Commonwealth of Massachusetts
Department of Public Health
Helping People Lead Healthy Lives in Healthy Communities

Proposed Amendments to 105 CMR 130.000: *Hospital Licensure*

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

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Background

- This regulation, 105 CMR 130.000, *Hospital Licensure,* sets forth standards for the maintenance and operation of hospitals, pursuant to M.G.L. c. 111, § § 51 and 51G.
- This regulation ensures a high quality of care, industry standardization, and strong consumer protection for individuals receiving care in hospitals.
- 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.

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Proposed Revision Highlights

The proposed revisions will achieve the following:

- Eliminate outdated or unnecessary requirements;
- Clarify requirements for licensure;
- Require notice to employees and state agencies before the closure of essential services;
- Update the nurse to patient ratio to comply with M.G.L. c. 111 § 231;
- Align reporting of serious complaints and incidents with other state and federal requirements;
- Incorporate birth center provisions from the proposed rescinded birth center regulation (105 CMR 142.000);
- Update and consolidate the sections relative to Stem Cell Transplantation, Maternal and Newborn Services, and Cardiac Surgery and Cardiac Catheterization Services; and
- Update terminology, centralize generally applicable definitions and use plain language to make the regulation easier to read and understand.

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Proposed Revision Highlights: Outdated and Unnecessary Sections

The proposed revisions remove several sections which are no longer required or are otherwise unnecessary, including:

- Eliminating references to the Advocacy Office established pursuant to 105 CMR 131.000, as this regulation is proposed for rescission;
- Removing language requiring DPH to establish advisory committees where there is no statutory requirement for an advisory committee:
  - The committees have not met on a regular basis, and
  - DPH can request input from stakeholders when needed;
- Eliminating bed count reporting requirements, which were removed from M.G.L. c. 111 § 51 by chapter 402 of the acts of 2014;
- Removing outdated language for deadlines that have already passed; and
- Eliminating visitation provisions for county hospitals, as such hospitals no longer exist.

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Proposed Revision Highlights: Licensure Requirements

Current Regulation:

- There is currently no timeline for submission of an application for initial licensure or transfer of ownership.

Proposed Revision:

- Requires applications for initial licensure or transfer of ownership to be submitted at least 60 days in advance.
- Inserts a new section outlining the requirements for the transfer of ownership of a hospital.

Rationale:

- Provides specific timelines, eliminating delays in application review.
- Provides regulatory support for the transfer of ownership or location process required by DPH and eliminates current confusion around the process.
- Aligns with newly proposed amendments to 105 CMR 100: *Determination of Need.*

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Proposed Revision Highlights: Additional Licensing Updates

Additional proposed licensing revisions include the following:

- Updating evidence of responsibility and suitability requirements to more closely track the statutory requirements in M.G.L. c. 111 § 51;
- Eliminating the provisional licensure category, as M.G.L. c. 111 § 51 does not provide for such a license; and
- Eliminating duplicative licensure review for hospitals offering substance abuse services if they have already been approved by the Bureau of Substance Abuse Services, thereby reducing delay in opening new and expanded services.
- Ensuring submission of a community benefits plan, as required by M.G.L. c. 111 § 51G;
  - DPH will work to create consistency and eliminate duplication across overlapping regulatory and statutory provisions in this area.

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Proposed Revision Highlights: Closure of Essential Services

Current Regulation:

- Requires notice only to DPH at least 90 days in advance of closing an essential service.

Proposed Revision:

- Expands 90-day notice of essential services closures to:
  - The Health Policy Commission;
  - The Center for Health Information and Analysis;
  - The Attorney General's Office;
  - The Executive Office of Labor and Workforce Development; and
  - The health care coalitions and community groups identified by the hospital in its notice.
- Provides additional notice to the following groups 30 days prior to notifying DPH:
  - The hospital's patient and family council;
  - Each staff member of the hospital;
  - Every labor organization that represents the hospital's workforce;
  - Members of the General Court who represent the hospital district; and
  - A representative of the city or town in which the hospital is located.

Rationale:

- Enhances communication and notice of closures to interested parties in line with ongoing Public Health Council and stakeholder discussion.

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Proposed Revision Highlights: ICU Nurse Staffing

Current Regulation:

- Requires a ratio of 1 nurse for every 4 patients in Intensive Care Units.

Proposed Revision:

- Requires a nurse to patient ratio of either 1:1 or 1:2, depending on the acuity of the patient.

Rationale:

- Updated to comply with M.G.L c. 111 § 231.
- Aligns with CMS conditions of participation, which require a 1:2 ratio.

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Proposed Revision Highlights: Reporting Requirements

Current Regulation:

- Requires reporting of serious incidents, serious reportable events and healthcare acquired infections to DPH.

Proposed Revision:

- Adds reporting requirement for serious adverse drug events to DPH, and defines the term according to statute.
  - Sub-regulatory guidance will be crafted to ensure that implementation in accordance with statute is managed efficiently, using existing reporting mechanisms when possible.
- 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.
- Aligns with the reporting requirements of other health care facilities.

