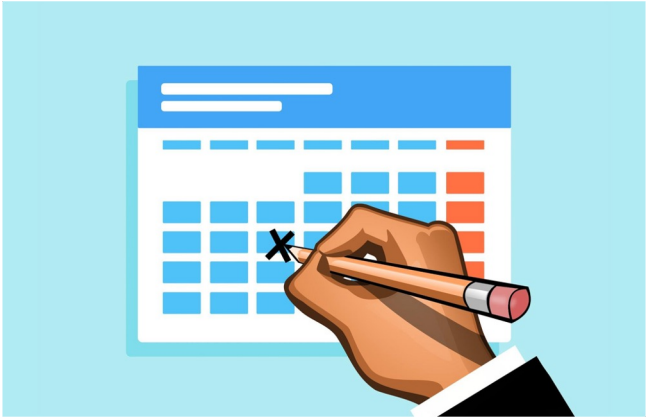
Wednesday, July 10, 2024, 2 - 3:30 pm

Roundtable discussion, Session 2

Monday, July 15, 2024, 2 - 3:30 pm

MASAM'S SUD Pearls for Practice

September 13th and 14th



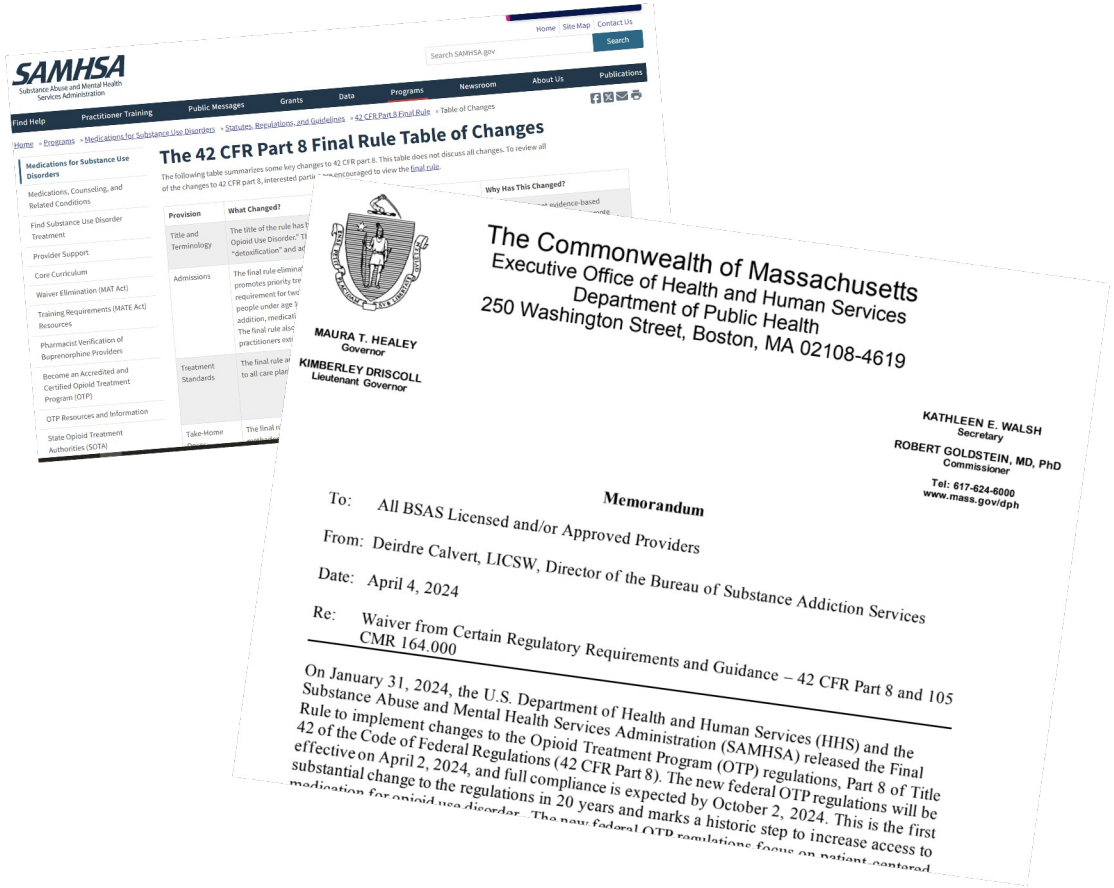
Resources

[42 CFR Part 8 Regulations](#)

- [Table of Changes](#)
- [FAQs](#)

[DPH BSAS Regulations](#)

[Provider and Patient Letters](#)



Thank you!

Questions? Ideas?

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