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To: Commissioner Monica Bharel, MD and Members of the Public Health Council

From: Eric Sheehan, Director, Bureau of Health Care Safety and Quality

Date: March 8, 2016

RE: Informational Briefing on Proposed Amendments to 105 CMR 130.000, *Hospital Licensure*

I. Introduction

The purpose of this memorandum is to request the Public Health Council (“PHC”) approve for promulgation the proposed revisions to 105 CMR 130.000, *Hospital Licensure*. The Bureau of Health Care Safety and Quality (“BHCSQ”), within the Department of Public Health (“DPH” or “the Department”), brought a draft revision of these regulations to the PHC on September 14, 2016, as part of the regulatory review process mandated by Executive Order 562.

The proposed amendments to this regulation updated terminology, centralized definitions, where appropriate, into a single section, and used plain language to make the regulation easier to read and understand. In addition, the proposed amendments deleted unnecessary or outdated regulations and reflected new statutory obligations on hospitals.

After review by the PHC, the Department held a public comment period, which included a public hearing on October 24, 2016. During the public comment period, the Department received comments from several stakeholders, a list of the commenters is attached to this memo. Upon review of the comments received, the Department made several additional changes to the regulation, as described below.

II. Public Comments and Additional Changes to the Regulation

105 CMR 130.020 (Definitions): Commenters requested clarification or amendments to several definitions for facility types, including Ambulatory Care Service, Campus, Chronic Care and Rehabilitation.

DPH notes that the service definitions are for services within a hospital, not hospital facilities themselves, and therefore did not change definitions where the suggested change would alter the

substance from defining a service to defining a specialized facility. However, DPH agreed that for consistency and clarity, the definitions for ambulatory care services, chronic care services and rehabilitation services were amended to defer to the Centers for Medicaid and Medicare Services (“CMS”) and to require these services to meet CMS criteria. In addition, DPH changed the definition of campus by replacing “essential healthcare services” with “health care services,” to ensure this definition is inclusive of hospital campuses that do not provide an essential service, such as chronic care or rehabilitation hospitals.

105 CMR 130.101(D) and (E) (Application for Licensure): Commenters requested amendment to sections requiring applicants to submit by-laws, and other ownership documents at every license renewal, suggesting submission only upon initial application, transfer of ownership, or if documents have changed.

DPH has removed 130.101(D), which required hospitals to submit by-laws to the Department. For administrative efficiency, the Department does not need to rely on the submission of paper documents to determine corporate status of the applicant. With respect to 130.101(E), which requires applicants to submit certain information resulting from a transfer of ownership of an acute-care hospital, this information is required by statute (see M.G.L. c. 111 § 51G) and therefore DPH did not remove it.

105 CMR 130.107 (Plan Review): A commenter noted that the Facilities Guidelines Institute has changed the name of its guidance document several times when updating the guidance. The commenter suggested that a more general reference to the guidelines would stay more relevant.

The Department agrees, and updated the language to “Facility Guidelines Institute’s Guidelines applicable to design and construction of hospitals and outpatient health care facilities” to anticipate future title changes.

105 CMR 130.108(B)(9) (Condition of Licensure): A commenter asserts language in this section is duplicative of the DoN CBHI, Health Priorities, AGO and IRS Community Benefits requirements. The commenter says it does not make sense to tie community benefits to essential health services, and requests clarification of intent and correction of the legal application.

The Department notes that submission of this information is required by state law (M.G.L. c. 111 § 51G). To limit duplicative filings, DPH has amended 130.108(B) to make clear that if a hospital submits a community benefits plan to the Attorney General's Office or for Determination of Need purposes and is made public, the requirements of this section will be met.

105 CMR 130.122 (Beds Out of Service and Discontinuation of Service): A commenter suggested licensed beds should be in service at all times in the absence of formal notification to DPH and to the public of bed closure or unavailability.

DPH has further amended this section in an effort to improve DPH oversight of hospital licensure and operations, while streamlining notification requirements and reducing confusion for licensees. Additional changes require hospitals provide notice to the Commissioner any time licensed beds are removed from service for longer than six consecutive months.

105 CMR 130.325 (Influenza Vaccination for Personnel): Commenters requested updates to this section that would remove the option for personnel to decline vaccination and that would require hospitals to offer the flu vaccination to patients.

DPH did not amend this section. The Department notes that hospitals have met and exceeded DPH's and Healthy People 2020's stated goal of 90% vaccination for health care workers. Additionally, vaccination of all patients over the age of six months is recommended by the CDC's Advisory Commission on Immunization Practices, and a state reporting requirements tracking patient vaccination would duplicate federal tracking efforts.

