



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: Elizabeth Kelley, Bureau Director, Bureau of Health Care Safety and Quality
Date: January 15, 2020
RE: Informational Briefing on Proposed Amendments to 105 CMR 140.000, *Licensure of Clinics*

I. Introduction

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to 105 CMR 140.000, *Licensure of Clinics*. The Bureau of Health Care Safety and Quality (“BHCSQ”), within the Department of Public Health (“DPH” or “the Department”), previously presented a draft revision of these regulations to the PHC as part of the regulatory review process mandated by Executive Order 562.

After the initial review by the PHC, the Department held a public comment period, which included a public hearing. During the public comment period, the Department received comments from many stakeholders.

In addition to holding the public comment period, DPH has worked collaboratively with MassHealth and the Department of Mental Health to update and refine the clinic licensure regulation to encourage better integration of mental health and substance use disorder treatment in clinic settings.

As a result of the comments received during the first public comment period and the collaboration with MassHealth and the Department of Mental Health, the Department recommends further amendments to the regulation as discussed below.

II. Summary of Proposed Changes

Further Changes in Response to Comments

105 CMR 140.010 (Scope) A commenter requested further clarification on language added to the proposed regulation stating that the scope of the regulation applies to “affiliates of a licensed

clinic”.

The Department has removed the term “affiliates” from the regulation as the term is not defined and is not used elsewhere.

105 CMR 140.020 (Definitions)

- A commenter requested the Department clarify the proposed changes to the definition of “surgical service”. The commenter noted that under the proposed regulation, only those endoscopic or operative procedures that require regional or general anesthesia constitute “surgical service”.

The Department agrees. The intent of the original change was to align the definition with evidence-based consensus definitions, consistent with the Massachusetts Medical Society, that ALL endoscopic procedures are surgical, procedure regardless of anesthesia type. The Department has clarified the definition of “surgical service” to more clearly show that difference.

- Commenters expressed confusion and concern about the definition of “urgent care”. Commenters were concerned that urgent care was a type of care provided by hospitals and health centers, along with primary and emergent, and that the definition confused the issue.

The Department has updated and clarified the definition and respond to the comments. This amendment clarifies the definition. The Department also updated “substance abuse” in the definition to more appropriate terminology.

- A commenter pointed out that the definition for “notice of intent” inadvertently included the words “long-term care facility” instead of clinic.

The Department has made the correction.

- The Department moved a definition of the term “Nutritionist” from the body of the regulation to the definition section for clarity and consistency.

105 CMR 140.101 (Requirement of License) A commenter sought clarification on when a clinic license is required.

The Department has clarified that an entity must obtain a clinic license from the Department covering all locations at which the clinic provides services.

105 CMR 140.305 (Emergency Transfer) Commenters expressed concerns with proposed changes to this section that removed a current requirement indicating clinics must have a written plan, procedure, and agreement with a nearby hospital for the transport of patients with an emergency condition or for those seeking emergency treatment.

DPH clarified language in this section to indicate that inter-facility transport agreements are not

precluded. The Department did not reinstate the requirement that each clinic separately enter into an agreement for emergency services with a nearby hospital as the Emergency Medical Treatment and Labor Act (EMTALA) requires all hospitals to stabilize and treat anyone presenting in the emergency department. Under DPH's Office of Emergency Medical Services' statewide access plan, the emergency services system rather than the clinic determines to which hospital a patient should be transported.

105 CMR 140.307 (Serious Incident Reports) A commenter expressed confusion about overlapping requirements of serious incidents and serious adverse drug events (SADEs).

DPH agrees. The reference to SADEs has been removed in 140.307(C) and placed into 140.307(D) for consistency. Multiple reports are not necessary.

105 CMR 140.308 (Serious Reportable Events and Serious Adverse Drug Events)

- A commenter expressed concern about the addition of verbal notice to patients seven days after a serious reportable error.

DPH agrees and has amended the regulation to allow for "oral" or written disclosure. Depending on best practice and patient preference, oral or written notice may be more appropriate, and one method does not preclude the other. This proposed change will align the reporting requirements with 105 CMR 130.000.

- Several commenters pointed out that the serious adverse drug event regulation inadvertently included "hospital" rather than "clinic" or "ASC".

The Department has made the correction.

105 CMR 140.530(B) (Staffing – Personnel Qualifications) A commenter opposed the proposed change that allowed only board certified psychiatrists to be included on the staff of a clinic.

The Department has changed the language to only require leadership positions within the clinic to be board certified in their appropriate field, as board certification transparently demonstrates ongoing competency in the designated area. This change is in alignment with hospital regulations.

105 CMR 140.607 (Adequate Assistance) A commenter requested language in the regulation requiring only registered nurses be allowed to function as circulating nurses be restored.

The Department agrees and has amended the language to incorporate the requirement by using the appropriate term and reference from the regulation for consistency. Scope and authority has also been noted for clarity.

105 CMR 140.902 (Birth Center Staffing): A commenter requested striking language that requires midwives to be supervised by a physician.

- The Department agrees. The regulation has been updated to reflect the autonomous practice of nurse midwives.
- The Department has also aligned the language with the hospital regulation by removing the requirement that these staff members be board certified, as the Department only requires board certification for leadership positions.

