NEW FEDERAL REGULATIONS IN OPIOID TREATMENT PROGRAMS:

WHAT DOES THIS MEAN FOR MASSACHUSETTS?

DIGITAL WEBINAR GUIDE
ORIGINAL WEBINAR: JUNE 2024
UPDATED CONTENT: NOVEMBER 2025

MASSACHUSETTS OTP TTA CENTER

Bureau of Substance Addiction Services

JSI

INTRODUCTION

This companion guide offers webinar and round table attendees a resource to supplement the information covered during the webinar and extend the webinar's benefits beyond the allotted presentation time. It contains:

- Presentation slides and additional detail
- Frequently Asked Questions
- Future events and resources

The Bureau of Substance Addiction Services (BSAS) has contracted with JSI to start a new training and technical assistance center specifically for opioid treatment programs (OTPs). Now is a critically important time for OTPs and we are excited to support OTPs through implementing the new regulatory changes and other promising practices that will help increase access to medications for opioid use disorder.

By the end of this webinar, participants will be able to:

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

NOTE: The content of this companion guide has been updated to reflect **July 31, 2025** revisions to the MA Waiver from Certain Regulatory Requirements and Guidance. The "NEW UPDATE" icon indicates information that has changed. We have also updated the Frequently Asked Questions to reflect the revised guidance.

New Federal Regulations in Opioid Treatment Programs

What does this mean for Massachusetts?

Our Mission

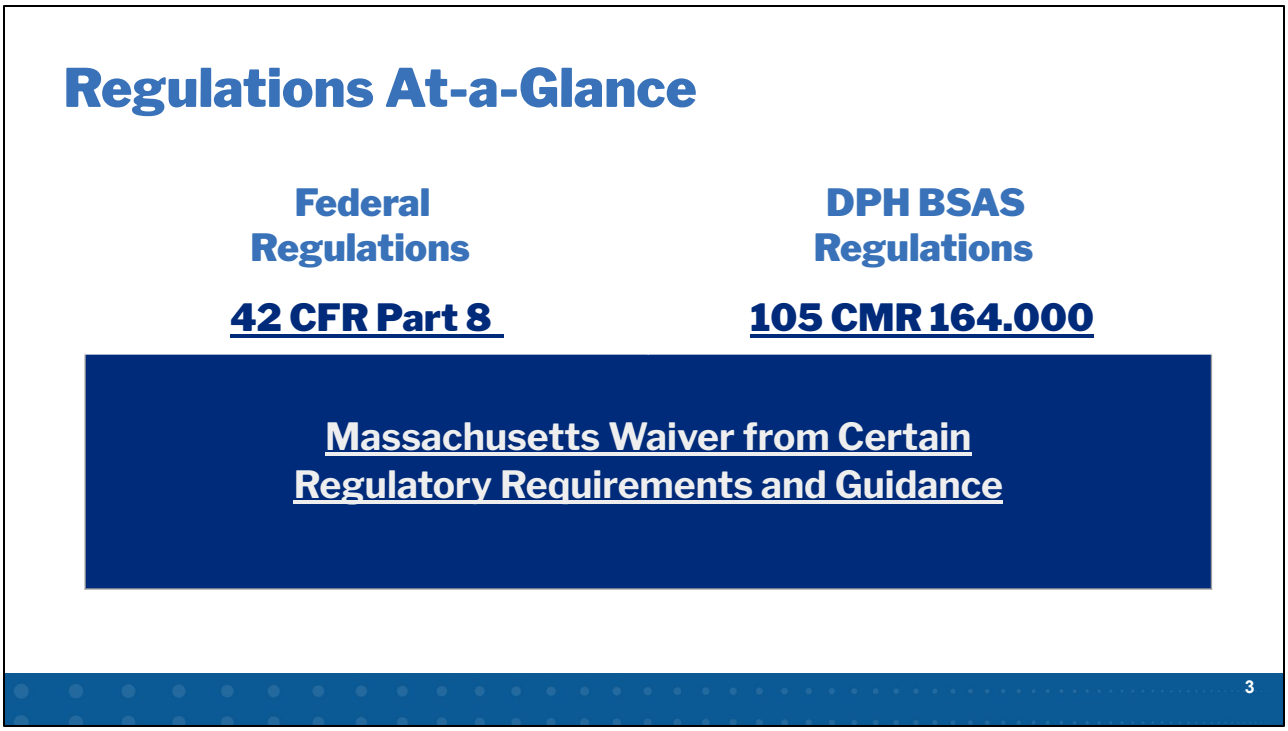
To foster innovation at Massachusetts OTPs by equipping staff with resources and support to deliver patient-centered care, address treatment barriers, and improve health outcomes.

Our Vision

A future where all individuals seeking treatment through Massachusetts OTPs have access to equitable, high-quality, and effective care.

Our Purpose

- Expand access to medications for opioid use disorder
- Enhance patient care and improve treatment outcomes
- Address barriers to equitable care
- Reduce stigma
- Foster collaboration



For the purpose of this presentation, we may denote

- 42 CFR part 8 as “federal regulations”
  - U.S. Department of Health and Human Services (HHS) & the Substance Abuse and Mental Health Services Administration (SAMHSA) developed the “Final Rule”.
  - The “Final Rule” modifies 42 CFR Part 8.
- 105 CMR 164.000 as “DPH BSAS regulations”
  - The MA Department of Public Health, Bureau of Substance and Addiction Services (BSAS) has issued guidance and specific regulatory waivers to align with changes to 42 CFR Part 8.

