



Proposed Amendments to 105 CMR 140.000: *Licensure of Clinics*

Sherman Lohnes, JD

**Director of the Division of Health Care Facility Licensure and Certification
Bureau of Health Care Safety and Quality**

Lauren B. Nelson, Esq.

**Director of Policy and Quality Improvement
Bureau of Health Care Safety and Quality**

Public Health Council

September 14, 2016



Background

- This regulation, 105 CMR 140.000, *Licensure of Clinics*, sets forth standards for the maintenance and operation of clinics.
- The regulation ensures a high quality of care, industry standardization, and strong consumer protection for individuals receiving care at clinics.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.



The proposed revisions will achieve the following:

- Improve readability by updating language;
- Update definitions where necessary;
- Reduce regulatory burdens on regulated parties operating a limited services clinic or small clinic with no more than 2 exam rooms, while maintaining high safety and quality standards;
- Align reporting of serious complaints and incidents with other state and federal requirements;
- Add flexibility for clinics providing mental health services; and
- Incorporate birth center provisions from the proposed rescinded birth center regulation (105 CMR 142.000).



Proposed Revision Highlights: Urgent Care

Current Regulation:

- The urgent care practice model is not addressed.

Proposed Revision:

- Adds a definition for urgent care to clarify that such a practice model requires licensure as a clinic.
- Inserts a requirement that urgent care clinics provide a copy of the medical record of a visit to a patient at the end of that visit, and with the patient's consent, provide a copy to the patient's primary care provider.

Rationale:

- Requiring licensure reduces confusion to operators of urgent care centers and the public.
- Providing medical records to the patient's primary care provider ensures patients have continuity of care.



Proposed Revision Highlights: Licensing Requirements

Current Regulation:

- Requires a clinic to notify DPH of any proposed change in name or location.

Proposed Revision:

- Adds specific timelines for submitting applications for renewal (90 days prior to the expiration of the license) and for notifying DPH of a proposed change in name or location (30 days prior to the proposed change).
- Inserts language to prevent clinics from having misleading names and requires clinics to seek approval from DPH prior to changing the clinic name.

Rationale:

- Specific timelines provide DPH with adequate time to review changes.
- Restrictions on misleading names will protect the public from confusion.



Proposed Revision Highlights: Clinic Facilities

Current Regulation:

- Exempts clinics providing only mental health services from physical plant requirements for clean storage and soiled workroom areas.

Proposed Regulation:

- Includes small clinics with no more than 2 examination rooms in the clean storage and soiled workroom area exemption.
- Allows limited service clinics and mobile or portable units that are located at or on the premises of another entity to share toilet facilities with that entity as long as the facilities meet other sanitary requirements.

Rationale:

- Reduces regulatory burden of regulated parties, while maintaining high quality and safety standards.



Proposed Revision Highlights: Reporting Requirements

Current Regulation:

- Requires reporting of serious incidents, serious reportable events (by ambulatory surgical centers) and healthcare associated infections to DPH.

Proposed Revision:

- Requires reporting of serious adverse drug events (SADE) to DPH.
- Updates the reporting requirements for serious incidents, serious reportable events and healthcare associated infections to comply with statutory requirements.

Rationale:

- Ensures compliance with federal and state reporting requirements, including SADE requirements, as required by statute.
- Aligns with the reporting requirements of other health care facilities.



Proposed Revision Highlights: Dental Surgery

Current Regulation:

- Requirements for the performance of dental surgery by clinics is not addressed in current regulation.

Proposed Revision:

- Inserts a new section requiring a clinic that performs dental surgical procedure to be licensed to provide surgical services.

Rationale:

- Ensures patient safety by allowing only those clinics that are appropriately licensed to provide surgical services to perform dental surgery.
- Protects access to dental services by underserved communities.



Proposed Revision Highlights: Mobile Health Services

Current Regulation:

- Includes detailed physical plant requirements of host sites for mobile services.

Proposed Revision:

- Removes prescriptive physical plant requirements of host sites for mobile services, and outlines examples of appropriate sites, including long-term care facilities, assisted living facilities, business locations, community centers, social service agencies and churches.
- Clarifies that space leased by a clinic requires licensure as a satellite.
- Prohibits clinics from storing medications at any host site or overnight in a mobile or portable unit.

Rationale:

- Allowing flexible siting of mobile services for clinics seeking to reach out to rural, isolated and underserved communities.
- Regulating the storage of medication ensures the safety of patients and prevents medication diversion.



Proposed Revision Highlights: Mental Health Services

Current Regulation:

- Caps mental health outreach visits and limits outreach clients to less than a majority of the clinic's patients.

Proposed Revision:

- Removes the cap on mental health outreach visits and eliminates the percentage limit on a clinic's outreach clients.
- Recognizes that the appropriate evaluation and diagnostic services vary depending on the patient's chief complaint or problem.
- Adds provisions for patients requiring brief treatment of 4 sessions or less.

Rationale:

- Removes a barrier to mental health treatment by allowing clinics to deliver services at sites in the community, without limitations on the number of patients and percentage of clients that can be served.
- Provides greater flexibility for clinics providing mental health services.



Proposed Revision Highlights: Birth Center Services

Current Regulation:

- Referenced 105 CMR 142 for regulation of birth center services.

Proposed Revision:

- Incorporates the requirements for free-standing birth centers operated by clinics, included in 105 CMR 142.000, which DPH recommends for rescission.
- Includes the necessary protocols for health and safety policies, staffing requirements, necessary specialized equipment, and specialized requirements for medical records, off-hour coverage, and a referral system for necessary transfers to hospitals.

Rationale:

- Birth centers operated by clinics were required to comply with all applicable provisions of 105 CMR 140.000 and 105 CMR 142.000, creating duplicative and confusing regulations.
- Incorporation of the birth center regulations will eliminate redundancy for clinics operating birth centers.



Proposed Revision Highlights: Additional Updates

Additional proposed revisions include the following:

- Includes definitions for mobile and portable care to expand authority for clinics to operate vehicles to serve patients in underserved and geographically isolated areas;
- Updates emergency transfer protocols by requiring clinics to have a written policy for calling 911 for patients in need of emergency treatment; and
- Requires the clinic administrator and professional services director to be physically present in the clinic as necessary to perform their duties and ensure patient safety.



Next Steps

- The Department will conduct a public hearing to solicit comments on the proposed revision.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this revision, and seek final promulgation.



Contact Information

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 140.000, *Licensure of Clinics*, please find the relevant statutory language (M.G.L. c. 111, § 3, 51 through 56) and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr140.pdf>