105 CMR 130.331(A)(7) (Serious Incident Reporting): Commenters requested removal of reporting requirement for surgery and anesthesia related complications as a serious incident, suggesting that this would create duplicative and unnecessary reporting as these cases fall within an existing reporting requirement as a serious reportable event ("SRE") to DPH and/or the Quality and Patient Safety Division ("QPSD") at the Board of Registration in Medicine.

DPH agrees that reporting it here is duplicative and unnecessary for hospitals, and has removed this requirement.

105 CMR 130.331(C) (Serious Incident Reporting): Commenters also expressed confusion about overlapping requirements of serious incidents, SREs and serious adverse drug events ("SADEs").

DPH agrees. The reference to SADEs has been removed in 130.331(C) and placed into 130.331(D) for consistency. Multiple reports are not necessary. The SRE requirements include additional recipients of the report – the patient and payer (130.332(b)(1)(a)) – and require a follow up report within 30 days.

105 CMR 130.332 (SRE and SADE Reporting):

- DPH had changed this section to permit hospitals to provide verbal notice to patients seven days after a serious reportable error. Several commenters expressed concern about this change, arguing that in some cases written notice is more appropriate.

DPH agrees and has amended the regulation to allow for oral or written disclosure. Depending on best practice and patient preference, oral or written notice may be more appropriate, and one method does not preclude the other.

- Several commenters expressed concern that SADE reporting requirements apply to all controlled substances, versus a subset of high risk drugs. Additionally, these commenters expressed concern that the regulation requires hospitals to report a SADE within seven days of the "date of discovery" of the error, versus within seven days of treatment at the facility. Finally, commenters were concerned that there are potential financial sanctions for failure to submit a SADE report.

The Department has not made further changes based on these comments because the

definition of SADE and the sanctions provision include both terms – “controlled substance” and “date of discovery” –as used in the statute (M.G.L. c. 111 § 51H).

105 CMR 130.341(B) and (C) (Discharge Planning): Commenters sought removal of words “licensed social worker or a registered nurse, preferably a community health nurse” in 130.341(B) and (C) and replacement with “licensed professional approved by the hospital” to allow for many appropriate staff to do discharge planning successfully and timely for patients.

DPH agrees with suggested language change, as this would be consistent with subsection (A) that allows for coordination by staff from other appropriate hospital departments as appropriate, and federal language which reads: "...registered nurse, social worker, or other appropriately qualified personnel."

105 CMR 130.342, .536, .616 (Staffing): Commenters asked that as providers develop integrated models of care, DPH should consider amending provisions to use more generic term clinician instead of physician. Often a nurse practitioner or physician assistant can competently and appropriately monitor and direct patient care and treatment.

DPH agrees and has adopted changes in part and where appropriate. Physician assistants and nurse practitioners were added to 130.342(B), (E), (F), (G), (H) and 130.536(4); neonatal nurse practitioner was added to 130.616(D)(2)(j).

105 CMR 130.601 (Definitions for Maternal and Newborn Services):

- Commenters requested revision of definitions in family centered care by removing the terms “father, mother and child” to allow the family situation to reflect other types of family arrangements.

DPH agrees. The definition is revised by removing the terms "father, mother and child" and instead using "parent(s) and child and may include other identified support persons".

- Commenters also requested that the definition of “lactation consultant” be expanded. The current definition requires certification as an International Board Certified Lactation Consultant (“IBCLC”) “or with equivalent training and experience.” Commenters requested that be expanded to include other training and certification.

DPH did not make this change. The IBCLC has clear, published criteria that include the level of training that is appropriate for the professional in this role in a hospital.

105 CMR 130.601 (Maternal and Newborn Services): Several commenters sought changes and clarifications in staff qualifications, including those for Maternal Fetal Medicine specialist, neonatologist, obstetrician, and pediatrician. They request DPH insert language allowing board eligible specialists, who may have up to seven years after their fellowship to pass their subspecialty boards, to practice during that time.

DPH agrees. "Board eligible" has been inserted throughout the regulation for positions where the provider is not leading a service. Throughout the regulation, providers who act in leadership roles are required to be board certified as this certification demonstrates excellence in this area and provides a transparent mechanism for assessing the provider's competency that is standardized throughout the commonwealth's health care facilities.

105 CMR 130.601-650 (Maternal and Newborn Services): Commenters sought changes and clarifications regarding requirements of pediatric nurses.

DPH agrees that consistency is needed and has amended the regulation to align experience requirements for pediatric nurses, across all levels, to that required for nurses in nursery and neonatal intensive care units.

