Commonwealth of Massachusetts
Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

105 CMR 130.000
Hospital Licensure

Final Regulatory Amendment Presentation

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Public Health Council
March 8, 2017

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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 130.000, *Hospital Licensure.*
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.
- This regulation sets forth standards for the maintenance and operation of hospitals, pursuant to M.G.L. c. 111, § § 51 and 51G, and ensures a high quality of care, industry standardization, and strong consumer protection for individuals receiving care in hospitals.

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Highlights of Preliminary Review

As a reminder, on September 14, 2016, the Department presented to the Public Health Council proposed revisions to 105 CMR 130.000, *Hospital Licensure*, to update terminology, reorganize and clarify definitions, eliminate outdated or unnecessary requirements, and include new statutory obligations on hospitals. Specific preliminary revisions included:

- Clarifying requirements for licensure;
- Requiring notice to employees and state agencies before closure of essential services;
- Updating the nurse to patient ratio to comply with M.G.L. c. 111 § 231;
- Aligning reporting of serious complaints and incidents with other state and federal requirements;
- Incorporating birth center provisions from the proposed rescinded birth center regulation (105 CMR 142.000);
- Updating and consolidate the sections relative to Stem Cell Transplantation, and Maternal and Newborn Services; and
- Updating Cardiac Surgery and Cardiac Catheterization Services to provide consistency with other services on a hospital license while improving transparency and retaining high standards for service.

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Highlights of Post-Comment Review

As a result of the comments received during the public comment period, including the public hearing on October 24, 2016, DPH recommends further revisions to 105 CMR 130.000, which will achieve the following:

- Clarify definitions and licensure requirements;
- Streamline administrative and staffing requirements;
- Remove duplicative and unnecessary reporting requirements and provide consistency when reporting is required;
- Update and clarify provisions for Maternal and Newborn Services; and
- Remove re-approval and peer review requirements for Cardiac Catheterization Services.

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Post-Comment Review: Definitions

Further amended definitions of hospital services to align with CMS service criteria.	
Current Regulation	Chronic Care Service. **A chronic care service is** a service, other than a rehabilitation, psychiatric, substance abuse, intermediate care facility, or skilled nursing facility service, **which** has an average length of inpatient stay greater than 25 days. **Any hospital licensed for a medical/surgical service, which otherwise meets the definition set out in 105 CMR 130.026(M) and which has had approved or has filed a complete application pursuant to 105 CMR 100.600 prior to the effective date of 105 CMR 130.026(M), shall continue to be licensed as a medical/surgical service.**
Proposed Change	Chronic Care Service **means** a service, other than a rehabilitation, psychiatric, substance **use disorder**, intermediate care facility, or skilled nursing facility service, **that** has an average length of inpatient stay greater than 25 days.
Further Change	Chronic Care Service means a service, other than a rehabilitation, psychiatric, substance use disorder, intermediate care facility, or skilled nursing facility service, that has an average length of inpatient stay greater than 25 days **and that meets the long-term care hospital patient level criteria issued by the Federal Centers for Medicare and Medicaid Services** .

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Post-Comment Review: Definitions

Updated the definition of "family-centered care" for Maternal and Newborn Services to reflect all types of family arrangements.	
Current Regulation	Family-centered Care **shall** mean a method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the father, mother and child and include other identified support persons (biologically or nonbiologically related) for the mother and infant.
Proposed Change	Family-centered Care means a method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the **father, mother** and child and include other identified support persons (biologically or nonbiologically related) for the mother and infant.
Further Change	Family-centered Care means a method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the **parent(s)** and child and**/or may** include other identified support persons (biologically or nonbiologically related) for the mother and infant.

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Post-Comment Review: Licensure

- The current regulation requires a hospital to submit paper copies of its bylaws each time it renews its license.
- Upon preliminary review, this requirement was moved to a different section of the regulation.
- In response to comments, the Department removed this requirement entirely for the following reasons:
  - Removing the requirement improves administrative efficiency by reducing paper submissions;
  - This is an unnecessary requirement because electronic public records are available for the Department to determine an applicant's corporate status.

