MHA MASSACHUSETTS HOSPITAL ASSOCIATION

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ONL Organization of Nurse Leaders MASSACHUSETTS & RHODE ISLAND

April 13, 2015

David Seltz
Executive Director
MA Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Re: HPC Proposed Regulations - 958 CMR 8.00: Registered Nurse-to-Patient Ratios in Intensive Care Units in Acute Care Hospitals

Dear Mr. Seltz,

The Massachusetts Hospital Association (MHA) and the Organization of Nurse Leaders of MA-RI (ONL), on behalf of our respective members, jointly submit this testimony regarding 958 CMR 8.00, that proposes Registered Nurse-to-Patient Ratios in Intensive Care Units in Acute Care Hospitals pursuant to M.G.L. Chapter 111, Section 231 (as inserted by Chapter 155 of the Acts of 2014).

It is worth remembering that Chapter 155 was not drafted as a resolution of any patient care issues in the ICUs of Massachusetts hospitals. It was designed as a political resolution to a political problem associated with two proposed public ballot questions. There is no evidence to be found in the testimony before the Commission or elsewhere that there are any quality of care problems in our ICUs. In promulgating regulations to implement Chapter 155, we urge the Commission to do nothing that will create clinical, operational, or financial problems where none exist today.

Throughout two recent hearings, the Health Policy Commission (HPC) heard a variety of perspectives about current practices and the intent of the law, including many inaccurate comments from a nursing union. The position from MHA and ONL panelists has been that the final regulations should be based on the clear language of Chapter 155 and closely focused on the needs of the patient.

The intensive care unit (ICU) cares for a wide range of patients, from those who are critically ill and suffering from multisystem failure requiring intensive monitoring and treatment, to patients needing observation prior to being transferred safely to a lower level of care. As a result, any staffing model for the ICU must take into consideration several factors, including but not limited to the overall census, the acuity of each patient, and the skill of the RNs and other care team members. In addition, the final regulations should not inhibit teamwork and communication among ICU staff, allowing for continuous reassessment by the nurses and resource realignment by the nurse manager to meet each individual's care needs around the clock.

Despite comments to the contrary, the record is clear and indisputable: there were no legislative hearings on Chapter 155; there was no legislative debate on the bill in either the House or the Senate; not one word was changed from what was agreed to in discussion among the parties prior to the bill being filed by the House and the Senate. Thus, Chapter 155 should be read and interpreted by

referring to the actual language in the law, and not added to or supplanted in the process of promulgating regulation. The term "patient assignment" was used in the statute, but there was no reference to "at all times" or "at any time." Yet the HPC created and inserted both of these terms into the proposed regulations. The statute states that the "patient assignment for the registered nurse shall be 1:1 or 1:2 depending on the stability of the patient as assessed by the acuity tool and by the staff nurses in the unit, including the nurse manager or the nurse manager's designee when needed to resolve a disagreement." There is no mention in Chapter 155 of a so-called "default staffing level of 1:1." If the legislation intended there to be a default staffing level, it would have so stated it.

While we provide detailed comments on each of the proposed regulations in the attached testimony, we ask that the HPC amend the final regulations to reflect the following key areas of concern that will inhibit the ability to appropriately care for our patients in an ICU as defined in 105 CMR 130.020(B):

- Removal of the words "at all times" or "at any time" in section 8.04, which prevents needed flexibility for nurses in hospital ICUs to effectively care for the dynamic needs of patients who are in or are coming into an ICU;
- Removal of the application of the regulations to Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU), Burn Units, and Coronary Care Units (CCU); if the statute had intended a novel or expansive definition of an ICU, then the legislation would not have cited a specific regulatory definition of an ICU in the statute, and would have simply said *all* ICUs without defining what that term meant. The proposed regulations pose a new definition of ICU that differs from the regulation cited in Chapter 155 by blending the definition of ICU with that of distinct and separate definitions of NICU, PICU, Burn, and CCU;
- Removal of the strict acuity tool requirements, such as a defined list of indicators and other criteria in sections 8.06 and 8.07. An acuity system is a complex tool: it will require a multi-disciplinary team to identify the right clinical tool for their institution, work with staff to ensure appropriate integration and interoperability within the IT system, and ensure appropriate time for testing, validation, and employee education; and
- Develop a more appropriate time frame for the implementation of the acuity system that allows hospitals to budget for the costs of implementing a system, as well as the time to choose, test, validate, and educate staff on any new system.

