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Massachusetts Department of Public Health – Final Hospital Licensure Regulations

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The ***Massachusetts*** Department of Public Health ***(DPH)*** has promulgated final Hospital Licensure Regulations. Approved by unanimous vote of the Massachusetts Public Health Council (PHC) on March 8, 2017, DPH anticipates that the Hospital Licensure Regulations (105 CMR 130.000, *et seq.*) will be published in the Massachusetts Register in April, 2017. The regulations will become effective as of the date of such publication.

As noted in our September 26, 2016 Blog Post, the amendments are part of DPH's overall regulatory review process needed to comply with Governor Baker's Executive Order 562, which directed all executive branch state agencies to review and, where possible, streamline, simplify and improve regulations. At Wednesday's PHC meeting, Commissioner Monica Bharel, M.D., MPH introduced the presentation of the final regulation by senior DPH staff, indicating that the regulation is part of DPH's public health informed view of system transformation. In its materials accompanying the presentation of the regulations, DPH noted that the regulation is intended to ensure a high quality of care, industry standardization, and strong consumer protection for persons receiving hospital care.

In response to comments received in response to the proposed revisions, DPH made a number of further revisions to clarify definitions and licensure requirements, streamline administrative and staffing requirements, and remove duplicative and unnecessary reporting requirements (aligning, when possible, reporting requirements of other state agencies). A summary of comments received, and DPH's responses to such comments, is contained in the Information Briefing provided to Dr. Bharel and the PHC.

Definition Changes

Key definition changes range from alignment with federal criteria to an acknowledgement of changing family arrangements. DPH aligns the definition of Chronic Care Service with CMS service criteria as follows: …"a service, other than a rehabilitation, psychiatric, substantive 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."* DPH also updated the definition of "family-centered care" to make "parent(s)," as used in the concept of family, gender neutral.

Reporting Requirements

The final regulations streamline the reporting requirements for serious incidents and serious reportable events (SRE) as well as for serious adverse drug events (SADE). The regulations remove duplicative reporting requirements for surgery and anesthesia related complications that are already reportable as SREs, clarify that multiple reports to DPH's Bureau of Health Care Safety and Quality are unnecessary when an incident is also a SRE or SADE; and allowing for oral and/or written disclosure to patients 7 days after a serious reportable event. DPH staff noted that this change will not preclude a hospital from offering both written and oral disclosure; of course, hospitals should document oral disclosures.

Maternal and Newborn Services Requirements

DPH modified proposed changes to Maternal and Newborn Services requirements clarify staffing requirements, address experience requirements for pediatric nurses in leadership roles, incorporate the role of neonatal nurse practitioners into Level I service, and require social work services across all levels of maternal and newborn care.

Cardiac Catheterization Services

Proposed revisions to regulations concerning cardiac catheterization services received comments from a variety of stakeholders, including the Invasive cardiac Services Advisory Committee (ICSAC). DPH further revised the regulations to remove the requirement that a hospital must re-apply for re-approval of its cardiac catheterization program at each hospital licensure review, and peer review of the program will no longer require that the peer reviewer must be an out-of-state physician. DPH also added language to provide that hospitals without cardiac surgery on-site may not perform certain procedures designated in DPH guidance, which DPH notes will be created in consultation with state and nationally recognized expert groups. Hospitals should consult Cardiac Catheterization Guidance, which DPH indicates will accompany the regulations, for important sub-regulatory program requirements.

Administrative Changes

Changes on the administrative front included codifying the current DPH process of not requiring filing paper copies of corporate documents that DPH can access through the Secretary of the Commonwealth's website. DPH also eliminates duplicative requirements concerning publication of an acute care hospital's community benefits plan, which is met by submission and publication of the plan to the Attorney General's Office or in connection with the filing of a Determination of Need.

In response to questions from PHC members, DPH counsel clarified that publication of a hospital's community benefits plan may be met in a variety of ways, including public reports through the Attorney General's website or the Determination of Need Program's website, and that the hospital must confirm publication to DPH.

Vaccinations

Staff also confirmed that DPH will continue to require hospitals to follow the federal vaccination guidelines to supply vaccinations to all patients 6 months and older, and noted that vaccinations are tracked at both the state level through the Massachusetts Immunization Information System (MIIS)

and federally through CMS. Staff assured the PHC that Massachusetts hospitals are complying with the vaccination requirements.

Commissioner Bharel commended DPH staff for their diligent efforts and thanked the PHC members for their continuing support of the regulatory review process. Commissioner Bharel also noted that DPH is hopeful that DPH will receive increased funding in two key areas: additional funding for the Plan Review Program would help streamline that process for all facilities; and a proposed $970,000 line item increase would allow DPH to add inspectional staff to conduct surveys and respond to complaints.

Of course, this Blog Post highlights but a few of the regulatory changes and hospitals will need to carefully review the Hospital Licensure Regulations in their entirety. In application of the amended regulations, hospitals will likely come upon areas of uncertainty. In such cases, DPH staff will be available to provide necessary guidance.

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