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

MONICA BHAREL, MD, MPH
Commissioner

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

To: Commissioner Monica Bharel, MD and Members of the Public Health Council

From: Deirdre Calvert, Director, Bureau of Substance Addiction Services

Date: January 15, 2020

RE: Informational Briefing on Proposed Amendments to 105 CMR 164.000, *Licensure of Substance Use Disorder Treatment Programs*

I. Introduction

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to 105 CMR 164.000, *Licensure of Substance Use Disorder Treatment Programs.*

This regulation sets forth standards for the licensure or approval of substance use disorder treatment programs operating as standalone facilities, within other Department of Public Health or Department Mental Health licensed settings (such as a hospital or clinic), or within penal facilities. The proposed revision includes substantive changes across four main categories: 1) Increase access, reduce barriers and ensure individualized treatment; 2) general streamlining, reorganizing, and modernization; 3) implementation of chapter 208 of the acts of 2018 (the CARE Act); and 4) encourage better integration of mental health and substance use disorder treatment.

II. Proposed Revisions

A summary of the Bureau of Substance Addiction Services' ("Bureau") proposed revisions to the regulation is included below:

General Streamlining, Reorganizing, and Modernizing

- Terminology: This revision as an opportunity to ensure our terminology is patient-centric, destigmatizing, and aligns with the industry:
    - The term "client" has been changed to "patient" to emphasize that addiction is a medical disease.
    - The term "detoxification" has been changed to "withdrawal management" to reflect evidence-based practice and terminology.
    - Terminology for BSAS licensure and approval types changed to "services" from

"levels of care", which incorrectly implies sequential succession through each level and doesn't fully acknowledge there's no "wrong door" to accessing care.
    - Use of the term "inpatient" related to Acute Treatment Services and Clinical Stabilization Services has been changed to "24-hour diversionary" to more appropriately reflect the type of care provided and for consistency with current MassHealth payment terminology.
    - Added a definition for Office-Based Addiction Treatment to reflect office-based treatment includes addiction treatment beyond opioid use disorder alone.
    - Updated definition of "outpatient withdrawal treatment services" from "outpatient detoxification" and to require the capacity to treat with FDA-approved medications for addiction treatment.
- Provision of Service: Updates described here put the patient first, whether by directly improving treatment access or indirectly by improving clinical workflows.
    - Ensure patients have access to all FDA-approved medications for the treatment of addiction across all services to be provided directly or by contract.
    - Ensure patients have increase access to treatment by allowing providers to initiate treatment based on a brief assessment.
    - Ensure patients are directly connected with another treatment provider,
    - Ensure that patients are not denied treatment based upon the primary substance used by the patient, a mental health diagnosis, or any prescription medications required by the patient.
    - Ensure patients receive equal access to treatment regardless of any medications currently used.
    - Require mental health services including screening and crisis intervention for patients with co-occurring disorders, and health services including primary care and oral health care.
    - Update lab testing requirements to ensure providers test for opioids, cocaine, benzodiazepines, alcohol, all FDA-approved medication assisted treatment medications, and any other drugs the provider determines clinically indicated or that DPH lists in guidance.
    - Require patient-staff and patient-patient boundaries be part of both staff and patient orientations, as well as annual staff training requirements and ongoing supervision topics.
    - Align serious incident reporting and other required notice processes with provisions in other DPH licensure regulations. Align Social Model Recovery with American Society of Addiction Medicine (ASAM) standards for residential settings by requiring counseling**.**
- Opioid Treatment Programs: The Opioid Treatment Program (OTP) section has been fully aligned with federal regulations, in order to promote individualized treatment and increase access to take home medications as clinically indicated. By aligning OTP provisions for take-home doses and required hours of operation with federal standards, patient access to take-home medications will improve.
    - Currently, state regulations require OTPs be open seven days per week; whereas federal regulations allow OTPs to close one day per week, as well as on government holidays, provided patients are given take-home dosing for all days closed regardless

of time in treatment.
    - Aligning with federal regulations allows patients access to take-home dosing immediately; additionally, federal alignment ensures patients access to a higher number of take-home doses over time. For example, current state regulation does not permit take home doses until a patient has started the third month of treatment; as changed, patients will be eligible for take home dosing within the first 90 days of treatment, at the program's discretion.
- Physical Plant: Building/physical plant requirements have been streamlined and aligned with the Massachusetts Building Code.
- Staffing: Throughout the regulation, proposed changes support critical workforce development by creating work and training opportunities for clinicians seeking independent licensure and uniformly require licensed personnel for clinical supervision and leadership roles.
    - Senior Clinician – as updated, senior clinicians must be independently licensed. This will assist in workforce development and retention, as direct care staff seeking independent licensure will have their clinical hours and supervision counted towards their license.
    - Standardizing licensure requirement for social workers and mental health counselors throughout the regulation.
    - Ensuring clinical supervision conducted by appropriately licensed staff for both licensed and unlicensed direct care staff.
- Regulation Organization: The regulation has been significantly reorganized for ease of use, reduction of administrative burden on the licensee, and readability. By reorganizing the regulation into inpatient and outpatient settings, regulatory requirements are easier to follow and will allow the Bureau to move towards issuing a single license specifying the services a licensee provides. As updated, the regulation establishes the following service types by care settings:
    - 24-Hour Diversionary: 24-Hour Diversionary Withdrawal Management Services and Clinical Stabilization Services
    - Outpatient: Outpatient Withdrawal Treatment Services, Office-Based Opioid Treatment, Acupuncture Withdrawal Management, First and Second Offender Education, Day Treatment
    - OTPs
    - Residential: Residential Rehabilitation for Adults, Residential Rehabilitation for Adults with their Families, Residential Rehabilitation for Adolescents and Transition Age Youth, Residential Programs for Operating Under the Influence Second Offender Programs, and Co-occurring Enhanced