MHA, ONL, and our respective members have been and remain committed to working with the HPC in developing appropriate and meaningful regulations that are consistent with the language of the law. Should you have any questions about our comments on the proposed regulations, please do not hesitate to contact either organization.

Sincerely,

Lynn Nicholas

Lynn Nicholas
President and CEO
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Sharon Gale
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Massachusetts Hospital Association and the Organization of Nurse Leaders of MA-RI Joint Response to HPC Proposed Regulations - 958 CMR 8.00: Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Care Hospitals

Definition of ICU under the Proposed Regulations (958 CMR 8.02)

As the HPC finalizes its regulations, it must ensure that the terms and definitions are consistent with the plain language of the law.

M.G.L. Chapter 111, Section 231 (as inserted by Chapter 155 of the Acts of 2014) specifically states that "the term 'intensive care units' shall have the same meaning as defined in 105 CMR 130.020" under the Department of Public Health (DPH) regulations. In examining 105 CMR 130.020, there is only one distinct definition of an intensive care unit (ICU) within the subpart (B) of the term "services." ***This definition provides that an ICU is:*** "A unit physically and identifiably separate from general routine (and other) patient care areas, in which are concentrated special equipment and skilled personnel for the care of critically ill inpatients requiring immediate and concentrated continuous care and observation, and which meets the Medicare requirements in 42 CFR 413.53(d) for intensive care type inpatient hospital units." This definition clearly does not take into account or reference a coronary care unit (CCU), burn units, pediatric intensive care units (PICU), and neonatal intensive care units (NICU).

We ask that the HPC take into account that if the law was meant to apply to any other services other than an ICU outside of this definition, then the legislation would not have cited a specific regulatory definition of what an ICU meant in the law. Rather, the legislation would have simply said that the law would apply to "all ICUs." The proposed regulations in effect create an altered definition of ICU by blending different types of "Service" categories, which is not reflected in the statute. Specifically, the law cites an ICU that is distinctly listed under the term "Service" in 105 CMR 130.020 subpart (B) and is separate from other more specialized "Services" such as a CCU defined under Subpart (C), a Burn Unit defined under subpart (D), a PICU defined under subpart (F), and a NICU defined under subpart (G)(2).

Therefore, it would be inaccurate for the HPC to interpret the law in a manner that is not based on clear wording of the statute, which did not include these separate terms. As a result, we request that the ICU definition in the proposed regulations be removed and replaced with the definition listed above and as further defined within the term "service" contained in 105 CMR 130.020 Subpart (B).

As the MHA and ONL representatives testified throughout the two hearings, our concern with amending the definition is based on the need to ensure that we can appropriately care for patients. Under the proposed regulation, the HPC inappropriately expanded the law to include services such as a CCU, burn unit, PICU, and NICU. These services are clearly not included in the ICU definition of "Service" within 105 CMR 130.020 subpart (B) that corresponds to language in the law and such application is beyond the scope of the HPC's authority.

We believe that the interpretation of the law by the HPC is legally incorrect because the NICU, PICU, CCU, and Burn Unit services are defined separately and distinctly from an ICU in the

DPH regulations. Therefore, the requirements of the proposed regulation cannot apply to these distinct services (NICU, PICU, CCU, Burn) under the language of Chapter 155.

- A CCU is not described or listed as an "ICU" within the definition of a "service" (contained in 105 CMR 130.020 Subpart (B)). Instead it is separately defined as a distinct licensed service (under the term "services" within 105 CMR 130.020 subpart (C)).
- The Burn Unit is not described or listed as an "ICU" within the definition of a "service" (contained in 105 CMR 130.020 Subpart (B)). Instead it is separately defined as a distinct licensed service (under the term "services" within 105 CMR 130.020 subpart (D)) and follows its own criteria for purposes of licensure and architectural design.
- A PICU is also not described or listed as an "ICU" within the definition of a "service" (contained in 105 CMR 130.020 Subpart (B)). Instead it is separately defined as a distinct licensed service (under the term "services" within 105 CMR 130.020 subpart (F)) and is further defined under its own regulation at 105 CMR 130.701.
- Similarly, a NICU is not described or listed as an "ICU" within the definition of a "service" (contained in 105 CMR 130.020 Subpart (B)). Instead it is separately defined as a distinct licensed service (under the term "services" within 105 CMR 130.020 subpart (G2)), it is further defined under 105 CMR 130.601, and it is separately regulated through 105 CMR 130.750. It is also important to note that unlike the ICU, the NICU requires a separate and distinct Determination of Need approval. Additionally, there is a separate Plan Review consideration to have a licensed NICU provided within a facility with a "Level III service."

