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**TO: PENAL FACILITIES OPERATING SUD TREATMENT PROGRAMS
AND STAKEHOLDERS**

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

**SUBJECT: UPDATES TO REGULATIONS 105 CMR 164.600 – LICENSURE OF
SUBSTANCE USE DISORDER TREATMENT PROGRAMS – PENAL
FACILITIES**

DATE: NOVEMBER 11, 2022

The Department of Public Health is amending its regulation 105 CMR 164.000, *Licensure of Substance Use Disorder Treatment Programs*.

This memo summarizes updates to 105 CMR 164.600, which outlines the requirements for substance use disorder (SUD) treatment programs operated by penal facilities. The Bureau of Substance Addiction Services (BSAS) has issued additional memos and guidance related to other provisions of the regulation. 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>

Given the unique nature of penal facilities, these settings experience unique circumstances beyond other BSAS licensed facilities, including: the population served, the physical layout of the facility, and the added security concerns not typically present in traditional SUD treatment facilities. Given this, BSAS created a separate section of the regulation with regulatory provisions tailored to these settings.

BSAS recognizes that each situation has its unique facts and circumstances and encourages stakeholders with specific questions to contact your License Inspector: <https://www.mass.gov/service-details/information-for-licensed-substance-use-disorder-treatment-programs>

Summary of Requirements

SUD treatment programs operated within penal facilities must be approved by BSAS under the provisions outlined in 105 CMR 164.600 as well as any standards set forth by the Department; however, unlike other SUD programs, the administrative provisions of Part One of the regulation are not

applicable to penal facility operated programs. This is intended to ease the administrative burden on penal facility programs and to take into account that these programs are operated by a state entity.

Minimum Treatment Services 164.612: Penal facility operated SUD treatment programs must provide directly, or through appropriate agreements, certain minimum services to the standards set forth pursuant to 164.000, including:

- Medications for treatment of addiction, including all FDA-approved medications for addiction treatment
- Overdose prevention education as part of evidence-based practices
- SUD therapies
- Case management, including directly connecting patients and residents to appropriate providers based on continuum of care and individual educational, vocational, financial, legal, and housing needs
- Relapse prevention and recovery maintenance counseling and education
- Planning for patient's or resident's completion of treatment

Required Notifications to the Department 164.620: The Approved Provider must notify BSAS of certain adverse events and changes in operation that are *specifically related to the SUD program* within the penal facility. Revisions to this section include reporting incidents such as death of a patient immediately and other serious incidents within five (5) business days. Notifications are submitted on Department-specified forms.

Below includes, but does not limit, incidents which must be reported to BSAS immediately. These incidents are significant and pose a serious and imminent threat to patient, resident, and/or staff health and safety at the Program. Notifying the Department immediately means **as soon as the Licensed or Approved Provider learns of the incident occurring under the auspice of the licensed or approved program**. The following are examples; however, this is not an exhaustive list. The expectation of Licensed and Approved providers is to assess each event and report accordingly.

- **Death or Serious injury that occurred under program auspices**
 - Serious injuries such as a non-fatal overdose, adverse medical event, instances of self-mutilation, or suicidal ideation with intent.
- **Alleged abuse, neglect, physical or sexual assault, harassment, or other serious staff misconduct**
 - Report should also indicate the type of violation (such as boundary violations, sexual harassment, or sexual misconduct)
 - Staff being impaired at work
- **Report of abuse and/or neglect involving a staff member and/or filed against the program of a:**
 - Child or children
 - Elder(s)
 - Individual(s) with disabilities
- **Medication Errors and Events**
 - Medication errors that have the potential for harmful adverse effects.
 - Medication diversion by patient, resident, staff or any other individual

- Unaccounted for count discrepancies of controlled substances or substances with a high likelihood of misuse (i.e., gabapentin).
- **Loss of Essential Services**
 - Any incident that results in immediate health and safety risk or causes significant loss of services
- **Information or Data Breach**
 - Unauthorized access of confidential information such as a hacker stealing information, stolen information by staff or former staff.

The following includes, but does not limit, incidents which may be reported to the BSAS within 5 business days from the date of the incident. The following are examples; this is not an exhaustive list. Providers are expected to assess each event and report accordingly.

- **Staff Misconduct**
 - Staff misconduct that does not pose a serious and imminent threat to health and safety or patients, residents, and other staff. This may include staff actions that adversely impact patients/residents or violates the program’s policies and procedures.
 - Staff misconduct includes, but is not limited to, staff stealing belongings of patients/residents, falsification of patient/resident records, and any action by staff that violates patients’/residents’ rights.
- **Other Medication-Related Events**
 - Unaccounted for count discrepancies for non-narcotics, medication errors that do not have the potential for adverse effects as determined by appropriately trained health care professional.
- **Change in Operational Capacity/Change in Program Status**
 - Insufficient staffing for census
- **Other Violations of 42 CFR**
 - Disclosure of patient information without an appropriate, signed consent form

Waiver of 164.623: BSAS acknowledges that flexibility may be necessary in implementing these provisions. Therefore, Approved Providers may request waivers to requirements under 105 CMR 164.623. BSAS may issue a waiver upon receiving written confirmation of all of the following conditions:

- Compliance with the requirement would cause undue hardship to the provider
- The provider is in substantial compliance with the spirit of the requirement
- The provider’s non-compliance does not jeopardize the health, safety, or well-being of its patients or residents
- The provider supports their request with written documentation

*Penal facility operated programs contracting with a vendor agency for the provision of SUD services are required to apply for a certificate of approval to offer the services, and the contracted vendor agency must be licensed by the Department or apply for licensure to provide SUD treatment.