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Proposed Revision Highlights: Maternal and Newborn Services

The proposed revisions to the maternal and newborn services sections include the following:

- Updates definitions to reflect changes in current practice;
- Reorganizes and consolidates duplicative sections;
- Removes overly prescriptive language that could limit a hospital's ability to develop new and innovative approaches to patient care based upon current standards of practice;
- Reduces prescriptive data collection and reporting requirements while providing DPH flexibility to request more data, pursuant to guidelines; and
- Restructures the requirements of each level of maternal and newborn service to build off the level below.
  - For example, a Level II service which includes special care nurseries must comply with the requirements of the baseline Level I service, well baby and continuing care nurseries, plus additional mandates.

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Proposed Revision Highlights:
Maternal and Newborn Services: Patient Services

Current Regulation:

- Includes specific requirements for patient and family services.

Proposed Revision:

- Removes specific requirements for patient and family services while retaining the requirement that hospitals develop policies and procedures for such services.

Rationale:

- Allows hospitals to develop policies for patient and family services that reflect the needs of their community.
  - For example, strict language relating to family relationships, like "mother and father" have been replaced with broad terms like "family", thereby allowing recognition of varied family systems.

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Proposed Revision Highlights:
Maternal and Newborn Services: Physical Plant Requirements

Current Regulation:

- Includes specific physical plant requirements for maternal and newborn services.

Proposed Revision:

- Aligns physical plant requirements with the nationally recognized, evidence-based, industry standards of the Facility Guidelines Institute requirements for maternal and newborn services.
- Removes the requirement to have the number of bassinets in the newborn nursery be one more than the number of maternity beds.

Rationale:

- Provides consistency with other health care facility licensure regulations.
- Provides flexible, streamlined development using contemporary standards to reduce regulatory burden.

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Proposed Revision Highlights: Birth Center Services

Current Regulation:

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

Proposed Revision:

- Incorporates the requirements for free-standing birth centers operated by hospitals that are 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 the parent hospital.

Rationale:

- Birth centers operated by hospitals were required to comply with all applicable provisions of both 105 CMR 130.000 and 105 CMR 142.000, creating duplicative and confusing regulations.
- Incorporation of the birth center regulations will eliminate confusion for hospitals operating birth centers.

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Proposed Revision Highlights: Cardiac Catheterization Services

Current Regulation:

- Limits approval of cardiac catheterization services through department guidance.

Proposed revisions:

- Update the regulations to reflect medical advances and changing national standards for the provision of service; and
- Remove all references to mobile cardiac catheterization, as there are currently no mobile cardiac catheterization programs in Massachusetts, and DPH does not anticipate the need to add any new mobile services.

Rationale:

- **Streamlines** multiple application and approval methods into a single, predictable method.
- **Standardizes** confusing and outdated processes to bring cardiac catheterization services in line with other hospital services.
- **Modernizes** the approval and oversight of cardiac catheterization to ensure minimum requirements for the safety and quality of a long-standing service type.

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Proposed Revision Highlights:
Cardiac Catheterization Services: Licensure

Current Regulation:

- Limits approval of cardiac catheterization services through department guidance

Proposed Revision:

- Establishes a licensing process to provide cardiac catheterization services.
- Provides application review to determine whether hospitals meet regulatory standards and quality and access requirements necessary to operate a service.
- Permits hospitals to seek approval to operate each of the following services, regardless whether they perform cardiac surgery on site:
  - diagnostic catheterization;
  - diagnostic and interventional catheterization;
  - pediatric catheterization; and
  - electrophysiology

Rationale:

- Comprehensive guidance, with data-driven approach to patient safety will replace all current circular letters to remove the moratorium on new cardiac catheterization programs within a 30-minute ambulance ride of another program.
- Allowing any hospital to apply for approval of a service will provide consistent, predictable rules for operation and may increase geographic access.

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Proposed Revision Highlights:
Cardiac Catheterization Services: Service Volumes

Current Regulation:

- Hospitals that perform diagnostic and/or interventional catheterizations must annually perform a stated number of procedures.

Proposed Revision:

- Requires hospitals to meet service volume minimums, which are based on the evidence-based guidelines and standards issued by the American College of Cardiology, American Heart Association and Society for Cardiac Angiography and Interventions.
- Retains condition to submit Quality Assessment and Performance Improvement (QAPI) quarterly reports if minimums are not met.

Rationale:

- Enables efficient responsiveness to changes in nationally recognized consensus documents, which are updated approximately every 2 years, while maintaining safety and quality care for patients.

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Proposed Revision Highlights:
Cardiac Catheterization Services: Physician Volumes

Current Regulation:

- Physicians who perform percutaneous coronary intervention (PCI) must meet a minimum volume of 75 PCI procedures annually.

Proposed Revision:

- Eliminates physician/operator volume minimum requirement;
- Directs the hospital to establish criteria for granting privileges; and
- Requires the hospital to ensure that its staff is appropriately trained and competent to perform the service.

Rationale:

- Reflects changing national standards for the provision of such services.
- Current consensus documents have moved away from strict volume minimums as the prevailing indicator of safe practice.
- Physicians with higher than expected mortality outcomes are identified annually through MassDAC and the Department follows up appropriately.

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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.

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Contact Information

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 130.000, *Hospital Licensure,* please find the relevant statutory language (M.G.L. c. 111, § 3, 51 through 56, and 70) and the full current regulation here:
  https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111
  http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr130.pdf

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