Beyond our legal objections to applying Chapter 155 requirements to NICU, PICU, CCU, and Burn Units, from a clinical and patient need perspective of NICUs, you have heard from several nurse leaders during the hearings that there are only ten (10) NICUs statewide, and that these units treat a wide range of patients, not all of whom are actively critically ill, but who are placed in NICU-level care. Under DPH regulations, *only* a unit with a "Level III maternal and newborn service" or a unit within a "freestanding pediatric hospital with neonatology specialty services" is considered to be a NICU. However, following appropriate medical standards of care for newborns, most NICUs are structured to offer both level III (NICU) and level II (intermediate) care. Nurse leaders who testified at the hearings reiterated that varying factors influence patient placement decisions in the NICU, including anticipated and unanticipated deliveries, transports, and unavailable level II beds. There are a limited number of beds, nurses, and physicians available to care for NICU patients. Imposing strict acuity system standards and staffing ratios on these infants would likely result in NICUs being unable to accept urgently and emergently transferred patients who need NICU level care because of their staffing levels at that point in time. In addition, the NICU was designed to be able to care for both critically ill and non-critically ill babies to assist with various patient and family-focused reasons that differ from those in an adult ICU where patients are moved to a lower level of care once they are stable. If the proposed regulations are applied to a NICU, then the HPC will eliminate this flexibility for NICUs and diminish access to care that could result in harm to both infants and families.

We strongly believe that the HPC interpretation of applying the law to a NICU is incorrect, and there were several inaccurate comments made throughout the hearings about the care and treatment of newborns within a NICU. To refute those comments and to further demonstrate why the proposed regulation *should not* apply to NICUs for the wellbeing of patients and their

families, we offer the following examples that were also raised by the MHA and ONL panelists during the hearings:

- It is very difficult to predict patient volume in the NICU because of uncertainty around the time of patient admissions from multiple entry points that can include transfers from other hospitals, labor & delivery, and newborn nurseries. Potential admissions to NICUs are assessed regularly day and night, but many staffing decisions cannot be anticipated because there will always be deliveries and transports that are not predictable under any acuity system or tool. For example, a NICU could accept a transport for extracorporeal membrane oxygenation (ECMO), and less than 10 minutes after the team leaves to pick up the baby, the same NICU could receive a call from Labor & Delivery that a woman with 26-week twins came in to triage and would deliver within the hour. Once the infants are admitted, the assignments are assessed and patients reassigned. The resources to admit these infants require a reassignment of patients that requires flexibility, which the proposed regulations do not provide or consider.
- Staffing ratios would negatively impact patient care, safety, and outcomes for NICU infants in cases where the infant may need to be transferred due to ratios. For example, if a mother delivers her baby in a hospital outside the Boston area, the nearest alternative NICU may be a couple hours away. The NICU at the delivering hospital may ordinarily choose to keep the infant and adjust patient assignments to avoid separating the mother and infant. However, if there are strict NICU staffing requirements, the delivering hospital might not be able to accept another NICU admission and would be forced to transfer the infant. This would separate the baby from the mother, cause emotional stress, prevent breastfeeding that is shown to be healthiest for infants, and pose other health and wellness issues. If NICUs are forced to transfer infants to comply with nurse staffing ratios, this will lead to lower quality care for patients and families.
- Similar to the scenario above, and in contrast to the inaccurate comments made during the Boston hearing, it is very common to have multiple births from a single pregnancy that are admitted to a NICU, and it is very common that in a multiple birth, one infant is determined to be a level II patient while the other infant is a level III. In such cases, it is clinically appropriate and in the family's best interest to keep both infants together in the NICU, rather than separate them. ***Under the proposed regulation that defines a NICU as only providing care to critically ill patients, hospitals will be required to deny the admission of a non-critical (though in need of acute level care) newborn into the NICU, which could very well result in a transfer of the newborn with a higher level of need (but not necessarily a NICU service) to another hospital, separating families.***