Today's Objectives

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

1. Describe the revised **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

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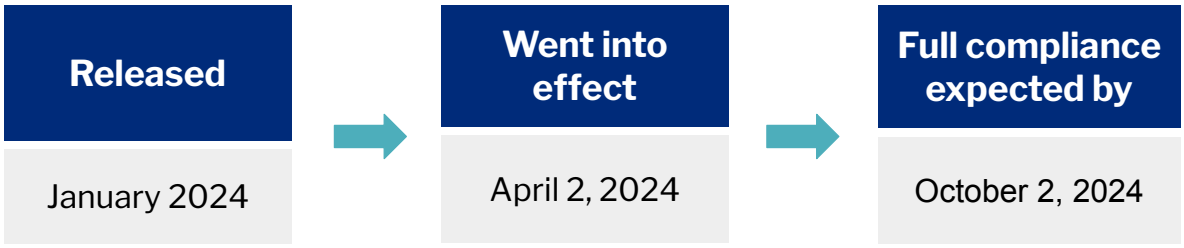
Timeline: New Federal OTP Regulations



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The new federal regulations are the first significant change to OTP treatment and methadone medication delivery standards in over 20 years. They are supported by evidence-based research and draw on lessons learned from necessary policy and guideline changes, as well regulatory exemptions, initiated during the COVID 19 Public Health Emergency.

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

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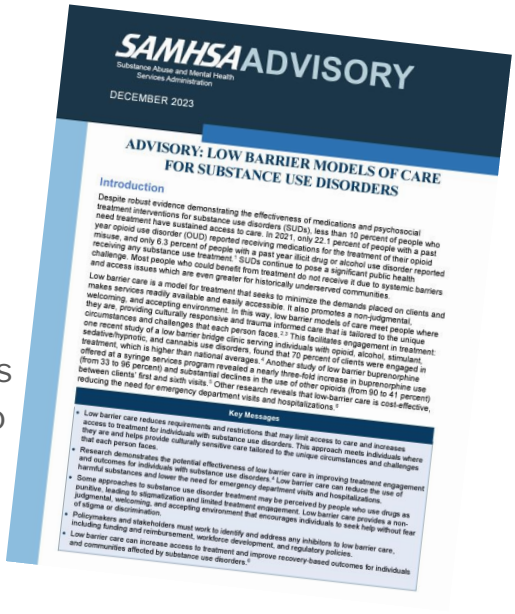
These shared values create opportunity to:

- See more patients
- Improve retention in care
- Expand the reach of OTPs with mobile units
- Expand the reach of OTPs with med units in other services

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]

BSAS aligns with SAMHSA's revised rule which supports low barrier access to care by increasing access to treatment for people with SUD. The revised rule:

- Supports people by helping prevent injury, infectious disease transmission, and death
- Meets people where they are and promotes any positive change
- Addresses social determinants of health and focuses on increasing protective factors

SAMHSA's Advisory: Low Barrier Models of Care for Substance Use Disorders | SAMHSA Publications and Digital Products

- While primary audiences may be PCP, FQHC, or other HC setting and focusing on BUPE, the sentiments in this Advisory echo those in the Final Rule.

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

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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

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The Department is issuing a blanket waiver from the requirements that only a Medical Director shall ensure all dosing of an opioid agonist treatment medication is ordered. Prior to the federal regulation changes, only physicians could initiate and make dosing changes in an OTP. The Final Rule allows for practitioners to initiate and make dosing changes and to write all med orders in an OTP. A midlevel waiver exemption submission is no longer needed from SAMHSA or the State Opioid Treatment Authorities (SOTA). Therefore, Mid-level Exemption applications are no longer accepted by BSAS as of April 2, 2024.

Appropriately licensed Mid-level practitioners are now able to order all medications for opioid use disorder in an OTP.

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 physical and behavioral health assessment within 14 days of admission

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The updates to the new regulations clear a path for removing barriers and expediting OTP admissions ultimately benefiting the program and patients in reducing the time to get into treatment. The next several slides discuss these changes and options.

To help expedite & streamline OTP admissions, the updated regulations separate the admissions intake into two sections. The first section is the screening exam and allows for medication to commence at time of initial intake; SAMHSA and BSAS recommend methadone medication induction **not** be delayed until the full examination is completed.

For a screening examination, refusal of lab testing for co-occurring physical health conditions should not preclude a patient from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications.

As for a full history and examination

- It should be noted that serology testing and other testing deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, and drawn not more than 30 days prior to admission to the OTP, *may* form part of the full history and examination.
- The physical examination must be done within 14 days of admission.

Assessments and Examinations

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

What if 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

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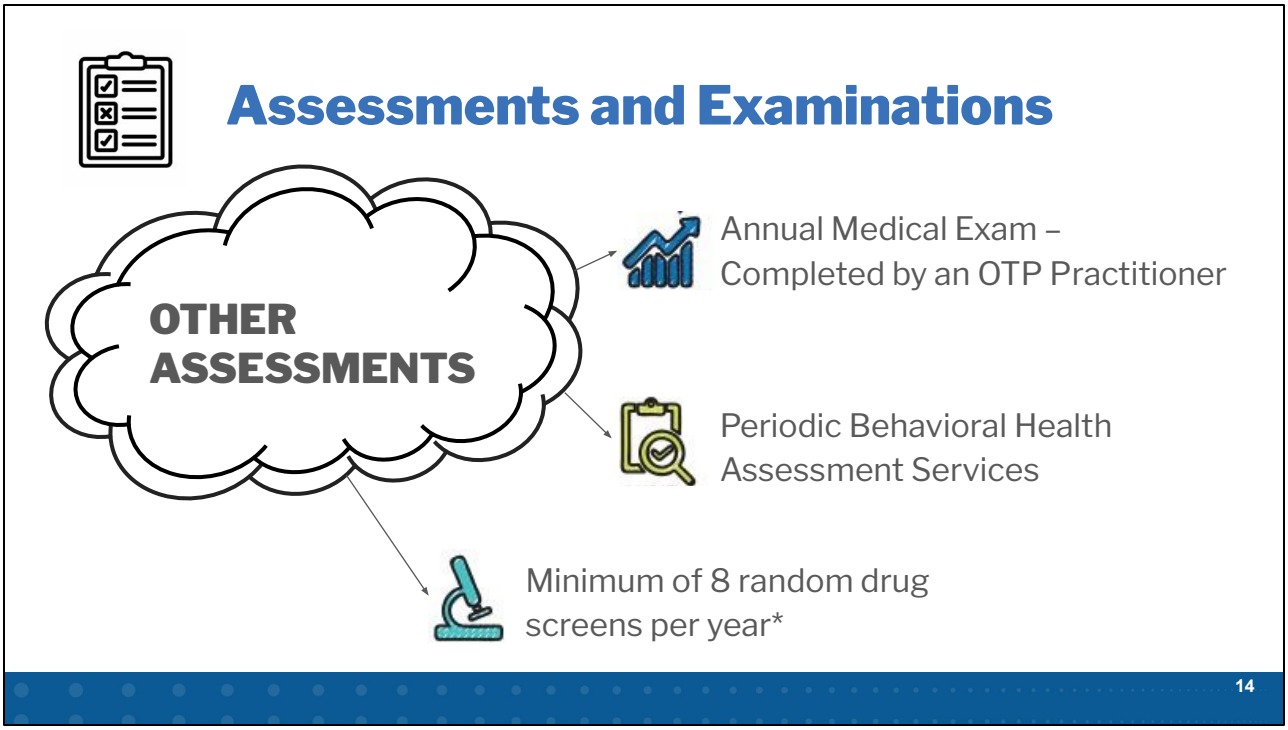
Another change which can help expedite the OTP admission process is the new federal regulations that allow for a practitioner outside of the OTP to complete the screening examination. This is an opportunity to decrease the amount of time a patient may wait to get into treatment as the OTP can now review a non-OTP practitioner's examination results, document that they reviewed and agree, and use that as the required screening exam prior to writing the medication order.

