

April 6, 2015

David Seltz  
Executive Director  
Health Policy Commission  
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Boston, MA 02109

*Via Electronic Mail to [HPC-regulations@state.ma.us](mailto:HPC-regulations@state.ma.us)*

Dear Executive Director Seltz:

Thanks for you the opportunity to provide comments regarding *958 CMR 8.00 – Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Hospitals* as authorized by M.G.L c. 111, § 231.

Lahey Health System (Lahey) has been, and continues to be fully committed to ensuring a safe patient care environment, which includes staffing the appropriate ratio of nurses to patients in its Intensive Care Units (ICU). A review of the Health Policy Commission’s (HPC) proposed regulations regarding nurse staffing rations in ICUs, however, demands greater attention to the balancing of patient care needs and a hospital’s operational requirements, including staffing issues. Critical to this balancing act is the need for flexibility, and as set forth below, the mandating of fixed nurse staffing ratios “at all times”/”at any time” prohibits the flexibility a hospital needs in addressing staffing, operational and patient needs.

Furthermore, the fast approaching and ambiguous certification timeline of October, 2015 does not allow Lahey to appropriately plan and budget for the high costs involved in creating, developing, and implementing acuity tools in its ICUs. Moreover, while it is important that ICU patients receive the focus and time of ICU staff nurses, this cannot be at the cost of other patients in the hospital whose care may be directly impacted by the inflexible staffing regulations.

Lahey offers the following specific comments to the proposed regulation:

#### 8.04. Staff Nurse Patient Assignments in Intensive Care Units

##### *Comment*

Inclusion of “at all times” and “at any time” will introduce unintended consequences. An acute care hospital operates as a complex and dynamic ecosystem with interdependencies between clinical departments that work together to coordinate safe, timely, effective and evidence based patient care for all patients. Based on research, for example, the Institute for Healthcare Improvement (IHI) has recommended the use of Rapid Response Teams (RRT) or Medical Emergency Teams (MMT). At many institutions, these teams are staffed by experienced ICU nurses who have the unique set of skills and experiences to address unpredictable and life threatening events throughout the hospital. For example, consider a patient who unexpectedly deteriorates with an acute emergency such as cardiac arrest. A Lahey Rapid RRT or MMT, comprised of 2 to 3 nurses, physicians, respiratory therapists, and other medical staff, would provide the response to this type of event. Responding ICU nurses would momentarily ‘hand-off’

their patient(s) to other ICU nurses during the response, potentially in violation of the “at all times”/“at any time” standard. The rigidity of this requirement would significantly decrease an ICU’s flexibility in allocating appropriate resources and expertise during these critical events.

While rapid response emergencies are unpredictable there are other more foreseeable events that can also introduce operational challenges and unintended consequences in an ICU required to maintain nurse to patient ratio’s “at all times”/“at any time”, including bathroom breaks, emergency phone calls, family discussions, and breaks for breastfeeding. In practice today, most nurses manage these more predictable events through sound assessment of their patient, professional judgment and team collaboration. The “at all times”/“at any time” provision will make it very difficult for nurses to manage direct patient care along with other predictable but necessary events.

### 8.05(3) Assessment of Patient Stability and Determination of Patient Assignment

#### *Comment*

This provision does not account for whether a hospital’s acuity tool is either manually entered/recorded by a staff nurse or automatically entered/recorded via an electronic program such as a transparent interface to EHR data. This statement should be modified to generically refer to acuity being calculated at a minimum of intervals stated in 8.05(3)(a),(b), and (c).

### 8.06(2)(a) Development of Selection and Implementation of the Acuity Tool

#### *Comment*

Make-up of the committee membership as written is unclear. Further, the HPC should explore whether other committees within the hospital or hospital system would be appropriate to make the required recommendations as opposed to the mandated formation of an additional committee.

### 8.06(2)(c) Development of Selection and Implementation of the Acuity Tool

#### *Comment*

An acuity tool must be validated and tested at varying intervals to ensure that as case mix and care practices change, it continues to be a valid tool to assess acuity. To support this, a process to test, validate, and recommend revisions must be in place for continued evaluation – and not solely prior to implementation.

### 8.07(4)(a) Required elements of the Acuity Tool

#### *Comment*

Inclusion of physiological systems is not required as the general statement “Clinical indicators of patient stability related to physiological status and clinical complexity...” speaks to a variety of patient classification and methodologies. Specifying parameters may limit or create extra documentation that does not result in any value to the acuity calculation.

### 8.08(1),(2) Records of Compliance

#### *Comment*

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(1) Acuity Tool Certification, Enforcement by the Department of Public Health

##### *Comment*

Statement is ambiguous in regards to requirements of submission for certification and time of submission. The implementation of an acuity tool requires sufficient time for vendor selection, facility and patient population customization, and validation and reliability testing. Lahey anticipates that this process would take at least 6-9 months. 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.

#### 8.10 Public Report on Nurse Staffing Compliance

##### *Comment*

Records of compliance should clearly state that this requirement 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 and are not evidence-based or appropriate medical indicators of assessing a hospital’s quality or safety.

#### 8.11 Collection and Reporting of Quality Measures

##### *Comment*

Quality measures should only be issued through sub-regulatory guidance and not as a regulation. Such measures should track DPH’s Adverse Event reporting requirements to the maximum extent feasible to avoid unnecessary duplication and because events have already been identified as those in which public reporting promotes public safety and health. DPH or HPC should issue quality reports to be publically available, as this type of data is often collected by these agencies through the regulation. Similarly, it is administratively burdensome to post such reports on a hospital’s website.

#### 8.13 Implementation Timeline

##### *Comment*

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. There will likely be a 6 month backlog, at a minimum, for those hospitals that purchase an acuity tool from market vendors. The October 2015 deadline also is misaligned with most hospital’s fiscal year. Therefore, hospitals will be required to expend capital that was not accounted for their FY2015 budgets (October 1, 2014 – September 30, 2015).

Furthermore, a fixed timeframe should be set forth in sub-regulatory guidance and not through regulation. The public hearing and comment process should inform the deadline for certification, and HPC should have flexibility to set the appropriate deadline as more information and discussion become available.

Cost Estimates

Lahey estimates that the development and implementation of an acuity tool, purchased through a license agreement with a vendor, will cost between \$170,000 - \$500,000. Lahey further estimates that the operational expenses, including vendor consulting fees and maintenance arrangements, will cost between \$500,000 - \$2,500,000. These costs include building out appropriate support systems, interfacing, and mapping across Lahey ICUs.

Lahey would incur additional costs by having to hire at least one employee to manage/operate the acuity tool on a full time basis (including testing the tool's reliability, validity and ensuring compliance). In addition, and as set forth above in Section 8.04, Lahey Health will incur additional (and substantial) costs by having to hire additional ICU nursing staff (by way of a "shift or flex" nurse) to ensure appropriate staffing coverage in compliance with the "at all time" staffing requirement. Again, Lahey estimates that it would cost several million dollars on an annual basis to hire additional nursing staff for Lahey's 9 ICUs. These significant costs will compete with broader organizational integration efforts and strategies to provide high quality patient care at a lower cost.

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

Sincerely,

*Scott V. Hartman*

Scott V. Hartman  
Vice President, Government Relations