Finally, you heard from several of the panelists that all NICUs have already adopted and are following a comprehensive, nationally-endorsed and infant-specific tool that determines staffing levels within the NICU. NICUs use the American Academy of Pediatrics Guidelines for Professional Registered Nurse Staffing for Perinatal Units written by the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN), and endorsed by the National Association of Neonatal Nurses (NANN), which differentiates level III (intensive) and level II (intermediate) care. These guidelines help determine patient assignments based on the level of care, family needs and skill level of the practicing nurse. To efficiently manage care with the limited number of NICU beds in the state, NICUs must have the flexibility to use an appropriate

acuity system based on existing and nationally endorsed perinatal guidelines. Clinicians, including staff nurses, must have the flexibility to use their clinical judgement and these guidelines to ensure those patients and their families receive the best care possible. Forcing NICUs to adopt an acuity tool that is better applied to an adult-based system, as outlined in the proposed regulations, will hinder the existing culture of collaboration and prevent ongoing assessment of patient needs and appropriate resource allocation within NICUs. Therefore, clinically and operationally, it is inappropriate to require NICUs to adopt and follow the acuity tool standards as outlined in the proposed regulations.

It should be noted that similar to arguments listed above, there are a more limited number of PICUs and Burn Units in the state. Our concerns with applying this law to PICUs are similar to those for NICUs. There are only 8 PICUs in the state located within 6 hospitals, which makes it difficult to plan for census surges in these units. Like NICUs, this law should not apply to PICUs because meeting a strict operational requirement will cause delays in patient care and denied admissions. If PICUs are required to staff in the manner outlined in the law at all times, this could also result in unnecessary transfers that could prevent critically ill children from accessing PICU services they desperately need.

Similarly, only 3 Massachusetts hospitals have an actual burn center verified by the American Burn Association. No other hospitals in New England have verified burn centers, so only 3 hospitals in the region have units equipped to treat burn patients, and one of those hospitals cares strictly for children. Like PICUs and NICUs, a comparatively small number of nurses have completed the more specialized training required to work in a burn unit, preventing hospitals from maintaining a sufficient number of alternate staff nurses to fill in during emergencies or times of high census. Given the fact that the burn unit is not listed as an ICU and that there are a limited number of burn units responsible for treating all severe burn patients in the entire region, forcing a strict and inflexible operational requirement on the state's burn units will create substantial patient flow problems and should not be applied under the HPC regulations.

Holding these limited but important resources to a restrictive standard would jeopardize patient care. ***Therefore, we request that the HPC replace their proposed definition with the legally correct definition that does not apply to NICUs, PICUs, CCUs, and Burn Units.***

Applicability (958 CMR 8.03)

Contrary to the clear language in M.G.L. Ch. 111, §231 that defines an ICU as a "unit physically and identifiably separate" from all other services, the proposed regulations erroneously apply the requirements to an ICU service *and* an ICU bed. Both the law and the DPH regulations provide standards for the ICU *service or unit*, and neither of these pertains to a specific *bed* type. The proposed regulations contradict the clear language of the law and ***we request that the HPC remove the term "ICU beds" as listed in this section 8.03***.

Staff Nurse Patient Assignment in the ICU (958 CMR 8.04)

MHA and ONL are very concerned with the wording of the proposed regulations. The law clearly provides, and was specifically drafted to state, that a patient assignment matches either one or two patients with a nurse who will care for this assignment for the duration of his or her

shift. A patient assignment does not require that all nurses be physically with a patient or patients "at all times." Each patient is unique and should be paired with a nurse according to the nurse's level of experience and the patient's care needs, which may include family care. While hospitals agree with the statutory requirement to provide care to one or two ICU patients per nurse, depending on each patient's condition, the law clearly does not require or mandate a standard of "at all times" and "at any time." The creation of these terms by the HPC promises to produce serious problems that did not exist in Chapter 155 as enacted by the Legislature. MHA and ONL were relieved to hear the HPC General Counsel state in a public full Commission meeting that the phrase "at all times" was not meant to convey the requirement that Chapter 155 ICU staffing was to apply during every moment, but rather to apply on every shift. However, that language was not subsequently removed from the proposed regulations. ***For these reasons, MHA and ONL request that the HPC remove the terms "at all times" in 8.04(1) and "at any time" in 8.04(2).***

