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TO: BSAS LICENSEES, PROVIDERS, AND STAKEHOLDERS

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

SUBJECT: UPDATES TO REGULATIONS 105 CMR 164.000 – LICENSURE OF SUBSTANCE USE DISORDER TREATMENT PROGRAMS

DATE: NOVEMBER 11, 2022

The Department of Public Health is amending its regulation 105 CMR 164.000, *Licensure of Substance Use Disorder Treatment Programs*. The changes are scheduled to go into effect on Friday, November 11.

This memo is intended to:

1. Summarize updates to the regulation
2. Provide information about delayed implementation for certain substantial updates
3. Provide additional resources for guidance related to changes to the regulation

The Bureau of Substance Addiction Services (“BSAS”) encourages all providers to review the updated regulation in its entirety, which may be found at the following link:

<https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs>

105 CMR 164.000 sets forth standards for the licensure and approval of substance use disorder treatment programs operating as (1) standalone facilities, (2) within other state licensed settings (such as a hospital or clinic) or operated by a state entity (such as a civil commitment program operated by the Department of Mental Health) or (3) within penal facilities.

I. Summary of Updates

The regulation is now divided into three Parts:

1. **Part One** encompasses administrative requirements for licensure.
2. **Part Two** includes the requirements for specific services for which the applicant is seeking licensure or approval. These services include: 24 Hour Withdrawal Management, Outpatient, Opioid Treatment Programs and Residential Services.

3. **Part Three**, which is newly created, sets forth the requirements for programs (1) located within other state licensed settings, (2) operated by a state entity, or (3) located in Penal Facilities. Because of the unique nature of these three types of entities, their administrative requirements for licensure or approval are distinct from the Part One administrative requirements and are therefore separately listed in Part Three.

The updated regulation includes substantive changes across five main categories:

1. General modernization, reorganization, and alignment with federal standards
2. Implementation of Chapter 208 of the Acts of 2018 (the CARE Act)
3. Revisions that support implementation of the Executive Office of Health and Human Services (EOHHS)'s behavioral health redesign effort
4. Response to the COVID-19 pandemic
5. Establishing a regulatory framework for programs located in Commonwealth facilities such as Section 35 civil commitment programs operated by the Department of Mental Health (DMH) and Penal Facilities

Below are key examples of changes within each of the five categories:

1. General Modernizing, Streamlining, and Alignment with Federal Standards

Updates were made to reflect most recent evidence-based practice and terminology including:

- Increased Requirements for Personnel in Supervision and Leadership Roles:
 - Requiring Senior Clinicians to be independently licensed to assist in workforce development (164.048). The regulation will provide a glide path for current staff serving in these positions to meet the new criteria by January 2028.
 - Ensuring clinical supervision is conducted by appropriately licensed staff for both licensed and unlicensed direct care staff (164.044).
- Access to MAT: Requiring licensed or approved providers to provide all FDA-approved medications for addiction treatment (MAT) directly or by contract with a qualified vendor (164.074, 164.574 and 164.612).
- Office-Based Opioid Treatment (OBOT) Licensure: OBOTs were licensed by BSAS for the first time in 2016, as a result of a 2014 session law. The standards applicable to these entities have been enhanced to align with other treatment settings for overall consistency of service delivery (164.250).
- Direct Connect: Requiring providers to directly connect patients with another care provider or other services, such as certified sober housing or group therapy, prior to discharge (164.076 and 164.576).
- Lower Barriers for Admission: Prohibiting providers from automatically denying treatment based upon the primary substance used by the patient, a mental health diagnosis, or any prescription medications required by the patient (164.070 and 164.570).

- Central Registry for Opioid Treatment Programs (OTPs): Establishes requirements for all OTPs to participate in a Central Registry (164.305). The Registry database was procured by BSAS and will be offered at no cost to providers. It serves as both an electronic verification system and includes a disaster assistance module to ensure the uninterrupted delivery of medication in case of emergency. OTPs using the Registry will be able to immediately and in real time verify a patient's medication and dosage and prevent a patient's simultaneous enrollment in more than one OTP. It will also facilitate disaster response and allow access to treatment during emergencies throughout the Commonwealth and any of the other 15 states currently using this vendor. Additional benefits include a far more 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 much more in-depth analysis of demographic breakdowns on race and ethnicity.
- Reorganization: The regulation has been significantly reorganized and streamlined to reduce confusion and improve the efficiency of the licensing process. This includes:
 - Reorganizing Part Two of the regulations (164.100-164.400), which establishes service setting-specific requirements, by grouping standards by setting of care: 24-Hour Diversionary (Acute Treatment Services (ATS) /Clinical Stabilization Services (CSS)), outpatient, OTP, and residential.
 - Creation of Part Three (164.500- 164.000) to provide a streamlined approval process for entities already licensed by the Commonwealth or programs run by Commonwealth and those programs found in a Penal Facilities. This section is further discussed below.
- Alignment with Federal Standards, 42 CFR for Opioid Treatment Programs: The previous regulation included provisions that were more restrictive than federal standards, which created unnecessary barriers to take-home medication. While the Department issued waivers in April 2020 in response to the COVID-19 pandemic, the updated regulation codifies this existing practice and aligns state and federal standards (164.300):
 - The updated regulation strikes the requirement that OTPs remain open seven days per week to align with the federal regulation, which allows OTPs to close one day per week (as well as on state and federal holidays). Patients are provided with take-home doses or an alternative means to receive their dose on the closed dates, regardless of time in treatment.
 - The updated regulation allows patients to access take-home dosing immediately if appropriate based on a clinical assessment, instead of waiting for a prescribed number of days, and also provides for more take home doses per patient as appropriate.