It is recommended that OTPs collaborate with their referral partners to discuss what information is needed and helpful in order to expedite the admissions process for patients.

- If the Practitioner is not an OTP practitioner, the screening and full examination must be done no more than 7 days prior to admission.
- 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.



The annual medical exam must be completed by a OTP Practitioner in addition to periodic behavioral health assessments.

- The combination and frequency of various services should be dictated by an individualized assessments and shared decision-making between the patient and clinical team.
- The plan must be reviewed and updated to reflect responses to treatment and recovery support services.
- Adjustments are made to the plan that reflect changes in the context of the person's life, including their current needs for and interests in medical, psychiatric, social, and psychological services. Additionally, current needs for and interests in education, vocational training, and employment services should be assessed.

*Drug screens shall, at a minimum, test for opioids including, but not be limited to, buprenorphine, methadone, and fentanyl. Screens can also test for cocaine; benzodiazepines; alcohol; and any other drugs that the Licensed or Approved Provider determines are clinically indicated, or as approved by the Commissioner of the Department of Public Health and listed in BSAS guidance.

- Drug screening does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.
- Drug screening is to be used as a clinical tool to aid in treatment decisions.
- Trauma informed care and measures should be incorporated into program policies and decision making.

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

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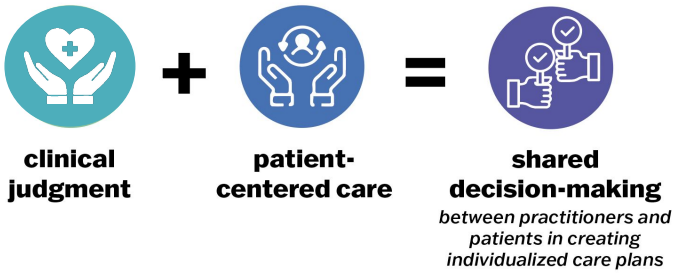
The new federal regulations removed these potential barriers to accessing OTP treatment. BSAS has aligned with these changes through the provision of the regulatory waivers.

Assessments and Examinations

Care Planning

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

Shared decision-making is emphasized.



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As mentioned, the underlying spirit of the new regulations call for individualized treatment and shared decision making to meet each patient's needs. This new paradigm prioritizes the need for patients to get and stay in treatment

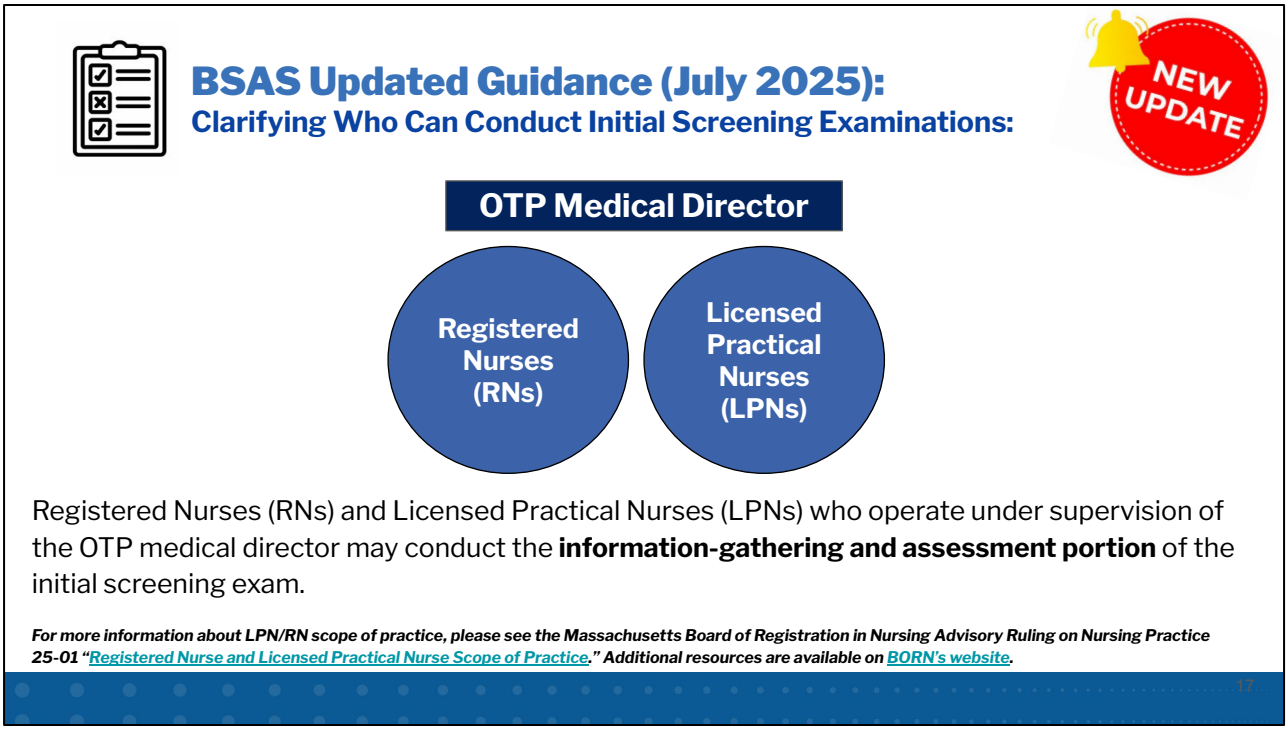
.