The language of "at all times" and "at any time" does not appear in the statute for good reason, as it was neither intended, nor is it feasible. If the legislation was intended to include such significant language that brings with it profound consequences, the legislation would have included such language. The insertion of the "at all times" and "at any time" provisions exceeds the intent and requirements of Chapter 155, is inconsistent with sound clinical models of care, would force extraordinary costs on hospitals, and create unintended stress on other hospital units (such as emergency departments) in cases where the hospital may need to pull nursing staff from other units to meet the "at all times" or "at any time" provision, all without any proven benefit to patient care and have a potentially deleterious effect on the patient. The consequences may include diminished ICU capacity across the state, as well as limited access to other hospital services, delays in patient care and the needless transfer of patients who require intensive care to other hospitals. This is simply bad public policy that would entail higher costs, an increase in mandatory nurse overtime to cover staff absences due to the scenarios listed below and result in unnecessary confusion and/or chaos, as well as increased risks to safety for patients within ICUs and those in need of ICU access.

Throughout the public hearings on the proposed regulations, both staff nurses and nurse leaders have articulated that an inflexible model cannot be so rigidly applied at all times. The panelists all discussed how ICU patient conditions in general are not continuously unstable. At times, patients in ICUs only require intensive treatment using specialized equipment and nursing vigilance to monitor those that are at high risk for actual or potential life-threatening health problems. For example, a patient with newly instituted therapy, such as Bi-level Positive Airway Pressure (BIPAP) or Continuous Positive Airway Pressure (CPAP) therapy that requires continuous monitoring of oxygen levels and a breathing mask, warrants close observation and respiratory monitoring, but is otherwise stable.

As you have also heard throughout the hearings, ICU nurses are critical thinkers, highly skilled, able to prioritize, and can handle the unexpected. ICU nurses also participate in family care, which warrants dedicated time and communication. The voice of the nurse is essential in situations involving family meetings when new treatments or withdrawal of care must be discussed. The ICU nurses are generally part of the response team for codes and rapid response calls within the hospital. There are intervals during a shift when a nurse may have to bring a

patient to another unit for services, assist in a bedside procedure, assist with emergency transport of a patient, console a grieving family member away from the patient's bedside, and other circumstances that require a measure of flexibility in order to maintain sound, sustainable and sensible delivery of patient care. As a result, ICU nurse-patient assignments must be flexible to meet the needs of all patients and to address unexpected situations.

Within an ICU, there are times when one patient will require the assistance of multiple nurses. The addition of the "at all times" and "at any time" language would eliminate all flexibility, offers no benefit to patients, has no grounding in appropriate patient care, and is not evidence based. The re-direction of resources that would be required to comply with this inappropriately inserted language holds potentially dire consequences for other hospital units and patients, and would have significant negative impacts on access to other services.

The "at all times" and "at any time" requirements added to the proposed regulations are problematic for all acute hospitals and particularly for community hospitals. HPC should be aware of the comments made by many community hospital representatives. Specifically, community hospitals do not have the same resources as larger academic medical centers which would struggle under the proposed "at all times" and "at any time" requirements and it is critical that community hospital ICU nurses have the flexibility to monitor patients, but assist their colleagues during the many situations described above. However, if community hospitals are required to meet a strict standard as contained in the proposed regulations, it may prevent community hospitals from caring for patients in the communities where they live.

The main concern is that the "at all times" and "at any time" language would prohibit the collaborative practice between the whole care team that is necessary to provide high quality care for all patients in the ICU. Compartmentalizing ICU nursing care to 1:1 assignments "at all times" or "at any time" was not stated in the law, was not intended to be part of the law, and in fact, would negatively impact the ability to safely care for all ICU patients with adequate resources.