Additional Changes Recommended by the Department

105 CMR 140.020 (Definitions)

- The following changes to the definitions section of 105 CMR 140.000 are suggested to better encourage integration of mental health and substance use disorder treatment in clinics:
 - DPH added definitions for “mental health and “substance use disorder” that refer to the current edition of the Diagnostic and Statistical Manual of Mental Disorders.
 - DPH clarified in both the “mental health service” and “substance use disorder treatment service” definitions that service-specific licensure requirements apply only to those providers with separate, identifiable mental health or substance use disorder treatment services.

105 CMR 140.103 (Other Licensing Requirements) Consistent with other DPH regulations, language has been added indicating licensees must comply with all applicable state and federal laws and regulations, including applicable MassHealth laws and regulations.

105 CMR 140.301(B) (Administrative Records) DPH added a requirement that clinics have policies and procedures for documenting clinical supervision of health care staff by licensed staff members. This update emphasizes the expectation that clinics ensure appropriate clinical supervision.

104 CMR 140.302(B) (Patient Records) DPH added a provision requiring patient records include a release of information to a receiving provider to emphasize the importance of this standard practice for patient continuity of care.

105 CMR 140.308 (Serious Reportable Events and Serious Adverse Drug Events) The Department corrected a regulatory reference and amended language regarding reporting for MassHealth members to align with hospital regulations.

105 CMR 140.318 (In-service Training for Health Care Staff) DPH amended this section to ensure ongoing training provided to all clinic staff is appropriate and evidence-based.

105 CMR 140.361 (Radiologist) and 140.362 (Radiologic Technologist) The Department has aligned the language with the hospital regulation by removing the requirement that these staff members be board certified, as the Department only requires board certification for leadership positions.

105 CMR 140.500 (Applicability of 105 CMR 140.510 through 140.560) DPH has clarified that the mental health service specific licensure requirements apply only to those providers with separate, identifiable mental health services.

105 CMR 140.510 (Mental Health Services) DPH has emphasized the potential for co-occurring substance use disorders in mental health patients and the importance of substance use disorder screening. To ensure staffing flexibility, DPH has amended this section to clarify that mental health services may be provided by contracted non-clinic employees.

105 CMR 140.520(A) (Adequate Mental Health Services – Intake Services) DPH amended this section to require a substance use disorder screening at intake.

105 CMR 140.520(B) (Adequate Mental Health Services – Evaluation and Diagnostic) DPH has removed the provision requiring a patient evaluation be complete before a treatment plan is developed for patients receiving services. Instead, DPH has amended this section to allow patient treatment to begin prior to concluding the evaluation and has removed language exempting clinics from providing certain evaluation and treatment planning requirements for patients receiving care beyond four sessions. Additionally, DPH has modernized the evaluation and diagnostic criteria.

105 CMR 140.520(C) (Adequate Mental Health Services – Treatment Planning Services) DPH has updated this section to allow for longitudinal treatment planning. This section also provides providers flexibility to tailor the treatment plan to the patient's specific complaint or problem, instead of applying one-size fits all requirements.

105 CMR 140.520(D) (Adequate Mental Health Services – Treatment Services) To ensure greater staffing flexibility, DPH has updated this section to clarify that clinics may contract with appropriately licensed individuals with the authority to prescribe medications.

105 CMR 140.520(E) (Adequate Mental Health Services – Emergency Services) DPH clarified its requirement that mental health services provide clinic coverage 24 hours per day by indicating a pre-recorded message does not fulfill the requirement for access to a qualified professional during non-business hours. In addition to an on-call roster of clinicians available to speak to clients, DPH has added the requirement that mental health clinics maintain information on available regional services.

105 CMR 140.530(A) (Staffing) DPH has amended this section to ensure clinic staff are appropriately trained to assess and treat mental health conditions, including substance use disorder.

105 CMR 140.530(B) (Staffing – Personnel Qualifications) DPH has amended the minimum staffing requirements for a social worker by allowing for a licensed independent clinical social worker, instead of a licensed clinical social worker, as the current regulation is impractical since a licensed clinical social worker must be supervised by a licensed independent clinical social worker.

105 CMR 140.530(C) (Staffing – Mental Health Clinic Leadership Responsibilities) To provide mental health clinics with greater staffing flexibility, DPH has amended this section to allow a licensed mental health professional or the professional services director, if also a mental health professional, be the mental health clinic lead. Currently, this role must be filled by a psychiatrist or other physician.

105 CMR 140.550 (Additional Recordkeeping) DPH has added language requiring appropriate clinical oversight by licensed clinicians when unlicensed clinicians record progress notes or implement treatment plans. Additionally, this section clarifies that patient records must be maintained in accordance with all federal and state laws and regulations.

105 CMR 140.560(E) (Mental Health Outreach Programs) DPH has streamlined this section by removing duplicative requirements that are found elsewhere in the clinic regulations. Additionally, DPH has clarified that if the mental health outreach program is leased, rented or otherwise under the control of the clinic, the mental health clinic must obtain approval for the outreach program as a clinic satellite.

105 CMR 140.605 (Pre-Operative Evaluation) The Department has aligned the language with the hospital regulation by removing the requirement that these staff members be board certified, as the Department only requires board certification for leadership positions.

105 CMR 140.801 (Substance Use Disorder Treatment Services) DPH has clarified that the substance use disorder treatment service specific licensure requirements as set forth in 105 CMR 164.000 apply only to those providers with separately identifiable substance use disorder treatment services.

III. Summary

DPH intends to conduct an additional public comment hearing 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 140.000 are attached to this memorandum.