Note: the term treatment plan has been changed to **care plan**. This demonstrates the shared decision making which should occur when developing each patient's plan to reflect their own specific goals, needs, and circumstances. There should not be a one size fits all approach to care planning.

Care plans should be:

- Based on individualized assessment
- Created using shared decision making between patient and clinical team
- Updated, reviewed with the patient, and amended as necessary
- Tailored to meet each patient's needs
- Reflective of each patients' individualized counseling needs and ability to engage in counseling
- Prepared within 14 days of admission and include the initial psycho social evaluation

One important update to the federal regulations is that patients should not be discharged from treatment for not attending counseling. Medication should not be contingent upon attending counseling.



Process:

- RN or LPN collects vital signs & relevant data
- Information is transmitted to an **OTP practitioner** (Medical Director, Physician, Physician Assistant, Advanced Practice Registered Nurse, etc.)

Key Benefits:

- Increases staffing flexibility
- Supports timely patient admissions (e.g., off-hours, during an emergency, weekend, on a mobile or medication unit)

BSAS Updated Guidance (July 2025)

Step 1

RN or LPN conducts the information-gathering and assessment portion of the initial screening exam

Step 2

OTP Practitioner reviews nurse's assessment

Step 3

OTP Practitioner makes final admission determination & orders medication

To Note:

- The OTP practitioners review and involvement must be clearly documented in the patient's record.
- RNs and LPNs **cannot** make independent admission/treatment decisions

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

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As a reminder, medical orders and dosing initiation decisions can only be determined by an OTP Practitioner who can be either a Physician, Physician Assistant, or Advanced Practice Registered Nurse.

In line with providing individual care and not a one size fits all approach, the new regulations allow for the use of practitioner's clinical discretion when admitting patients. Specifically, initial dosing caps for the first day of treatment have been increased to a cap of 50 mg. These initial caps can be increased if the OTP practitioner finds sufficient medical rationale which must be recorded in the patient's medical record. Examples include, but are not limited to, transfer of a patient from another OTP, or the initial dose does did not alleviate withdrawal symptoms.

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

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In alignment with the changes to the Federal Rule, the Department waived the one-week waiting period requirement between withdrawal attempts. Providers should use clinical judgment in consultation with the patient when deciding on supervised withdrawal, and the rationale for the decision should be recorded in the patient's file.

The Department waived the requirement that a **physician** determine rate of decreased dosing as opposed and instead either a program physician or a practitioner make that determination for each patient.

The Department waived the requirement for Licensed or Approved Providers to obtain at least one drug screen per month if the withdrawal management period extends beyond 30 calendar days. As per 42 CFR § Part 8.12(f)(6), it's expected that a program physician or practitioner will decide on the frequency of drug screens for each patient in medically supervised withdrawal based on clinical judgment, ensuring that the minimum number of random drug screens is met.

The Department waived the requirement prohibiting Licensed or Approved Providers from providing take-home medication for withdrawal management. This adjustment aligns with the new federal OTP regulations on take-home medications at 42 CFR § 8.12(i). Additionally, licensed or approved OTPs are expected to evaluate each patient's eligibility for take-home medication upon admission and monthly during treatment.

BSAS Updated Guidance: (July 2025) Telehealth

OTPs may now conduct the **screening and full examination** via telehealth before initiating methadone.

To note:

- The medical practitioner must determine that the exam is adequate & comprehensive, when completed virtually
- In the case of **buprenorphine** treatment: both the screening and full exams may be conducted using either audio-visual or audio-only telehealth platforms

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The expansion of the use of telehealth is another example of the intention of these federal regulatory changes to provide opportunities to increase immediate access to treatment and make treatment more easily accessible to patients whether it is through the admission process or receiving counseling via telehealth.

Previously, the BSAS guidance on telehealth allowed for only preliminary screenings to be done via telehealth; an in-person exam was required before methadone initiation. New guidance allows for both the initial screening and the full examination to be conducted via telehealth if the OTP practitioner or primary care provider determines and documents that an adequate evaluation that would provide a comprehensive assessment of potential physical health impacts of a patient's opioid use disorder can be accomplished this way.

BSAS Updated Guidance: (July 2025) Telehealth

1. Technology

Telehealth examinations must be conducted using an audio-visual telehealth platform.

Audio-only devices are permissible only as a **last resort** when the patient does not have access to audio-visual technology.

*In this case, the patient must be in the **physical presence** of a licensed practitioner who can prescribe controlled medications.*

BSAS Updated Guidance: (July 2025) Telehealth

2. Compliance

All telehealth services must adhere to privacy and security requirements, including HIPAA and 42 CFR Part 2.

Programs are expected to develop clear policies and provide staff training on the appropriate use of telehealth.