Development or Selection and Implementation of the Acuity Tool (958CMR 8.06 and 8.07)

Prior to commenting on the provisions within 8.06 and 8.07 for the development of an acuity tool, we would first request that the HPC revise the definition of an "Acuity Tool" as listed in 958 CMR 8.02 to reflect the applicable usage of the term "acuity tool" as articulated by national provider associations, as well as by local providers. The common definition used by peer groups for the term "acuity tool" is one that: "determines patient assignments by matching the level of patient need with appropriate nursing staff while accounting for the patient's physical, mental, and social considerations, as well as nurse expertise and experience; which then matches a nurse to a patient or patients for the duration of the shift for the provision of nursing care." This definition provides a better framework for the two sections in 8.06 and 8.07. ***We strongly urge the HPC to replace its proposed definition of an "acuity tool" with this language.***

In developing and implementing an acuity tool, hospitals consult with a variety of staff that often include staff nurses, nurse managers, nurse educators, nurse directors, chief nursing officers, vice presidents of patient care services, nurse practitioners, physicians, IT staff, and more. ***Therefore we support the language in 8.06(2)(a) that calls for an advisory committee to consult with key***

staff, including staff nurses. However we ask that this language be clarified to reflect that RNs who are part of the committee be limited to ICU nurses as they are the ones who will be directly affected and will be key to developing an acuity tool for the ICU area. It is also important to ensure that the advisory committee be made up of other staff within the hospital. Staff nurses would not have knowledge of IT infrastructure and interoperability with other systems the hospital is currently using, as well as the costs to apply the system to each ICU within a hospital. Having an advisory committee to review and make recommendations for the hospital to consider will be an important part of implementing this law and the final regulations.

We specifically request the removal of Section 8.06(3) in its entirety, which adopts a provision related to the conformance of the regulations with collective bargaining agreements. This language was not included or mentioned in the law. Further, it is language that is not focused on the care of the patient, but a provision that is clearly intended to reflect union contractual and financial concerns that were never the intent of the law. Without specific statutory requirements or consideration, it is not clear how the HPC can, on its own authority and interpretation, require a retroactive or proactive impairment of the contract rights of private parties. Therefore we request that this language be removed.

We would also request that the HPC eliminate sections 8.07(3) through 8.07(5) in their entirety. We have stressed in prior hearings and during the two public hearings on these proposed regulations that ICU staffing determinations are based on collective knowledge, not sole reliance on the acuity tool or diagnoses. Acuity tools inform patient assignment determinations, but other considerations such as the experience and skill level of the staff nurse, the complexity of a patient's condition, and additional physical, mental, and social factors such as family situations all play a role in ICU staffing decisions. The acuity system offers critical information which in complement with the decision-making and assessment skills of staff nurses and nurse managers would enable hospitals to make the best decisions for patient care.

In any well-functioning ICU, the acuity system must be able to quantify the patient care workload via a score or level that the charge nurse and staff nurses can translate into patient assignments for current and future shifts. Therefore, at its most basic level the system must be able to identify available staff, identify patient census, and score/level the patients. Further, and most importantly, it must be patient-centered, objective, valid, and reliable. While this may seem to be an easy task, nothing is simple in today's healthcare environment with increased patient and nursing practice complexity. In order for a hospital to meet the requirements, intent of the law and the proposed regulations, it must be allowed to create or select an acuity tool that can assist in differentiating between a single or double assignment status. Completion and utilization of the tool must be efficient and seamless to nursing practice. It must reflect the organization and patient population by supporting all types of critically ill patients, staff competency levels, and have a holistic methodology that includes physiological, psychosocial, education, and care coordination needs of patients. Most importantly the tool should not be burdensome to the nurse. By requiring or prescribing measurement of specific clinical indicators as detailed in 8.07 (4), the calculation of acuity for an organization that opts for a manual system will be extremely time consuming.

The key for a well-functioning ICU is to ensure that the resource nurses, staff nurses, and nurse managers collaborate frequently throughout the course of a day. Nurses, whether staff nurses or nurse managers, must be empowered to advocate for their patients and use clinical judgment to address the appropriateness of patient assignments. Staff nurses and nurse managers design a plan of care that addresses each patient's individual needs on a day-by-day, hour-by-hour, and even minute-by-minute basis, adjusting when the patient's condition changes. Therefore, the proposed regulations appropriately require that ***there is validity and reliability of the content used in the acuity tool. In other words, the acuity tool is attempting to track and measure information that is needed to arrive at a conclusion about a patient's health status to determine staffing.*** By mandating a fixed set of clinical indicators, the proposed regulations would end the flexibility and patient focus we have been asking the HPC to consider.