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Post-Comment Review: Licensure

- Hospitals are statutorily required to file a community benefits plan as a condition of licensure, however this requirement is not included in the current regulation. M.G.L. c. § 51G
- Upon preliminary review, this requirement was added to the regulation.
- In response to comments, the Department mitigated concerns of duplicative filing by clarifying that the hospital licensure requirement is met by submission and publication of the required community benefits plan to the Attorney General's Office or for Determination of Need purposes.

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Post-Comment Review: Beds out of Service

Currently, 130.122(A) and (B) provides for the following:

- Commissioner approval prior to a hospital removing chronic or rehabilitation service beds from service for 3 months or more,
- Temporary removal of any other beds from service within the hospital's discretion,
- Commissioner approval prior to hospital removal of medical/surgical beds, incident to a construction project, for more than 6 consecutive months in one fiscal year.

Upon preliminary review, 130.122(A) and (B) was amended for language consistency and efficiency.

Upon further review, both subsections, which commenters found unnecessarily lengthy and confusing, were deleted and replaced with a straightforward provision allowing a hospital, within its discretion, to remove beds from service temporarily, but requiring written notice to the Department at least 30 days prior to removal if the hospital intends to remove beds from service for more than 6 months.

- This retains hospital discretion to remove beds temporarily, while improving DPH oversight of licensure and operations and streamlining notification requirements.

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Post-Comment Review: Administration and Staffing

The current regulation used the term "physician" throughout to designate the health care providers in a given service.

Upon preliminary review, physician assistants and nurse practitioners were included in select sections.

In response to comments, further amendments include:

- Integration of physician assistants and nurse practitioners, including neonatal nurse practitioners, throughout the regulation, to modernize and align with these practitioners' existing scope of practice and to recognize more integrated models of care;
  - Example, change reflects that, in discharge planning, several licensed providers may be involved in the process, not only physicians; and
- Removing language requiring physician supervision of certified nurse midwives to reflect current operations and existing scope of practice.

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Post-Comment Review: Board Eligible Specialists

The current regulation distinguished between "board certified" or "an active candidate for certification" in the staffing requirements for specialized hospital services.

Upon preliminary review, "an active candidate for certification" was removed.

In response to comments that qualified staff could not practice while they waited to take their specialty boards, the regulation was further amended to provide the following:

- "Board eligible" specialists may continue to fulfill staffing requirements for a specialized hospital service if the specialist is not in a leadership role.
- Providers who act in leadership roles must be board certified, as this certification demonstrates excellence in the specialty service area and provides a transparent mechanism for assessing the competency of the provider and standardizes hospital oversight to help ensure the quality of the regulated service.

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Post-Comment Review: Reporting Requirements

The current regulation included duplicative and conflicting reporting requirements for serious incidents and serious reportable events (SRE).

Upon preliminary review, additional requirements were outlined in statute for the reporting of serious adverse drug event (SADE), and existing requirements were streamlined across all health care facilities.

In response to comments, further amendments streamline reporting requirements and include:

- Removal of reporting requirements for surgery and anesthesia related complications, which are already reportable as SREs for this facility type;
- Clarifying that multiple reports to the Bureau of Health Care Safety and Quality are not necessary when an incident is also an SRE or SADE; and
- Allowing for oral and/or written disclosure to patients 7 days after a serious reportable event to account for best practices and patient preference.
  - Nothing precludes a hospital from offering both written and oral disclosure if hospital recordkeeping or patient preference indicate.

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Post-Comment Review: Maternal and Newborn Services

The current regulation provided highly detailed and prescriptive requirements for each level of maternal, newborn and pediatric care.

Upon preliminary review, these sections were streamlined to set forth clear, graduated standards as the service level increases.

In response to comments that the revision retains inconsistencies with respect to the required experience of staff in different service levels, further amendments include:

- Aligning experience requirements for pediatric nurses in leadership roles, across all levels, to those required for nurses in leadership roles in nursery and neonatal intensive care units;
- Incorporating the role of neonatal nurse practitioners into Level I service;
- Reinstating masters-prepared licensed social workers for Level III service;
- Standardizing social work services across all levels of maternal and newborn care by requiring all levels of care to provide licensed social work services;

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Post-Comment Review: Maternal and Newborn Services