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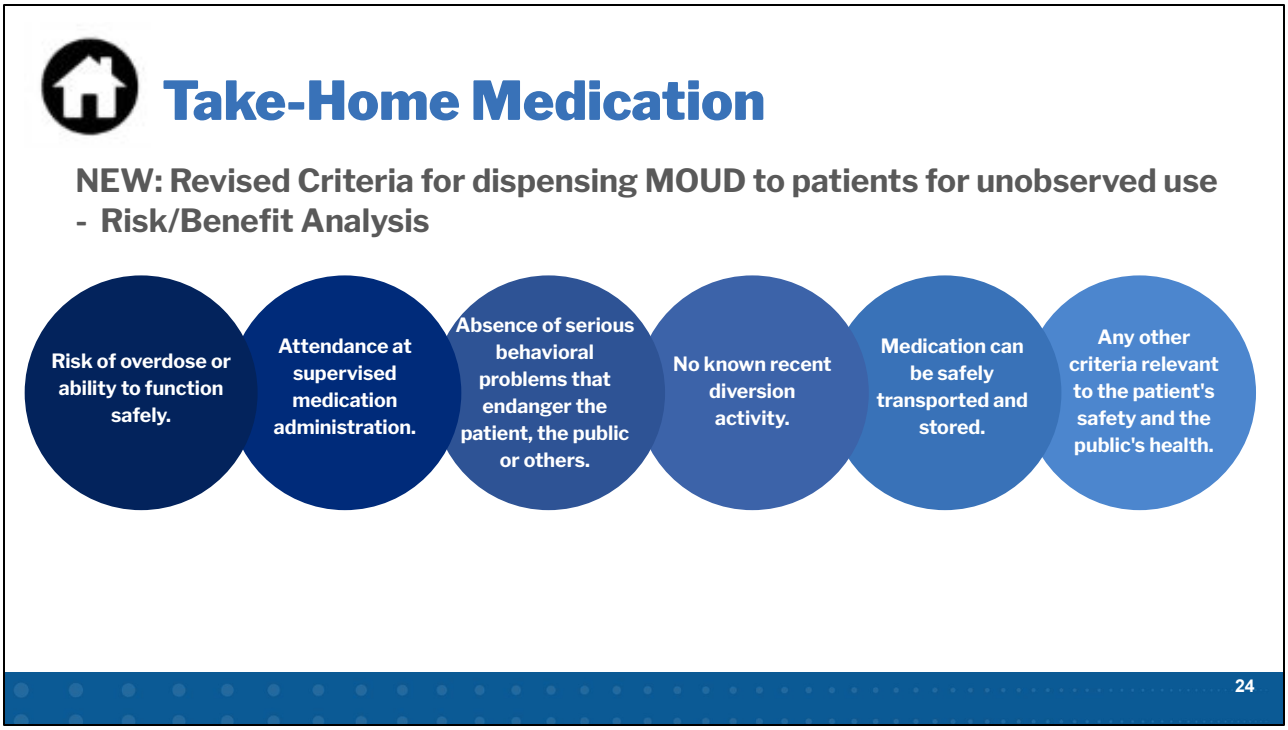
Each program is expected to:

- Develop Telehealth policies and protocols
- Provide appropriate training to staff
- Abide by all relevant privacy laws in implementing this feature of the new regulation

Resource: Telehealth Use in the Commonwealth and Policy Recommendations - January 2023

These requirements were included in the original guidance, but are reiterated here to underscore their importance.



Unobserved or “take-home” medication doses may be provided under the circumstances listed on the slide.

Risk/benefit analysis should consider:

- Absence of active substance use disorders, other physical or behavioral health conditions that
- increase the potential for overdose, or the ability to function safely;
- Regularity of attendance for supervised medication administration;
- Absence of serious behavioral problems that endanger the patient, the public, or others;
- Absence of known recent diversion activity;
- Whether take-home medication can be safely transported and stored; and
- Any other criteria that the medical director or medical practitioner considers relevant to the patient’s safety and the public’s health.

Decisions on dispensing MOUD to patients for unobserved use shall be determined by an appropriately licensed OTP practitioner.

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. Justification for why the patient is eligible or ineligible
2. Justification for 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

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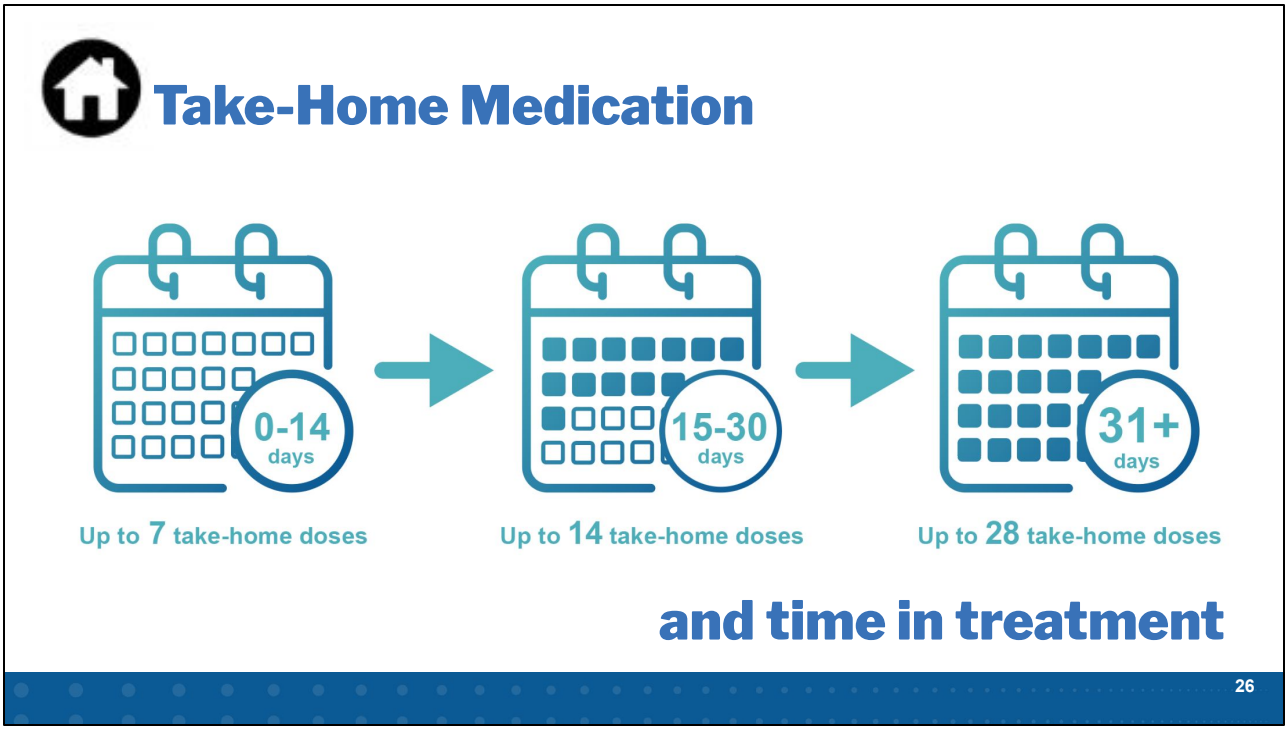
In order to ensure that each patient is assessed for the amount of take-homes that they're eligible for it is the Department's expectation that OTPs assess each patient's eligibility for take-home medication upon admission and monthly during
treatment. The spirit and the intention of this requirement is to ensure that the OTP is assessing for the eligibility but not mandate that the patient attend the assessment session. The BSAS guidance discusses this minimally and this training is now outlining the spirit and explanation.

