



Proposed Amendments to 105 CMR 145.000: *Licensing of Out-of-Hospital Dialysis Units in Massachusetts*

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Slide 1



- M.G.L. c. 111 § 51A mandates state oversight of dialysis facilities.
- This regulation, 105 CMR 145, *Licensing of Out-of-Hospital Dialysis Units in Massachusetts*, ensures a high quality of care, industry standardization and strong consumer protection for individuals receiving dialysis in out-of-hospital dialysis units.
- 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.

Slide 2



The proposed revisions will achieve the following:

- Improve readability by updating language;
- Clarify and update staffing requirements to reflect appropriate practice in units;
- Provide flexibility in physical plant requirements while still ensuring patient safety;
- Consolidate and update affiliation agreement requirements;
- Clarify reporting requirements;
- Make emergency planning consistent with clinics;
- Align the regulations with state and federal laws, regulations and procedures.

Slide 3



Current Regulation:

- Special project approval and regulatory waivers are not addressed.

Proposed Revision:

- Permits dialysis units to apply for special project approval and for regulatory waivers.

Rationale:

- Permits units to innovate in care delivery that does not risk patient health and safety.
- Ensures consistency with all facility licensure regulations.

Slide 4



Current Regulation:

- Requires a dialysis unit to have a governing body that sets the policies of the unit.

Proposed Revision:

- Allows designation of an authorized individual or small group of individuals, reporting to the governing body, to be responsible for day-to-day operations.
- Requires the medical director to work with the governing body to grant privileges to staff.
- Requires the dialysis unit have medical staff bylaws approved by the governing body.

Rationale:

- Makes the regulation consistent with federal law and other health facility licensure regulations.

Slide 5



Additional proposed revisions to staffing requirements include:

- Updating language to reflect that a patient's primary care provider may be a nurse practitioner, physician's assistant or physician;
- Clarifying that the unit administrator and medical director must be physically present in the unit as necessary to perform their duties and ensure patient safety;
- Allowing Licensed Professional Nurses, in addition to Registered Nurses, to be counted toward the requirement that the dialysis unit have sufficient direct care nursing personnel on duty to provide nursing care;
- Updating the title of "Technical Assistants" to "Clinical Hemodialysis Technicians", who are allowed, after training, to assist the nursing staff and be given appropriate responsibilities.

Slide 6



Proposed Revision Highlights: Physical Plant Requirements

Current Regulations:

- Requires 110 square feet of floor space per dialysis station.
- Requires adequate provision of space for patient belongings and toilet and handwashing for patients and staff.

Proposed Revisions:

- Removes specific square footage requirements.
- Updates the requirements for dialysis unit support space without unnecessarily prescriptive specifications.
- Adds requirement that rooms without direct access to outside air have a ventilation system, consistent with other health care facilities.
- Adds requirements for the physical space and equipment necessary if dialysis units provide a room for home dialysis training.

Rationale:

- Provides flexibility for dialysis units to maintain quality of care.
- Improves patient health and safety and compliance with federal requirements.

Slide 7



Proposed Revision Highlights: Affiliation Agreements

Current Regulations:

- Requires dialysis units have appropriate, individual affiliation agreements with hospitals for specific services, including emergency transport.

Proposed Revision:

- Consolidates affiliation agreements that consider all aspects of care, including inpatient care; routine, chronic maintenance and emergency dialysis; and other hospital services.
- Removes requirement for emergency affiliation agreements, and updates emergency transfer protocols by requiring clinics to have a written policy for calling 911 for patients in need of emergency treatment.

Rationale:

- Streamlines separate and duplicative affiliation agreement requirements.

Slide 8



Current Regulations:

- Does not address the reporting of health care associated infection data and serious incidents, or serious complaint response procedures.

Proposed Revision:

- Adds a new section requiring dialysis units share health care associated infection data with DPH, consistent with federal reporting;
- Adds a new section requiring the establishment of procedures to ensure units respond promptly and completely to serious complaints; and
- Adds a new section requiring units report serious incidents to DPH.

Rationale:

- Ensures patient safety and standardizes serious incident reporting and serious complaint procedures across all health care facilities.

Slide 9



Current Regulations:

- Federal regulation requires reporting of quality data.

Proposed Revision:

- Adds a new section requiring a dialysis unit to establish a program to regularly review and evaluate the quality of care provided.

Rationale:

- Enhances quality improvement and aligns state regulation with federal requirements.

Slide 10



Current Regulations:

- Does not directly address storage and administration of drugs, which is governed by M.G.L. c. 94C.

Proposed Revision:

- Adds a new section providing that if a dialysis unit stores and administers controlled substances, it must obtain a MA Controlled Substance Registration and comply with federal and state laws and regulations for the storage and administration of controlled substances.

Rationale:

- Clarifies already existing obligations.
- Ensures safe handling of controlled substances.

Slide 11



Current Regulation:

- Requires a patient beginning chronic maintenance dialysis to be admitted to the dialysis unit only after initiation of dialysis in an affiliated hospital which has a chronic dialysis service that agrees to accept the patient for in-patient care and other services as needed.

Proposed Revision:

- Allows for admission or transfer of a patient without prior initiation of dialysis in an affiliated hospital.
- Permits direct initiation of patient services at a dialysis unit.

Rationale:

- Reflects the current practice and avoids potentially unnecessary hospitalization.

Slide 12



Current Regulation:

- Requires a dialysis unit to have a written plan to deal with fire and other disaster.

Proposed Revision:

- Requires a comprehensive emergency preparedness plan for patients and staff.
- Requires documentation of emergency preparedness training.
- Adds a new section, consistent with federal regulation, requiring a dialysis unit to have and maintain emergency supplies and equipment on the premises at all times.

Rationale:

- Makes emergency planning consistent with the emergency planning requirements for clinics.

Slide 13



- 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.

Slide 14



- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 145, *Licensing of Out-of-Hospital Dialysis Units in Massachusetts*, please find the relevant statutory language (M.G.L. c. 111, § 3, 51A, 53) and the full current regulation here:

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

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr145.pdf>