Records of Compliance (958 CMR 8.08)

We are very concerned with this section as 958 CMR 8.08 is not based on any objective standards tied to clinical need or practice. We are concerned with the overly broad provisions of this section, which could be read as requiring hospitals to document and maintain substantial information (emails, documents, correspondence, and other materials) related to the process of developing and implementing the acuity tool for a ten year period. While there is a precedent for maintaining reports or minutes from a formal group that is mandated by a statute, there is no precedent for such an administratively burdensome requirement over such a long period of time. To track and maintain information as required in the proposed regulations, hospitals would have to expend unreasonable and unnecessary costs and staff resources. For example, during any given year hospitals could experience changes in staffing, updates to information technology systems, updates to their systems from various vendors, and education/ retraining of staff that may lead to slight or substantial procedural changes in the acuity tool. Therefore, it is unrealistic and inappropriate to require a 10 year record retention process for the amount of information contained in 958 CMR 8.08(1). The impact on smaller community hospitals that may not have staff resources to accomplish all that is laid out in this proposed regulation must be considered as well. ***We would request that subsections (a) through (d) be removed; and that instead, hospital(s) be required solely to maintain any reports or minutes from the advisory committee, available upon request by the Department, for a period not to exceed three years.*** Our proposed three year period of time would give the Department sufficient time to review documentation.

We also have similar concerns with the documentation of staffing compliance in 958 CMR 8.08(2). For the same reasons listed above, there is no requirement in the law for developing or maintaining the results of each patient assessment under the acuity tool. In FY2013, there were over 434,800 patient days spent in ICUs in Massachusetts hospitals. As drafted, the proposed regulations would require every hospital to expend substantial administrative time and costs to document and maintain the individual assessment of each patient each day that they are in the ICU for 10 years, which was never intended under the law. Further, this type of a mandate goes against the goals of Massachusetts healthcare reform and the Health Policy Commission, which are to lower costs and require streamlined administrative procedures. The HPC has stated that the acuity tool can be a manual one. These details and exhaustive criteria would clearly eliminate the manual acuity tool option at a time when not all hospitals are in the position to purchase an electronic platform. ***Therefore, we urge the HPC to remove 8.08(2) in its entirety.***

Acuity Tool Certification (958 CMR 8.09)

It is not possible for a hospital to convene a multi-disciplinary group to review the final regulations, consider the vendors and types of tools that are available, consider the patient characteristics of each ICU, receive staff input on the tool, work with the hospital's information technology system to ensure the tool is compatible, test the tool within the system and with staff, consider ways to measure the acuity tool's effectiveness, and finalize a tool to be submitted for certification no later than October 1, 2015.

Regardless of the system that is chosen, either electronic or manual, the MHA and ONL panelists have consistently noted that these are complex tools to implement. Either type of tool will require a team to complete a market scan to identify tools that fit their environment and needs. There will need to be a process for requesting proposals from different companies to narrow the choices and select an option. Hospitals must then submit and get approval for budget allocation for purchasing, development, testing, validation, training, implementation, and maintenance costs. Contrary to the comments made during the Worcester hearing, it is not simple for a hospital to just reach out to a vendor and choose a tool that can be readily adopted in a hospital. While there are several tools that a hospital can review if an electronic acuity tool is selected, this will require system integration and interoperability via interfaces and mapping for staffing, human resources, and electronic health record solutions. Any decision must be made in the context of understanding an organization's IT infrastructure, financial resources, and available and required expertise. Without this consideration, it will not be possible to quickly and adequately review and develop an acuity tool for DPH review/certification in such a limited time frame. ***Instead, we urge the HPC to provide that any process should occur no earlier than the start of the next hospital fiscal year on October 1, 2016.***

Public Reporting on Nurse Staffing Compliance (958 CMR 8.10)

We urge the HPC to remove 8.10(2) entirely and revise 8.10(1) to reflect an annual reporting requirement that can be done through the DPH Health Care Facility Reporting System. The law provides for a single method of reporting staffing compliance. The proposed regulations, however, outline two redundant and duplicative reporting systems (reporting to DPH and on the hospital website). This duplicative process will add costs and increase staff time, adding no apparent value. Also, quarterly reporting would require developing a substantial reporting and verification system of each unit's data. Further, the proposed regulations ask for details on *any* instance that a hospital does not meet the ratios under the regulations. This level of detail was not stated in the law, and could lead to considerable confusion and misinterpretation.

