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TO: BSAS LICENSEES, PROVIDERS, AND STAKEHOLDERS

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

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

DATE: NOVEMBER 11, 2022

This document is intended to issue guidance to all providers licensed/approved by the Massachusetts Department of Public Health's (DPH) Bureau of Substance Addiction Services (BSAS) regarding compliance with new requirements for required notifications in BSAS' regulation for *Licensure of Substance Use Disorder Treatment Programs*, 105 CMR 164.000.

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>

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>

Requirements and Clarifications

Providers must ensure that any event that results, or may result, in a risk to patients', residents', or staff health and safety be reported to BSAS. **New requirements in 105 CMR 164.035 (F) distinguish which types of events must be reported to the Department immediately** (under 105 CMR 164.035 (F) 1), or **within five business days** (under 105 CMR 164.035 (F) 2).

As noted on the *Health and Safety Required Notifications Reporting Form*, reportable events require Providers to submit detailed information in a narrative format which include but are not limited to: the individuals involved, circumstances around the event, date of the event, date of patient admission, shift during which this event occurred, location of event, and any other relevant information.

To access the *Required Notification Reporting Form* please visit: <https://www.mass.gov/doc/health-and-safety-required-notification-form-0/download>

Events to be reported immediately in accordance with 105 CMR 164.035(F)(1), 164.535 (F) (1) and 164.620 (F) (1):

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
- **Communicable Diseases**
 - Confirmed communicable disease with a high rate of transmission that could have an impact on the health and safety or operations of the program (such as COVID-19).
 - Report should include information related to program response, patient care required, and other notifications made to Local Boards of Health or the DPH Bureau of Infectious Disease and Laboratory Sciences.
- **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**
 - Evacuation due to a fire in the program or building

- 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.

Events that must be reported within 5 business days of the date of the incident in accordance with 105 CMR 164.035(F)(2)

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
- **Police Activity**
 - Activity that is not the result of a serious health or safety event at the program such as execution of a warrant.
- **Conditions at the program**
 - Unsanitary conditions that do not impact to health and safety or the ability to provide services

Please note, BSAS staff are available to discuss an incident with Providers should there be any questions about the need to report.