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April 2, 2015

Mr. David Seltz, Executive Director
Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA

Re: 958 CME 8.00, regarding Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Hospitals

Dear Mr. Seltz:

The Conference of Boston Teaching Hospitals (COBTH) and our fourteen member hospitals appreciate this opportunity to provide comments on the Health Policy Commission's (HPC or the Commission) proposed regulations 958 CME 8.00, regarding Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Hospitals. These comments are offered in a spirit of cooperation and commitment toward final regulations that are consistent with MGL. Ch. 111, section 231, and its legislative intent.

We appreciate the time, effort and consideration the HPC staff and commissioners have dedicated to developing these draft regulations, but we are very concerned that the prescriptive nature of the proposed regulations will deprive hospitals of the flexibility necessary to continue to provide the outstanding high quality care currently found in our Intensive Care Units (ICU). Key to the success of our hospital's ICUs is their ability to react nimbly to unforeseen events - whether they are events in the care of an individual patient or during a disaster such as the catastrophic bombings at the Boston Marathon in 2013. Successful outcomes and innovations to medical care result where there is flexibility.

The proposed regulations, however, particularly those concerning the development and implementation of the acuity tool, will strip ICU care teams of much of the flexibility they need to innovate and improve patient outcomes and medical care. Therefore for several sections of the proposed regulations we request the Commission move its suggestions to sub regulatory guidance.

The overall prescriptive nature of the proposed regulations also carries a financial impact for hospitals. As written, the proposed regulations create new and expansive administrative burdens and measures for hospitals. We therefore ask that the Commission conduct an analysis, under M.G.L. c. 30A section 5, of the fiscal effect of their proposed regulations will have before it adopts any of the proposed regulations.

8.02 – Definitions

Intensive Care Unit – We request that the commission adopt the established definition of Intensive Care Unit (ICU) created in 105 CMR 130.020 and delete its additions to the definition.

The Commission includes "coronary care unit, burn unit, pediatric care unit and neonatal intensive care unit" in its proposed definition of Intensive Care Unit (ICU). However under the definition for "Service" in 105 CMR 130.020 each unit included by the Commission is separately defined and distinct from the definition of an ICU. Not only would it be inconsistent with established regulations for the HPC to group these distinct services within its definition of an ICU, but it would be inconsistent with legislative intent. Chapter 155 specifically states that "intensive care units" shall have the same meaning as 105 CMR 130.020. By expanding its definition of ICU, the Commission goes beyond its regulatory authority and creates confusion and inconsistency within the Code of Massachusetts Regulations . We ask that the Commission strike its alterations and adopt the standard definition of ICU.

ICU Patient – We request the commission include in its definition of an ICU patient the language from the definition of an ICU which refers to the patients therein.

The definition for an ICU defines patients within its unit as "critically ill inpatients requiring the immediate and concentrated continuous care and observation." We request that this language be incorporated into the Commission's definition of an ICU patient to relate the two terms to each other. We suggest the new definition for ICU Patient read: "A *critically ill inpatient requiring the immediate and concentrated continuous care and observation and* occupying a bed in the ICU."

Nurse Manager – We request the phrase "for the ICU" be stricken from the Commission's definition of a Nurse Manager.

We feel that a nurse manager with responsibility for nursing services allows for flexibility and more accurately reflects the nature of nurse managers in the hospital.

8.04 – Staff Nurse Patient Assignment in Intensive Care Units

We request that the Commission amend subsection (2) to read "The maximum Patient Assignment for **the** Staff Nurse **shall** not exceed two ICU Patients." and strike subsections (1) and (3) as they are incorporated in subsection (2) as amended.

The three subsections of 8.04 each convey the same message. To reduce repetition and lend to greater clarity we request that subsections (1) and (3) be stricken and subsection (2) as amended be adopted as it most succinctly conveys the intent of the statute. The amendments two words altered in subsection (2) reflect the statutory language as drafted. Deletion of the "at all times during a Shift" is necessary to reduce confusion and potential liabilities unintentionally created by the proposed draft language. Similarly, the phrase "at all times" unnecessarily confuses its application; it applies to a nurse's Patient Assignment during a Shift and not to direct bedside care. This ambiguity has led many stakeholders to infer that ICU nurses would be precluded from responding to emergency codes, or any of the other reasons listed in the following paragraph.

Inclusion of the phrase at all times has the potential to create undue burden on hospitals – teaching hospitals and community hospitals -- who will have to account for all times when a nurse may need to briefly step away from his/her duties whether to consult with a doctor or another nurse, or simply to use the restroom. As drafted "at all times" imposes a duty on hospitals to add nursing staff in the position of a "floating" nurse to make up for any such brief departures however brief.

8.05 – Assessment of Patient Stability and Determination of Patient Assignment

We ask that subsection (1) be amended and include the following bolded phrases: "For purposes of determining a Patient Assignment, the Staff Nurse assigned to care for the ICU Patient shall assess **together with other team members** the stability of the ICU Patient utilizing:"

We ask that the Commission shift subsection (3) to come before subsection (2) so that the regulations may read in an order more true to the sequence of care delivery.

We ask the commission to adopt the friendly amendment of switching the reading order of section 8.05 so that what is currently subsection (3) comes before subsection (2). We feel that this order make better sense and more accurately reflects delivery of care.

We ask that subsection (3) be redrafted to read: "The Staff Nurse assigned to care for the ICU Patient shall **utilize** the acuity tool **to aide in the in assessment of the ICU Patient**." And delete the three subsections stating when the acuity tool shall be used.

