



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MARGRET R. COOKE
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

TO: BSAS LICENSEES, PROVIDERS, AND STAKEHOLDERS

FROM: DEIRDRE CALVERT, DIRECTOR, BUREAU OF SUBSTANCE ADDICTION SERVICES

SUBJECT: UPDATES TO REGULATIONS 105 CMR 164.300 – REQUIREMENTS RELATED TO OPIOID TREATMENT PROGRAMS

DATE: NOVEMBER 11, 2022

The purpose of this memo is to provide guidance to all programs licensed/approved by the Massachusetts Department of Public Health's (DPH) Bureau of Substance Addiction Services (BSAS) regarding compliance with new requirements related to Opioid Treatment Programs (OTPs) in BSAS' regulation for *Licensure of Substance Use Disorder Treatment Programs*, 105 CMR 164.000.

This guidance seeks to inform providers of changes to the regulations and point them to particular sections that fall within the topical area covered by this memo. BSAS encourages all providers to review the updated regulations in their entirety, which may be found at the following link: <https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs>

BSAS recognizes that each situation has its unique facts and circumstances and encourages stakeholders with specific questions to contact your Regional License Inspector:

<https://www.mass.gov/service-details/information-for-licensed-substance-use-disorder-treatment-programs>

Amendments to 105 CMR 164.300 ensure alignment with the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment Code of Federal Regulations 42 CFR Part 8. Additionally, in response to the ongoing COVID-19 pandemic and opioid crisis, SAMHSA and the Drug Enforcement Agency (DEA) have made additional changes that BSAS has incorporated into the regulation. These updates will provide increased flexibility to expand access to opioid treatment within the OTP system and to allow programs more flexibility to make changes to services based on the needs of the patients.

This includes:

- New regulatory definitions for Mobile OTPs, Medication Units, and Interim Maintenance

- Allows OTPs to close one day per week, as well as on state and federal holidays
- Allows patients access to take-home dosing sooner
- Allows patients access to a higher number of take-home doses over time
- Initiates the OTP Central Registry System
- Expedites the assessment and admission process
- Changes the requirements for specific functions previously carried out by “Medical Directors” to be done by a “Physician” or “Practitioner”

Expectations

OTPs are required to develop policies and protocols which incorporate each of the regulatory amendments listed below.

Amendments

164.305(A) Provision of Services – Opioid Treatment Program Central Registry System

The Central Registry System serves as both an electronic verification system and includes a disaster assistance module to ensure the uninterrupted delivery of medication in case of emergency. Using the Central Registry System, OTPs will verify a patient’s medication and dosage and prevent a patient’s simultaneous enrollment in more than one OTP.

Additional benefits include an efficient method of communication between BSAS and OTPs and between the OTPs themselves and their patients and staff, including during emergencies.

Finally, the Registry will allow for expedited data collection and reporting and real-time data collection on OTP census. This will allow for more in-depth analysis of demographic data of the OTP system.

See the Central Registry Guidance found here <https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs>

164.305 (C) Assessment

This amendment updates the previous requirement of 105 CMR 164.072 that an initial assessment must be conducted before treatment can proceed. A provider can now initiate patient treatment prior to the completion of the assessment required by 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation. The patient must be seen by a Qualified Healthcare Professional prior to initiating an FDA approved medication for the treatment of opioid use disorder.

164.305 (D) Initial Medical Examination

In addition to the assessment required, changes to this section require the Provider to ensure that each patient has an initial medical examination by a Practitioner, or by a qualified healthcare professional under the supervision of a program physician prior to administration of the first dose of medication.

164.305 (G) Interim Maintenance

The new regulation aligns with Federal allowance for OTPs to provide Interim Maintenance upon receiving Department and Federal approval. Interim Maintenance Treatment is defined under 164.005 as maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

164.307(B)(2) Drug Screening

The new regulation aligns with Federal requirements for OTPs to conduct 8 random drug screens per year, rather than the previous requirement of 15.

