



# 105 CMR 145.000

## *LICENSING OF OUT-OF-HOSPITAL DIALYSIS UNITS IN MASSACHUSETTS*

### FINAL REGULATORY AMENDMENT PRESENTATION

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# Background

- The purpose of this presentation is to request final promulgation by the Public Health Council of the proposed revisions to 105 CMR 145.000, *Licensing of Out-of-Hospital Dialysis Units in Massachusetts*.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.
- This regulation ensures a high quality of care, industry standardization and strong consumer protection for individuals receiving dialysis in out-of-hospital dialysis units.



# Overview of Pre-Comment Changes

As a reminder, the Department presented to the Public Health Council proposed revisions to 105 CMR 145.000, *Licensing of Out-of-Hospital Dialysis Units in Massachusetts*. Specific preliminary revisions included:

- Adding a requirement for dialysis units to report serious incidents;
- Clarifying and updating staffing requirements;
- Providing flexibility in physical plant requirements while still ensuring patient safety;
- Consolidating and updating affiliation agreement requirements; and
- Aligning the regulations with state and federal laws, regulations and procedures.



# Overview of Post-Comment Changes

As a result of the comments received during the public comment period, including the public hearing, DPH recommends further revisions to 105 CMR 145.000, which will achieve the following:

- Allow dialysis to begin in an out-of-hospital unit when appropriate;
- Clarify that the care of a patient must be under the supervision of a qualified practitioner;
- Streamline medical record requirements; and
- Update definitions for clarity and consistency with federal requirements



## Final Amendments – Changes based on comments received

105 CMR 145.010 Scope

### SUMMARY OF PRE-COMMENT CHANGES

- The current regulation allows an out-of-hospital dialysis unit to only perform chronic maintenance dialysis.

### SUMMARY OF PROPOSED FINAL AMENDMENT

- The Department amended the regulation to broadly include any other type of dialysis permitted by state or federal law, consistent with federal law and Department sub-regulatory guidance.



## Final Amendments – Changes based on comments received

105 CMR 145.410 Patient's Designated Practitioner

### SUMMARY OF PRE-COMMENT CHANGES

- The current regulation requires the care of each patient at the unit to be under the supervision of a physician of the patient's choice or acceptable to the patient.

### SUMMARY OF PROPOSED FINAL AMENDMENT

- The Department clarified:
  - That each patient of the unit must be under the supervision of a qualified physician, physician assistant or nurse practitioner of the patient's choice or who is acceptable to the patient.
    - These changes are consistent with existing scope of practice for these practitioners.
  - This practitioner must be on the staff of the unit and must meet such requirements for practice as the governing body may set forth.

# Final Amendments – Changes based on comments received



## 105 CMR 145.540 Content of Medical Record

### SUMMARY OF PRE-COMMENT CHANGES

- The current regulation includes overly prescriptive medical record content requirements.

### SUMMARY OF PROPOSED FINAL AMENDMENT

- The Department clarified and streamlined the general requirements for the content of a patient's medical record, while ensuring essential and critical elements of the medical record are preserved.
- Specific content requirements are outlined in the regulation.



## Final Amendments – Changes based on comments received

105 CMR 145.020 Definitions

### SUMMARY OF PRE-COMMENT CHANGES

- The current regulation includes a restrictive definition of “home dialysis”, requiring home dialysis to be performed with the assistance of a trained partner.
- The current regulation does not differentiate between home hemodialysis and home peritoneal dialysis.

### SUMMARY OF PROPOSED FINAL AMENDMENT

- The Department has amended the definition of “home dialysis” to “home hemodialysis” and inserted a new definition for “home peritoneal dialysis” to reflect the differences between the support needed to safely perform home hemodialysis and home peritoneal dialysis, which does not require the assistance of a trained partner.
- The amended definitions maintain alignment with federal definitions.



# Next Steps

- Based on a comprehensive review of *105 CMR 145.000 Licensing of Out-of-Hospital Dialysis Units in Massachusetts*, and the incorporation of comments from stakeholders, DPH recommends Public Health Council approval of these amendments for promulgation.



# Contact Information

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 145.000, *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>