105 CMR 130.630(B)(5) (Level I Nursery): Commenters noted administration and staffing does not mention the role of nurse practitioner, who could clinically function in this area.

DPH agrees and has incorporated the role of neonatal nurse practitioners into Level I services.

105 CMR 130.630 (Level I Nursery): Commenters contend that, in Level II nurseries using certain ventilation equipment prior to infant transfer, requiring a neonatologist at an infant's bedside at all times is burdensome.

DPH agrees and has further amended this regulation to require that in these instances neonatologists be immediately available in the hospital, versus remain at bedside at all times.

105 CMR 130.640(A) and (B) (Level IIA and IIB Nursery): Commenters suggested removing the term "uncomplicated" to describe a pregnancy delivered at 32 or 34 weeks.

DPH agrees and has stricken the term "uncomplicated" from 130.640(A) and 130.640(B) (which refers to uncomplicated delivery at 32 or 34 weeks) because delivery at 32 or 34 weeks would be the result of a complication of pregnancy.

105 CMR 130.640(D)(3) (Level II Nursery): Commenters suggested adding educator to clinical nurse role.

DPH agrees and has added "educator" after clinical nurse in 105 CMR 130.640(D)(3).

105 CMR 130.650(D)(1)(e) (Level III Nursery): Commenters sought removal of the requirement that nurses for maternal patients be "Advanced Cardiac Life Support certified," as clinical staff are cross-trained to provide care that meets national and professional standards and it is unnecessary to require a specific certification.

DPH agrees and has added "or have equivalent training and experience" after Advanced Cardiac Life Support certified.

105 CMR 130.650 (Level III Nursery): Commenters expressed concern that the regulations

have removed the requirement for masters-level prepared social workers in NICU settings.

DPH agrees and will reinstate masters-prepared licensed social workers for Level 3 service. Proposed amendments standardize social work services across the other levels of care and require all levels of care to provide services by a licensed social workers

105 CMR 130.650(E)(2)(b)(iii) (Level III Nursery): Commenters noted NPs have professional responsibility for maintaining skills and do not require regular schedule rotations through a Level III NICU.

DPH agrees and has stricken section 130.640(E)(2)(b)(iii), as it is the responsibility of the hospital credentialing staff to ensure that the provider maintains competency.

105 CMR 130.811(B)(2) (Birth Center Staffing): Several commenters requested removal of language requiring physician supervision of Certified Nurse Midwives, as midwives do not require physician supervision, pursuant to 244 CMR 4.06(2).

DPH agrees and has amended the language to reflect the independent scope of practice of midwives.

105 CMR 130.900-130.982 (Standards for Operation of Invasive Cardiovascular Services):

- Commenters requested that the Department reinstate the detailed requirements for these services in the regulations.

DPH has retained the regulation as written. The Department is issuing guidance, based on national standards and consultation with experts in the field. This guidance will be updated as the national, data and research-based standards are updated, and therefore will better enable the Department to ensure that hospitals are providing appropriate services with the appropriate staff and resources.

- Commenters also requested that the Department consult with the Invasive Cardiac Services Advisory Committee (“ICSAC”) prior to finalizing these changes.

The Department has consulted with ICSAC, and has made some changes (detailed below) based on ICSCA’s guidance.

105 CMR 130.915(B) (Application to Provide Cardiac Catheterization Services):

Commenters requested removal of the requirement that hospitals seek re-approval of its cardiac catheterization program at every license renewal because this would add administrative burden.

DPH agrees and has removed this requirement, so the approval of cardiac catheterization services aligns with all hospital services.

105 CMR 130.935(A)(2) (Peer Review Requirements for Invasive Cardiac Services): The ICSAC indicated that, for hospitals required to request a peer review of the hospital’s cardiac

services, it is burdensome and costly to require the reviewer be an out-of-state physician and added that the regulation's requirement for the peer reviewer to disclose any conflict of interest and be approved by the Department eliminates potential issues around selecting an in-state reviewer.

DPH agrees, and has removed the requirement that peer reviewers must be out-of-state physicians.

105 CMR 130.975 (Cardiac Catheterization Services without Cardiac Surgery Services):

The ICSAC provided input on procedures that should not be performed without cardiac surgery on-site, and requested these procedures be specified in guidance.

DPH agrees and has included these procedures in guidance. Language has been added to 130.975 indicating hospitals without cardiac surgery on-site may not perform procedures listed in the Department's guidance.

III. Summary

The proposed amendments to 105 CMR 130.000, a chart of recommended changes and staff's response, and a list of commenters are attached to this memorandum.

DPH staff request that Public Health Council vote to approve these regulations for final promulgation.