164.307(C) Administration of Opioid Medication – Take Home Medication

This revision removes the previous BSAS Take Home schedule and aligns with the Federal OTP Take Home schedule and criteria. The Medical Director may reduce the number of times patients must present at the OTP by providing take-home doses to a patient. The Medical Director must ensure that all take-home decisions comply with federal take-home criteria, 42 CFR Part 8.12(h)(4)(i)(1-5), and federal guidance.

Additional language has been added requiring providers to support patients on maintenance treatment when they are admitted to a 24-hour setting, including provision of take homes as indicated or through the exception request process.

164.307 (H) Annual Medical Exam

This update adds the ability for providers to utilize a medical examination conducted within the last 12 months, provided there are no medical issues or changes that require examination per the clinical discretion of the provider.

164.308 Medication and Mobile Unit

The updated regulation adds a requirement that Mobile and Medication units shall be equipped to assess dosage levels and have the capacity to provide patients all related OTP services.

Under 165.005, a Medication Unit is defined as a component of an OTP that is geographically separate from a brick-and-mortar OTP. As such, a Medication Unit engages in the treatment of opioid use disorder, including maintenance and/or medically supervised withdrawal treatment with narcotic drugs in Schedules II–V, at a location or locations remote from, but within the State as, the licensed, certified, and registered OTP, and operates under the licensure and certification of the brick-and-mortar OTP.

Mobile Opioid Treatment Program (Mobile OTP) is defined as an OTP operating from a motor vehicle that serves as a mobile component of the brick-and-mortar OTP. As such, a mobile OTP engages in the treatment of opioid use disorder, including maintenance and/or detoxification treatment with narcotic drugs in Schedules II–V, at a location or locations remote from, but within Massachusetts as, the licensed, certified, and registered OTP, and operates under the licensure, certification, and registration of the OTP. The Mobile OTP is described in DEA regulation 21 CFR Part 1300.

All OTP services, including the provision of take-homes, may be provided on both the Medication Unit and the mobile OTP.

164.311(D) Involuntary Terminations – Hearing Procedures

The new regulation allows programs to conduct hearings by telephone, or by using an audio-visual, real-time, two-way interactive communication system, provided that notes are taken simultaneously during the hearing. Where hearing officers previously had seven (7) business days to issue a decision, they now have seven (7) calendar days.

164.314 Staffing Pattern

Medical Directors were previously required to have six months of clinical experience with alcohol or other drug dependent persons. Medical Directors are now required to have any documented clinical experience with opioid-dependent, alcohol, and other drug-dependent persons, or 40 hours of documented continuing education in addiction treatment. This continuing education must include all FDA-approved medications for treatment of opioid use disorder.

- OTPs are now required to provide sufficient counseling staff to ensure patient needs are met.
- LPNs or other Qualified Healthcare Professional may now supervise nurses.

164.315 Hours of Operations

The updated regulation allows programs to close one day a week and on federal and state holidays as approved by the Department. Programs must provide take homes or alternative in-person dispensing methods for patients to receive medication regardless of closure. Services must be provided during the hours that meet the needs of the majority of the patients, not necessarily a 9:00am-5:00pm Monday-Friday work model.

See BSAS OTP Program Closure and Holiday Alert 2022-2023

164.316 Severe Weather

The new regulation removes specific criteria regarding take-home provision and requires that, in the event of program closure due to severe weather, programs follow the federal and state regulations and guidelines for continued dispensing of medication.

See BSAS OTP Program Closure and Holiday Alert 2022-2023

164.317 Required Agreements

The new regulation requires OTPs to implement qualified service organization agreements for the following: psychiatric, acute 24-hour diversionary services, emergency services, and any specialized services a program receives.

Resources

- [Forms, resources, and regulations related to BSAS-licensed Alcohol & Drug treatment programs](#)
- [Code of Federal Regulations Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment 42 Part 8](#)
- [MA Department of Public Health Bureau of Substance Addiction Services Regulations 105 CMR 164.000](#)
- [MA Department of Public Health Drug Control Program](#)
- [Drug Enforcement Administration](#)
- [Federal Guidelines for Opioid Treatment Programs](#)
- [SAMHSA TIP 63: Medications for Opioid Use Disorder](#)
- [SAMHSA TIP 34: Disaster Planning Handbook for Behavioral Health Service Programs](#)