Additionally, in response to the ongoing COVID-19 pandemic and opioid crisis, the Substance Abuse and Mental Health Services (SAMHSA) made the following additional changes in September 2021 that BSAS has incorporated into the updated regulation including:

- Mobile Opioid Treatment Program (OTP) Vans Attached to Existing OTP: A recent change in federal regulation allows existing brick and mortar OTPs to use mobile units to travel to different geographical regions of the state to provide OTP treatment services to underserved populations. These mobile units may operate under the same license and certification of the OTP (164.005 and 164.300).
- OTP Medication Unit: BSAS also incorporated new flexibilities at OTP Medication Units

recently enacted at the federal level. OTP Medication Units are geographically separate from the parent OTP and can be found in healthcare settings. Previously, these units could only provide a narrow range of treatment limited to maintenance. Recent changes at the federal level allows these units to provide a wide range of services including induction, provide take home doses, and counseling.

2. CARE Act Implementation

Chapter 208 of the Acts of 2018 (the CARE Act) included several provisions related to BSAS licensure and enforcement. These statutory provisions have been implemented in the regulation as follows:

- Requiring all providers to accept patients with public health insurance and report the facility's payor mix to the Department on a quarterly basis.
- Adding a demonstration of need for the substance use disorder treatment program process for licensure, which will consider applicants based upon the following factors set forth in statute:
 - Geographic access to the continuum of care
 - Access to a balanced continuum of care in terms of proportion of each service type
 - Program size is conducive to the health and safety of the client population being served
 - Health disparities are addressed through access to services for underserved populations and persons with co-occurring mental illness and substance use disorder and the demonstrated ability and history to meet the needs of such populations.
- Adding new fining authority for DPH to fine a facility that doesn't correct a cited deficiency up to \$1,000 per day per deficiency.

3. Behavioral Health Redesign

DPH has worked collaboratively with several state agencies to update and refine the regulations in accordance with EOHHS's Behavioral Health Redesign initiative. Amendments based upon this collaboration are designed to encourage better integration of substance use disorder treatment and mental health in BSAS-licensed or approved settings, and include:

- Access to all FDA-approved medications for opioid use disorder (MOUD)
- Access to mental health services either directly or through a Qualified Service Organization Agreement (QSOA)

4. Response to the COVID-19 Pandemic

These changes have been made based on lessons learned during the COVID-19 pandemic, to allow providers to appropriately respond to any ongoing challenges related to COVID-19, and to have plans in place if necessary for a future public health emergency.

- All Hazard and Emergency Planning and Procedures: Enhancing emergency planning requirements in order to address future large-scale incidences (e.g., the COVID-19 state of emergency), requiring programs to describe how operations will be affected/changed to respond

to emergencies, and require contingency planning for when evacuation of a facility is not appropriate, including shelter-in-place procedures and procedures responsive to an extended state of emergency. The impact of COVID-19 and the public health emergency emphasized the need for clear policies and procedures specifically addressing continued operation of services.

- Expanded use of Telehealth: Allowing for use of telehealth/audio-visual technology use in patient care and for grievance hearings, reflecting the reality of a post-COVID-19 environment and the need for further use of telehealth/telecommunications in regular operations and proceedings.
- Staffing Pattern: Expanding the pool of professionals who can provide services in acute care settings. For example, the regulation allows providers to use Licensed Practical Nurses, or other Qualified Health Care Professionals who possesses the requisite skills and supervision experience in addition to Registered Nurses.
- Special projects: Creating a new Special Projects license. This license provides flexibility and is intended for the licensing of innovative service models that may not fall under an existing licensing category. Special Project services are intended to meet an unmet need and/or an underserved population within the treatment system.