Two additional sections have been added to the regulations, Part Three and Four have been added, which contains a subset of BSAS licensure requirements applicable to any Department of Mental Health (DMH)-licensed or operated facility operating a substance use disorder treatment program, any Bureau of Health Care and Safety Quality BHCSQ-licensed facility operating a substance use disorder treatment program, or any penal facility operating separate, identifiable substance use disorder treatment programs.

- These changes maintain an emphasis on standards for clinical care provided by a substance use disorder treatment program within these facilities, while also removing

administrative licensure requirements, such as general policy and procedure development, that duplicate DMH and BHCQ licensure requirements for these facilities.
    - Currently in Part One, there are cumbersome lists of all of the citations throughout the regulation which apply to DMH and HCQ settings. For ease of use, Part Three includes the text of these provisions which eliminates the need to cross reference.
    - Previously, there were separate requirements for DMH and HCQ facilities; now, there is a common list of standards for both.
- Separate section for penal facilities provides structure for approving substance use disorder treatment programs in these facilities.
    - The approval process for substance use disorder treatment programs in penal facilities builds upon the current application process for approving Medication for Opioid Use Disorder (MOUD) treatment services in correctional facilities. The regulation also outlines the ability for DPH to inspect the BSAS-approved portion of the DOC or HOC facility, and requires these providers submit required notifications to the department, such as serious incident reports, to ensure patient safety.

- Office-Based Opioid Treatment: State law requires Bureau licensure of any Office-Based Opioid Treatment provider serving 300 patients or more for opioid dependency. Previously, these providers were subject to only a subset of BSAS's minimum procedures and requirements for licensure. As their only license comes from BSAS (state law excludes licensed clinics and from the definition of OBOT), this revision aligns the requirements for OBOTs with other Bureau licensees, while maintaining the subset of clinical care standards which currently apply (these are now included in a standalone OBOT section in Part Two: Levels of Care).

CARE Act Implementation

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

- New fining authority for the Department to fine a facility that doesn't correct a cited deficiency up to $1000 per day, per deficiency.
- Providers are required to accept patients with public health insurance and report the facility's payer mix to the Department on a quarterly basis.
- Providers are required to demonstrate the following factors as part of the licensing application:
    - Need for the substance use disorder treatment program.
    - 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.

        - These factors will apply only to those providers who have not gone through the BSAS procurement process, which incorporates all of these factors.
- Provides structure for approving substance use disorder treatment programs in penal facilities, which are defined in the law to include both Houses of Correction (HOC) and institutions operated by the Department of Correction (DOC).

Integrated Mental Health and Substance Use Treatment

Proposed revisions align with updates to DPH's clinic licensure regulation, reduce barriers to accessing treatment, improve access to medication assisted treatment, require direct referrals to the full continuum of treatment and health services, streamline licensure across service delivery settings, and update staffing, supervision and training requirements to encourage better workforce development.

As part of implementing the CARE Act, the regulation ensures providers demonstrate their ability to meet the health needs of individuals with co-occurring mental health disorders and address disparities in treatment for patients with co-occurring conditions. A summary of these changes is included below:

- Prohibit provider admission policies from denying treatment based upon the primary substance used by the patient, a mental health diagnosis, or any prescription medications required by the patient.
- Require licensed or approved providers provide directly or through contract mental health services including screening and crisis intervention for patients with co-occurring disorders, and health services including primary care and oral health care.
    - To the extent possible, language in the BSAS regulation aligns with that included in the clinic licensure regulation.
- Allow a provider to defer certain testing or exams if the patient is directly admitted from an acute treatment setting, or the patient has had a medical exam in the past 12 months and there are no medical issues or changes.
- Ensure patient risk assessments and development of safety plans are included as part of staff training for co-occurring mental health disorders.
- Add Co-occurring Enhanced as a residential service type. This residential service type ensures patients with both substance use and mental health disorders receive appropriate services to address both disorders. Previously, this service designation existed through BSAS contracting only.
- Create a pathway for BSAS providers to add a separate, identifiable mental health service.
    - This revision is similar to the existing clinic regulation, which provides a pathway for licensed clinics to obtain BSAS approval for separate, identifiable SUD treatment services.

III. Summary

DPH staff intends to conduct the public comment hearing in the coming months and hopes to return to the PHC shortly after that to report on testimony and any recommended changes to the

proposed amendments. Following final action by the PHC, the Department will be able to file the final amendment with the Secretary of the Commonwealth.

The proposed amendments to 105 CMR 164.000 are attached to this memorandum.