We urge the state to work with the provider community to develop a streamlined process, using existing reporting systems (such as those developed and reported through the *PatientCareLink* website). There are reporting systems currently in place that would take less time and cost less that would meet the goal of the law.

Collection and Reporting of Quality Measures (958 CMR 8.11)

We commend the HPC for issuing four proposed quality measures that we feel will focus on patient outcomes and allow for the development of quality improvement initiatives. If adopted,

the state will be able to develop a system that is based on nationally accepted, valid, and reliable patient quality and safety indicators. As stated in our prior testimony, hospitals can carry out sound patient care using these measures and analyze benchmarks against national and statewide norms to ensure we are constantly considering ways to improve or enhance daily provided care. From an operational perspective, hospitals and state agencies can easily adopt three out of the four proposed measures in the ICU setting with minimal costs and time, but with maximum benefits.

As we have cautioned in previous testimony, any proposed additional measures that are not based on nationally accepted standards and not focused on quality outcomes would take considerable time and resources for the state and providers to adopt and report. This would include developing the reporting framework, ensuring uniform and standardized agreement on the definitions, and developing the outcome measurements for public reporting. Therefore we support the four measures with one request for a technical clarification.

We request that the proposed measure "Patient Fall Rate" be changed to "Patient Falls with Injury" as listed in the National Quality Forum approved measure (#202). Without relating to the injury level of minor or greater, the applicability to an ICU setting for quality outcome purposes is tenuous at best. Without this proposed change, providers will be limited in developing a uniform reporting metric to provide national and state based comparisons. We urge the HPC to clarify the last measure as patient falls with injury.

In response to a suggestion made during the Worcester hearing that hospitals should further track extra measures in addition to those that they will be required to report under this law, we ask that the HPC consider that hospitals already collect information on hundreds of indicators. Requiring additional indicators within the ICU, along with other indicators that are already collected was not included in the statue, and more importantly, it would divert scarce resources from the bedside to increased administrative functions.

The HPC should further consider a nationally endorsed reporting framework, aimed at advancing a shared agenda for quality improvement, reducing onerous and duplicative reporting requirements, and minimizing confusion for the public and providers. Currently hospitals report Pressure Ulcer Prevalence and Patient Falls with Injury to *PatientCareLink*, and CLABSI and CAUTI through the National Healthcare Safety Network (NHSN) under the MA DPH reporting requirement. ***To alleviate the administrative burdens and possible duplication, we urge the state to work with MHA and ONL to adopt the same reporting process and measures from PatientCareLink into the DPH Health Care Facility Reporting System (HCFRS).*** Please note that similar measures can have different definitions and calculation methodologies, and standardizing the measures based on the current reporting system within *PatientCareLink* would minimize this concern.

Nurse Staffing Plan (958 CMR 8.12)

This section should be removed as it extends beyond the plain language of the law. Other provisions of the proposed regulations already provide for public reporting on staffing compliance and require development of a reporting tool. Additional reporting would only add costs to the system.

Implementation Time Line (958 CMR 8.13)

For reasons stated above addressed by MHA and ONL panelists during public hearings, the HPC regulations must allow for an appropriate phase-in period for compliance with the law. This includes choosing, developing or purchasing, and implementing an acuity tool. It is not operationally feasible for a hospital to immediately choose and adopt an acuity tool given the prescribed process required by the proposed regulations.

Additionally, the proposed regulations would be finalized mid-budget year for the majority of hospitals. Therefore, it is not fair nor reasonable to assume that a facility can develop and purchase the external system, cover the costs and time for IT vendors to test and update internal systems to adopt the final tool, and deploy the necessary staff to test and determine the applicability of any final tools. We urge the HPC to provide at least a one year period to develop the final tool and submit it for the Department to certify. Further, there needs to be additional time after certification for the facilities to adopt the tool and train all staff. ***Therefore we urge the HPC to allow for a process that includes certification by October 1, 2016 and implementation at an appropriate time thereafter.***