5. Regulation of programs in Commonwealth agency-owned facilities and for SUD programs in Penal Facilities

The amended regulations establish a formal regulatory framework for BSAS to approve substance use disorder (SUD) treatment programs in settings operated by Commonwealth agencies. This includes:

- SUD programs operated by Agencies of the Commonwealth such as Civil commitments services under G.L.C. 123 §35 which are subject to the newly created 105 CMR 164.500
- SUD programs operating in all Department of Corrections (DOC) and House of Corrections (HOC) facilities (Penal Facilities), which are subject to a new stand-alone section (164.600).

II. Blanket Waivers

BSAS acknowledges that some updates to the regulation will require additional time to operationalize as there will be substantial changes and adjustments to current practices. In anticipation of this transitional phase into compliance, BSAS will provide waivers for several new requirements as follows:

30-Day Waivers

Compliance with the following provisions will be waived for the first thirty (30) days the regulation is in effect. Providers should use this 30-day period to make the necessary changes and updates to become fully compliant with these provisions.

164.072 Assessment: This provision requires providers to complete a comprehensive assessment for each patient and resident. BSAS will waive the new requirements under this section for thirty (30) days.

164.073 Individual Treatment Plan: This provision requires providers to complete an individual treatment plan based each patient's or resident's treatment, medical, psychiatric, and social histories. BSAS will waive new requirements under this section for thirty (30) days.

164.074 Minimum Treatment Service Requirements: This provision requires providers to provide directly or through other appropriate agreements certain minimum services. Among these services, providers must provide medication for treatment of addiction, including all FDA-approved medications for addiction treatment. New requirements under this section will be waived for thirty (30) days.

164.075 Termination and Discharge: This provision requires providers to ensure that patients or residents are directly connected to appropriate services upon discharge or within a reasonable time following a discharge. This requirement will be waived for thirty (30) days.

164.044 Supervision: This provision requires providers to create written plans for supervision sufficient to meet the needs of staff, patients, and residents, as well as to provide ongoing in-service training of all personnel. Clinical supervision must be provided by an appropriately licensed staff qualified to deliver supervision, and it must be documented. BSAS will waive new requirements under this section for thirty (30) days.

60-Day Waivers

Compliance with the following requirements will be waived for the first sixty (60) days the regulations are in effect. BSAS expects providers to use this 60-day period to make the necessary changes and updates to become compliant with these provisions.

164.006 Definitions: Senior Clinician: The new definition of Senior Clinician requires individuals to be licensed independently. Additionally, BSAS has granted a grace period until January 2028 for qualifying Senior Clinicians to become independently licensed.

164.034 Qualified Service Organization Agreements: This provision extends the renewal period for QSOAs from two years to five years.

164.074 (I) Minimum Treatment Service Requirements: As part of the new requirements, providers are required to directly provide or create appropriate agreements to provide health services, including primary care and oral care.

164.442 Provision of Service: This provision expands adolescent and transition age residential rehabilitation youth to residents under the age of 26. The provision also expands what is required for developmentally appropriate services. Treatment plans and services are also expanded to include supports for employment readiness, vocational skills development, and to strengthen community and family supports.

164.307(C) Administration of Opioid Maintenance: These provisions align state regulation with federal regulation regarding take-home medication.

90-Day Waivers

Compliance with the following requirement will be waived for the first ninety (90) days the regulations are in effect. BSAS expects providers to use this 90-day period to make the necessary changes and updates to become compliant with these provisions.

164.305 (A) Central Registry: As described above, the Central Registry System will establish a database to serve as an electronic verification system and disaster assistance module to ensure the uninterrupted delivery of medication in case of emergency. BSAS will waive this requirement for ninety (90) days allowing for OTP providers to work with the Central Registry vendor Light House towards integration and implementation of the system.

If additional time is needed beyond these time frames, providers may apply for additional time in accordance with the waiver process at 105 CMR 164.023.

III. Guidance

To assist current providers and future licensees, BSAS has issued several guidance documents related to substantial changes in the regulations. The guidance documents are intended to further illustrate the new requirements of the regulations as well as identify significant updates to the previous version.

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>

Guidance documents for the following topics can be found linked below:

<https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs>

1. *105 CMR 164.000 - Reorganization and Requirements*
2. *105 CMR 164.000 - Access to Treatment*
3. *105 CMR 164.035 - Required Notification*
4. *105 CMR 164.040 and 164.540 - Safety and Signs of Life Checks*
5. *105 CMR 164.044 - Supervision*
6. *105 CMR 164.048 - Staffing*
7. *105 CMR 164.099 - Special Projects*
8. *105 CMR 164.300 - Opioid Treatment Program*
9. *105 CMR 164.305 - Central Registry System*
10. *105 CMR 164.500 - Commonwealth Agency Licensed and/or Operated Programs*
11. *105 CMR 164.600 - Penal Facilities*