The cadence of the meeting schedule for the assessment should be discussed with the patient and the patient should be offered a meeting schedule and cadence that works for their specific situation.

For example, if a patient receives 14 take-homes and it's documented in the patient record that they want to stay on this amount for three months, that patient should not be required to come in monthly for the assessment because the record clearly states that that's the mutual decision.

The rationale for providing take-home doses should be documented in the patient's clinical record.

OTPs are required to update the OTP Central Registry take-home numbers for patient's who have consented to participate.



Besides the revised criteria moving toward more of an in individual risk / benefit analysis, time in treatment requirements have also changed. The changes allow for patients to receive methadone take homes earlier in treatment and a higher number of take homes.

This more “patient-centered” approaches that consider patient preferences, needs, and values and allows take home decisions to be individualized.

In order to align with the new take home regulations, the Department waived specific regulations including:

- requirement for Licensed or Approved Providers to dispense opioid agonist treatment medications daily under direct supervision at the facility. This aligns with the new federal OTP regulations on take-home medications.
- the requirement prohibiting Licensed or Approved Providers from providing take-home medication for withdrawal management. This adjustment aligns with the new federal OTP regulations on take-home medications.
- the requirement for the Medical Director to solely reduce the number of times patients must present themselves for observed medication ingestion by providing take-home doses.

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

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The spirit of this guidance is to ensure that each patient is being assessed for take home eligibility based on the new regs at admission and monthly thereafter.

The expectation is to create opportunities for patients regardless of where they are in their course of treatment to have a touchpoint to engage with OTP staff to discuss their treatment progress and to learn what is needed to advance in take homes. SAMHSA is setting the foundational expectations that BSAS is building off to ensure that there is individualized care.

If the patient does not receive take homes or does not meet eligibility status, the patient record should clearly indicate the reason, and there should be evidence that the patient understands the reason, including how to work toward getting take homes or more take homes, and when they can meet with the team again.

Programs should be taking the time now to revise their take-home policies and incorporate all of these changes and requirements.

BSAS Updated Guidance: (July 2025)
Take-Home Medication

Take-Home Dose Locked Container Requirement

- BSAS has issued a **blanket waiver** for the state regulation which previously required all take-home doses to be dispensed in locked containers
- This change aligns Massachusetts policy with the more flexible federal standards

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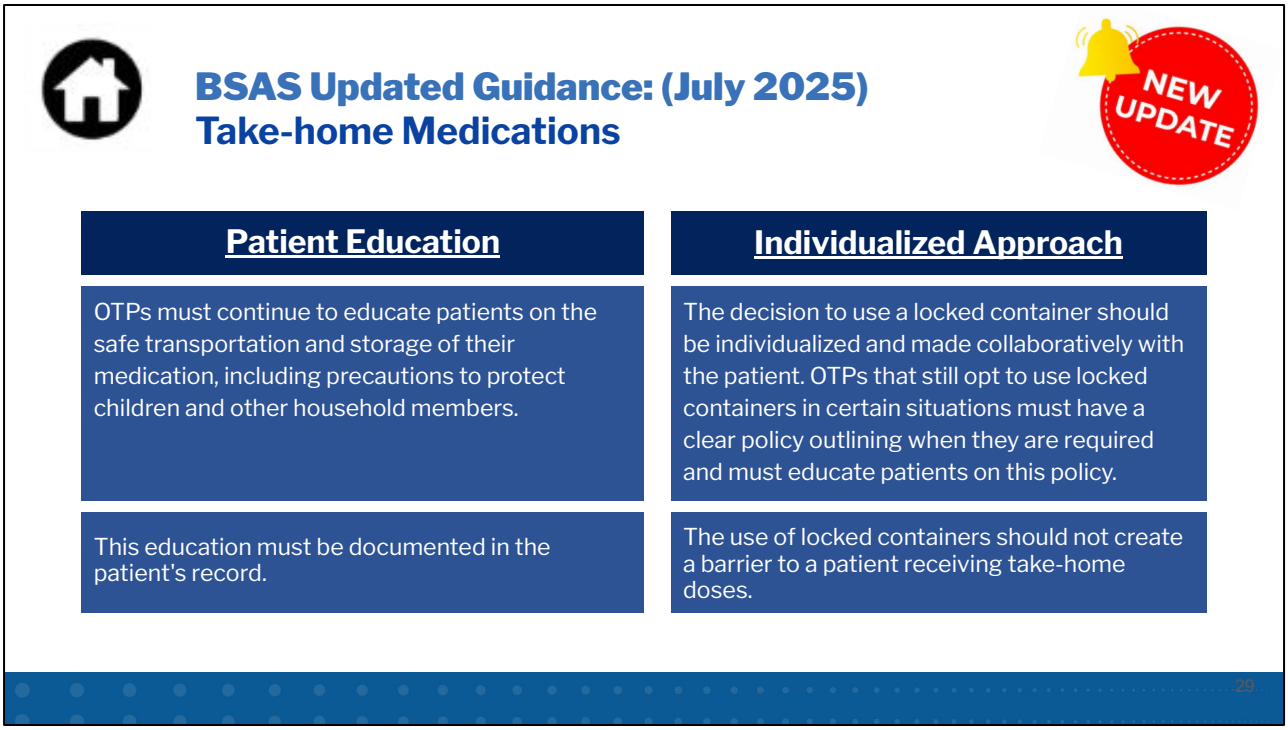
OTPs that provide patient-specific doses to Correctional Facilities and Skilled/Long Term Care Facilities must comply with applicable Federal and State regulations regarding locked container requirements. Please see the DEA Narcotic Treatment Manual (2022) Section 12.2 regarding locked container requirements when correctional facility or skilled nursing facility staff take custody of patient-specific medications.