Removed strict limitation on neonatologist's location during infant transfer with CPAP.	
Current Regulation	130.640(E)(5)(c) In a Level IIA service a mechanical ventilator or CPAP **(Continuous Positive Airway Pressure)** may be initiated and used in a Special Care Nursery prior to **such** transfer **only** when the Medical Director of the Special Care Nursery approves such use and **only** when all of the following conditions are met: (i) A neonatologist remains at the infant's bedside at all times.
Proposed Change	130.640(E)(4)(b) In a Level IIA service a mechanical ventilator or CPAP may be initiated and used in a Special Care Nursery prior to **a** transfer **to a Level III service** when the Medical Director of the Special Care Nursery approves such use and when all of the following conditions are met: (i) A neonatologist remains at the infant's bedside at all times.
Further Change	130.640(E)(4)(b) In a Level IIA service a mechanical ventilator or CPAP may be initiated and used in a Special Care Nursery prior to a transfer to a Level III service when the Medical Director of the Special Care Nursery approves such use and when all of the following conditions are met: (i) A neonatologist remains **immediately available in the hospital at all times.**

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Post-Comment Review: Maternal and Newborn Services

Removed misleading terminology for certain pre-term deliveries.	
Current Regulation	130.640 (A) Level IIA Service. Level IIA capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IIB or Level III services. Level IIA capabilities include the care and management of the stable to moderately ill **neonate:** well newborns, premature infants **; 34 weeks gestation,** and infants who require special care services (including retro-transferred infants).
Proposed Change	130.640 (A) Level IIA Service. Level IIA capabilities include the management of uncomplicated pregnancies **of 34 weeks gestation or greater,** and the management of pregnancy complications not requiring the facilities and resources of Level IIB or Level III services. Level IIA capabilities include the care and management of the stable to moderately ill **newborn,** well newborns, premature infants and infants who require special care services (including retro-transferred infants).
Further Change	130.640 (A) Level IIA Service. Level IIA capabilities include the management of ***[uncomplicated]*** pregnancies of 34 weeks gestation or greater, and the management of pregnancy complications not requiring the facilities and resources of Level IIB or Level III services. Level IIA capabilities include the care and management of the stable to moderately ill newborn, well newborns, premature infants and infants who require special care services (including retro-transferred infants). ***[change also made to section on 32 weeks gestation, as such a pre-term delivery would be due to a complication of pregnancy.]***

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Post-Comment Review: Cardiac Catheterization Services

The current regulation allowed for cardiac catheterization to be performed in hospitals with cardiac surgery on-site and through a complex system of waivers and pilot projects, largely set forth in sub-regulatory guidance.

Upon preliminary review, the regulation was amended to allow for approval of hospital services for diagnostic, diagnostic and interventional and pediatric cardiac catheterization and electrophysiology following:

- Completion of an application containing specific and robust requirements for operation and staffing; and
- Compliance with quality measures and procedures.

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Post-Comment Review: Cardiac Catheterization Services

In response to comments, including from the Invasive Cardiac Services Advisory Committee (ICSAC), the Department made the following further revisions to Cardiac Catheterization Services:

- Removal of the requirement that a hospital must re-apply for re-approval of its cardiac catheterization program at each hospital licensure review, to provide consistency with other services on a hospital license;
- Removal of the requirement, when peer review of a hospital's cardiac services is required, that the peer reviewer must be an out-of-state physician; and
- Addition of language to indicate that hospitals without cardiac surgery on-site may not perform certain procedures designated in Department guidance (created in consultation with state and nationally recognized expert groups).

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Post-Comment Review: Cardiac Catheterization Services

Cardiac Catheterization Guidance will accompany these regulatory changes and will contain:

- A comprehensive service application and attestation for diagnostic catheterization, diagnostic and interventional catheterization, electrophysiology and pediatric catheterization;
- Cardiac catheterization procedure volume minimums based upon national consensus documents, including additional monitoring requirements for:
  - Hospitals that do not meet the volume minimums; and
  - Hospitals with no existing cardiac catheterization services at promulgation.
- Outcome reporting requirements; and
- Procedures that may not be performed in services that do not have cardiac surgery onsite.

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Conclusion/Next Steps

- Staff requests the Public Health Council approve the proposed regulations for promulgation.
- Following Public Health Council approval, the Department will file the amended regulation with the Secretary of the Commonwealth for final enactment.

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Additional 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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