

# Massachusetts Dialysis Unit Licensing Proposed Regulations - Key Take-Aways

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As we've [previously reported](#), the Massachusetts Department of Public Health (DPH) has recently proposed a number of amended regulations in connection with the regulatory review and overhaul mandated by Governor Baker's [Executive Order 562](#). Senior DPH staff presented these proposed regulations at a Public Health Council Meeting on September 14 (the "PHC Meeting"). Today we are looking at [proposed regulations](#) related to Dialysis Units. For our prior analysis of the proposed regulations on hospital licensing, please see [here](#).

The proposed changes to the regulations are achieve a number of goals, including aligning Massachusetts requirements with federal requirements for dialysis facilities, ensuing high quality of care for dialysis patients, and creating enhanced operational flexibility for dialysis units in some key areas. Some of the key changes are summarized below.

- **Enhanced Flexibility**
  - To enhance operational flexibility, dialysis units would now be permitted to apply for special project approval and regulatory waivers. DPH will consider proposals for special projects for innovative delivery of dialysis services. DPH will also consider waivers of regulatory requirements if compliance would cause hardship, the unit is in substantial compliance with the spirit of such requirements, and the unit's non-compliance does not limit care or jeopardize patient health or safety.
  - Separate affiliation agreements with hospitals could be consolidated into one agreement to address all aspects of care, including inpatient care, routine and emergency dialysis, and other hospital services.
- **Unit Governance**
  - The proposed regulations update dialysis unit governance requirements to be consistent with federal requirements.
- **Staffing**
  - The unit's administrator and medical director would need to be physically present in the facility as necessary to carry out their responsibilities.
  - Licensed Professional Nurses (in addition to Registered Nurses) would count as toward the required nursing personnel ratio.
- **Square Footage Requirements**
  - Requirements for square footage per dialysis station would be written generally to provide more flexibility and would not include a specific minimum square footage per dialysis station.
  - At the PHC Meeting, council members voiced concerns about enforceability of a regulation without an objective standard and whether providers might minimize space too much. DPH noted that the new regulation would be consistent with federal regulations and reflects advancements in technology (smaller equipment, etc.).
  - Specific square footage minimums would be required for isolation and home dialysis training rooms.
- **Increased Reporting Obligations**
  - Health care associated infection data and serious health incidents would need to be reported to DPH. Serious complaint response procedures would also need to be established.

### For More Information

To see the related presentation from the PHC Meeting, see [here](#). The proposed dialysis unit regulations can be found [here](#).

If you are interested in voicing your opinion, DPH will conduct a public hearing on October 25 at 9:30am in Room 417 at 239 Causeway Street, Boston, MA. For more information see the Notice of Public Hearing [here](#). The written public comment period is open through 5:00 p.m. on October 28.

Authors



Ryan Cuthbertson