It is the Department's expectation that OTPs must maintain current procedures adequate to mitigate the theft or diversion of take-home medications, including labeling bottles or containers with the OTP's name, address, and telephone number. Programs must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91–601 (15U.S.C. 1471 et seq.).

Requirements under 105 CMR 164. 307(C)(6) remain in place for programs to provide each patient with education on safely transporting medication from the OTP to their place of residence and include the safe storage of take-home medication at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

Pregnant People

- 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)

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OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocols.

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

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In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

Whenever possible, written consent should be gathered. When not possible and if it presents a barrier to access verbal consent is acceptable. Evidence of verbal consent must documented in the patient record. Programs must include verbal/electronic consent to treatment in policies and protocols.

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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The final rule extends the potential duration of interim treatment from 120 days to 180 days. It also clarifies the circumstances in which interim treatment may apply and maintains priority access to comprehensive services for pregnant individuals.

The rule finalizes removal of the requirement for observation of all daily doses during interim treatment. It also finalizes the expectation that crisis services and information pertaining to locally available, community-based resources for ancillary services be made available to individual patients in interim treatment. A requirement of a plan for continuing treatment beyond 180 days of interim services is also a requirement.

Resources

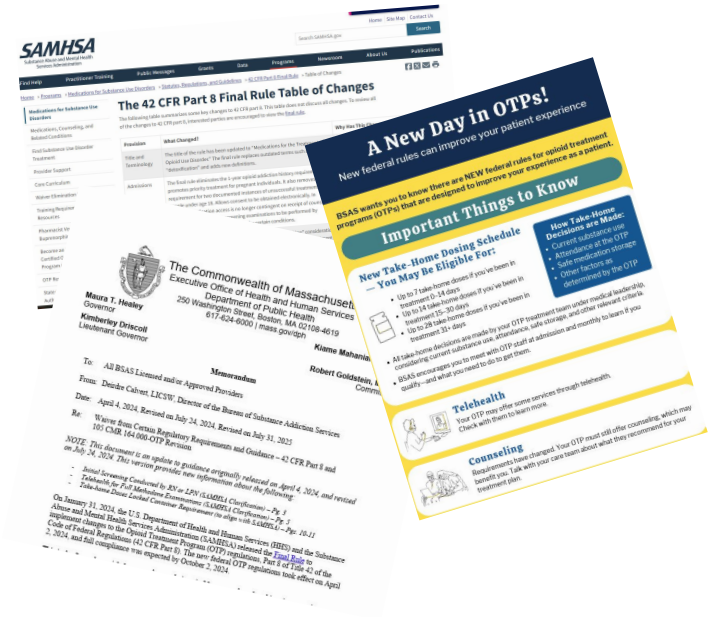
42 CFR Part 8 Regulations

- Table of Changes
- FAQs

DPH BSAS Regulations

Provider and Patient Letters

Patient Flier



42 CFR Part 8 Regulations

- Table of Changes
- FAQs

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Provider and Patient Letters

Thank you!

Questions?
Email us at **otptta-ma@jsi.org**

Want to learn more? Join us at future events!

Visit our website: **massotptraining.org** to browse and register for our current upcoming events

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42 CFR Part 8 Regulatory Webinars | Original: June 2024 | Updated: September 2025

QUESTIONS AND ANSWERS

Intake Assessment and Examination

1. Can the initial screening be done by a non-opioid treatment program (OTP) provider?	Yes, the screening can be conducted by a non-OTP provider. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days before OTP admission. Please refer to the Revised Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8., 105 CMR 164.000, and 42 CFR Part 8 Final Rule.
2. Can the physical be done by a non-OTP provider?	The full examination can be completed by a non-OTP practitioner if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws. Please refer to the Revised Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8., 105 CMR 164.000, and 42 CFR Part 8 Final Rule.
3. If a patient comes directly from an emergency department or medically-supervised withdrawal program, can an examination taken by practitioner cover the requirement for an initial physical examination and assessment if the OTP physician deems it sufficient?	The full examination can be completed by a non-OTP practitioner if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws. Please refer to the Revised Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8., 105 CMR 164.000, and 42 CFR Part 8 Final Rule.

4. Can the initial screening be done via telehealth?  	Previously, the BSAS guidance on telehealth allowed for only preliminary screenings to be done via telehealth; an in-person exam was required before methadone initiation. New guidance allows for both the initial screening and the full examination to be conducted via telehealth if the OTP practitioner or primary care provider determines and documents that an adequate evaluation that would provide a comprehensive assessment of potential physical health impacts of a patient's opioid use disorder can be accomplished this way.
5. Can the full medical exam for intake be done via audio-video telehealth?  	Yes. OTPs may now conduct the screening and full examination via telehealth before initiating methadone. Audio-only devices are permissible only as a last resort when the patient does not have access to audio-visual technology. In this case, the patient must be in the physical presence of a licensed practitioner who can prescribe controlled medications. **Compliance:** *All telehealth services must adhere to privacy and security requirements, including HIPAA and 42 CFR Part 2. Programs are expected to develop clear policies and provide staff training on the appropriate use of telehealth.*
6. For the medical history and physical exam, are there any specific topics that must be completed if the exam is completed outside the OTP?	All of the intake requirements per the regulations must be completed regardless of who conducts the intake. 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, verified by an OTP practitioner, and documented in the patient record.