8.06 – Development or Selection and Implementation of the Acuity Tool

We urge that the required elements for the development or selection, and implementation of a hospital's acuity tools be moved to sub regulatory guidance. Additionally we request that the composition of the advisory committee be more inclusive so that the hospital, as well as other individuals aware of new innovations in care delivery, that fall outside the parameters listed by the proposed regulations be allowed to weigh in.

COBTH and its member hospitals feel that the proposed regulations concerning the development and implementation of an acuity tool are as a whole overly prescriptive. Hospital case mix and care practices are unique and the specification and rigidity of parameters limits a hospital's flexibility in the development of the tool. As such, we believe that the proposed regulations governing the development and required elements of the Acuity tool be moved to sub regulatory guidance to allow hospitals the flexibility granted by Chapter 155 to develop the best acuity tool for their ICUs an patient population.

While the Commission's proposed regulations reflect great consideration on the part of the HPC staff to understand what elements may be part of vendor-based acuity tools currently on the market, making each element required limits the flexibility of hospitals and impedes innovation.

Additionally by defining the composition of the advisory committee the HPC does not allow hospitals the flexibility to include individuals it may feel are necessary to develop the best acuity tool for its ICU. Individuals who are at the forefront of new innovations in medical care may not be captured by the parameters set by the Commission's proposed language. It is therefore in the best interest for all involved to not limit the advisory commission's composition.

We ask that the phrase “make recommendations to” be stricken from section (2)(a) and in its place the phrase “consult in the development of” be inserted.

Inserting the phrase “consult in the development of” in place of “make recommendations to” provides necessary flexibility to hospitals as they work toward development of their own Acuity tools.

We urge the HPC to strike sub subsection (2)(b)(4) and move its suggestions to sub regulatory guidance.

While we appreciate the consideration the Commission and its staff has put into the environmental factors that should be addressed in development of the Acuity tool we find the inclusion of such factors overly prescriptive. Acuity tools should not hinder care providers from doing what is best for their patients. Rather an acuity tool should be a threshold from which the level of care provided may rise. By prescribing when environmental factors should be considered in the development of an Acuity tool the Commission is limiting the care team’s ability to innovate and improve patient care. As such we request the Commission’s proposed environmental considerations be moved to sub regulatory guidance to not impede growth.

We ask that subsection (3) be stricken as it exceeds regulatory authority.

A hospital’s bargaining with labor organizations or its collective bargaining agreements are outside the scope of Chapter 155. It is unnecessary to reference to such arrangements in these regulations, and exceeds the authority granted to the Commission by section 231.

8.07 – Required Elements of the Acuity Tool

We urge that the whole of section 8.07 be stricken from the Commission’s regulations and be submitted as sub regulatory guidance.

While we appreciate the time and thought the Commission and its staff has put into which elements should be required for the acuity tool, we find the elements overly prescriptive and inflexible. The care team should be allowed the flexibility to consider what elements are most critical to the care of their patient. The required elements of the acuity tool should be able to adapt to care innovation and not so inflexible as to impede improvements. As currently drafted the required elements of section 8.07 cannot adapt to changes in the field, for this reason we ask they be committed to sub-regulatory guidance to set the threshold for ICU care.

8.08 - Records of Compliance

We ask that the Commission remove the minimum 10 year period for record retention.

The 10 year retention period is administratively burdensome, costly, and not tied to any specific medical or legal requirement. Moreover, hospitals may use different vendors/electronic systems in implementing their acuity tools and a 10 year record retention period may be cost prohibitive and/or difficult to adhere to given frequent changes that may need to be made to an electronic acuity tool program.

8.09 - Acuity Tool Certification, Enforcement by the Department of Public Health

We request the Commission to clarify the required elements for certification of a hospital's acuity tool and to determine the time frame of submissions for enforcement of the acuity tool.

Section 8.09 is ambiguous in regards to requirements of submission for certification and the timing of submissions. The implementation of an acuity tool requires time for internal development or vendor selection, facility and patient population customization, and validation and reliability testing. Clarification of required elements and point of submission in complicated project timeline is required to ensure compliance and reduce waste of resources. The ambiguity of "periodically" makes determination of needed resources to meet requirements difficult and possibly onerous. COBTH requests the Commission to create fixed and identifiable intervals.

8.10 Public Report on Nurse Staffing Compliance

We ask that Section 8.10 include language that clearly states that public reporting of nurse staffing compliance is for the sole purpose of recording compliance with the law.

As drafted, reporting on the incidences and reason staffing ratios were not maintained could lead to unsound and misleading conclusions about a hospital's safety and quality. In addition, these numbers could have unintended legal consequences for hospital liability and could injure a hospital's reputation because compliance records are hard to interpret (for a lay person) and are not evidence-based or appropriate medical indicators of assessing a hospital's quality and/or safety.

8.13 - Implementation Timeline

We urge the Commission to adopt its Implementation Timeline as sub regulatory guidance, omitting Section 8.13 from the draft regulations.

An implementation timeframe of October 2015 for certification with DPH is insufficient given that the final regulation is anticipated to be approved in April 2015. At a minimum, there will likely be a 6 month backlog for those hospitals who may ultimately choose to purchase an acuity tool from market vendors, and significant processing for those who develop it internally.

Thank you for your consideration of our comments and recommendations. We look forward to continuing to work with the Commission and HPC staff.

Please do not hesitate to contact me if you have any questions or wish to have further clarification on the foregoing points.

Sincerely,

John Erwin
Executive Director
Conference of Boston Teaching Hospitals