7. What is the suggested process when a patient refuses or is a repeated “no-show” for the physical exam or behavioral health assessment?	It is the expectation that the program has policies and procedures in place to determine if a patient meets the criteria for admission. If the program is unable to determine whether the patient meets the criteria for admission to the OTP, the patient should not be admitted to the OTP. Best practice would include educating the patient on the risks and benefits of not participating in an OTP. Additionally, education about other MOUD services such as office-based addiction treatment (OBAT) and office-based opioid treatment (OBOT) should be provided. Harm reduction and other referrals should be provided.
8. Can you provide a checklist for the behavioral health assessment and physical exam?	Please refer to TIP 63 and the Federal Guidelines for Opioid Treatment Programs. See also 105 CMR 164.072 & 164.305 (D) within 105 CMR 164.000 Licensure of Substance Use Disorder Treatment Programs.
9. Can mid-level practitioners prescribe the initial dose upon admission?	The new federal OTP regulations permit practitioners in addition to physicians to initiate and make dosing decisions in OTPs. It is the expectation of the Department of Public Health Bureau of Substance Addiction Services (DPH BSAS) that the medical director is responsible for overall medical oversight of the OTP, however, a program practitioner or physician may ensure that all dosing of an opioid agonist treatment medication is ordered in accordance with federal requirements.
10. Are we meant to perform an in-person physical exam in addition to the assessment if the medical provider feels and documents that the assessment was sufficient?	All of the intake requirements per the regulations must be completed regardless of who conducts the intake.

11. Are OTPs required to meet monthly with patients to assess their take-home eligibility?	In order to ensure that each patient is assessed for the amount of take-homes for which they are eligible, it is the Department's expectation that OTPs assess each patient's eligibility for take-home medication upon admission and monthly during treatment. The spirit and the intention of this requirement is to ensure that the OTP is assessing for eligibility but not mandate that the patient attend the assessment session. The cadence of the meeting schedule for the assessment should be discussed with the patient and the patient should be offered a meeting schedule and cadence that works for their specific situation. **Case Example** - If a patient receives 14 take-homes and it's documented in the patient record that they want to stay on this amount for three months, that patient should not be required to come in monthly for the assessment because the record clearly states that that's the mutual decision. The expectation is to create opportunities for patients regardless of where they are in their course of treatment to have a touchpoint to engage with OTP staff to discuss their treatment progress and to learn what is needed to advance in take-homes. If the patient does not receive take-homes or does not meet eligibility status, the patient record should indicate the reason. Take-home policies should include processes to ensure these eligibility assessments occur.
12. With respect to the duration of OTP orders, our current system requires us to re-enter orders every 90 days. Is that a requirement? For example, we have a patient in long-term remission on methadone x 10 years who has 27 take-homes monthly. Does their order need to be re-entered every 90 days or can it be re-entered annually if no changes occur?	There are no state or federal OTP regulations regarding this specific question.

Annual Physical Exams	
13. For the annual physical exam, can those be done via audio-visual telehealth?	The full physical exam must be performed in person to treat a patient with methadone. To treat with buprenorphine, the screening and full exam may be conducted using audio-visual or audio-only platforms. Please refer to the Revised Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8., 105 CMR 164.000, and 42 CFR Part 8 Final Rule.
14. Can the annual physical exam be conducted by a non-OTP provider? For instance, by their PCP?	No, the annual physical exam must be completed by an OTP practitioner. Please refer to the Revised Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8., 105 CMR 164.000, and 42 CFR Part 8 Final Rule.
Other Comments and Questions	
15. **Comment:** I would recommend eliminating the language referring to pregnant people as women. It is more inclusive to use language like “pregnant people” or “birthing people” to make sure that all genders are represented. Thank you for considering this.	In future training offerings and resources, the Opioid Treatment Program Training and Technical Assistance (OTP TTA) Center and DPH BSAS will incorporate this language.

16. **Request for a resource:** Outline the differences with the Final Rule, providing examples of what exceptions are needed for take-homes for those who normally do not receive take-homes.	Exception Requests are required when an OTP treatment team proposes a deviation from limitations or protocols established by regulation 42 CFR Part 8 and 105 CMR 164.300. OTPs should be revising their take-home policies based on the waiver and guidance.
17. **Question**: If we have a community-based medication unit that has been Drug Enforcement Administration (DEA) approved to hold medication at the community-based site, do we need a nurse to go to the site to dispense or can another staff member dispense?	See DEA Regulation Chapter 21 Title II 1301.74(i): Narcotics dispensed or administered at a narcotic treatment program (OTP) will be dispensed or administered directly to the patient by either 1. the licensed practitioner, 2. a registered nurse under the direction of the licensed practitioner, 3. a licensed practical nurse under the direction of the licensed practitioner, or 4. a pharmacist under the direction of the licensed practitioner. Per the Final Rule, OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with federal and state law.

ACRONYM LIST

OTP - Opioid Treatment Program

MOUD - Medications for opioid use disorder

SAMHSA - Substance Abuse and Mental Health Services Administration

SUD - Substance use disorder

BSAS - Bureau of Substance Addiction Services

TTA - Training and Technical Assistance

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Want to learn more? Join us at future events!

Visit our website at: massotptraining.org to sign up for our listserv, browse resources and register for our upcoming events.

About the MA Opioid Treatment Program Training & Technical Assistance Center (MA OTP TTA Center):

The Bureau of Substance Addiction Services (BSAS) has contracted with JSI Research & Training Institute, Inc., to start a new training and technical assistance center specifically for opioid treatment programs (OTPs). Now is a critically important time for OTPs and we are excited to support OTPs through implementing the new regulatory changes and other promising practices that will help increase access to medications for opioid use disorder.