



TO: Health Policy Commission

FROM: Donna Kelly Williams, RN and President, Massachusetts Nurses Association

RE: Proposed regulations 958 CMR 8.00 Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Hospitals

DATE: April 13, 2015

The attached document contains the changes to the proposed regulations which the Massachusetts Nurses Association (MNA) believes reflect the intent of the law and agreement reached with the MNA to withdraw two ballot questions in exchange both for the explicit language as well as the passage of the law.

Beyond some simple housekeeping edit/suggestions, these changes fall into several general categories

- 1) A 1:1 patient limit standard. The clear intent that the assignment of an ICU patient is one to one except in limited circumstances where the patients' condition is stable enough for the nurse to be responsible for a second ICU patient.**

The foundation of the compromise law, the intent of the Legislature and the MNA's decision to withdraw the two ballot questions was grounded in a 1:1 patient limit as the standard. During the negotiations that created this law in exchange for the withdrawal of the ballot questions, several variations were offered – and rejected. Those variations included the concept of no more than two with a tool to staff up. In the end, the law was fashioned after the ballot question - the assignment shall be 1:1 or 1:2 if the patient is stable enough. This was deemed acceptable to assure a second patient would only be assigned when the patient assessed is stable enough to do so. Any regulations promulgated to reverse this agreement directly undermine the intent of the language negotiated and agreed upon.

This 1:1 patient limit standard was clearly the legislative intent as noted by the attached transcript of the floor debate.

The assessment of such patient condition brings us to the second area of changes;

- 2) The assessment by the staff nurses (plural) in the ICU.** That discussion was purposeful. During the negotiations we discussed that the nurses function as a team and

the assignments accepted by the nurses reflect that team effort. That assessment of the patients by the staff nurses in the ICU, the experts, was to be further supported by an acuity tool.

Only where a disagreement existed by the staff nurses (plural) and/or the tool was a manager or designee to be involved. It was readily acknowledged that managers are not present due to their work hours as well as their work often has them off the unit. The law clearly states that the assessment shall be done “by the staff nurses in the unit”. Any deviations from this must be corrected in the final regulations to reflect what is in the law.

This brings us to the third area of concern;

- 3) **Involvement of the nurse manager and non-nurses in the determination of an assignment which under the nurse practice act is ultimately a decision of the individual nurse whether he or she accepts or rejects an assignment.** This is why the law expressly excludes language indicating it is the manager’s discretion in making the final determination. The nurse managers are involved when there is a dispute to help resolve it, but in the final analysis, the individual licensed nurse must make the final determination whether he or she accepts an assignment. What the consequences of the nurse’s decision are as an employee is a different matter than his/her right and obligations under the nurse practice act whether he or she will accept the patient assignment.
- 4) **Creation of the Acuity Tool.** Similarly the creation of the acuity tool is to assist the assessment process, not to act as a managerial substitute for the professional judgment of the registered nurses. In order to assure this, the makeup of the Committee must have direct care ICU staff nurses working with management to formulate the tool. The direct care ICU staff nurses cannot be just a minority representative to a management process that historically has resulted in staffing tools masked as acuity tools whose ultimate function is to retrofit data to achieve budget limitations or goals.

Indeed there will be variations in patients and the nurses caring for those patients and of the facilities in which the patients have been admitted, but in the final analysis a fresh post op AAA (ascending aortic aneurysm) patient should be 1:1 no matter what nurse, what hospital. If the regulations for the formulation of an acuity tool allow a hospital to pursue such a patient as a 1:2, which we believe the regulations as proposed would do, then we will have failed the patients and the ICU law that seeks to assure a standard for patients in spite of the health care chaos around them.

- 5) **Required elements of the acuity tool.** In the proposed regulations, there is a list of indicators pertaining to “Staff Nurse workload associated with caring for the ICU Patient appropriate to the ICU Patient population in the ICU”. We believe that “behavioral

health and substance abuse” should be added to the list, as well as all the critical environmental factors listed in Section 8.06.

A further area of concern is centered on documentation and transparency.

- 6) **Transparency for patients, the public and nurses** means that the patient assessment carried out under these regulations should be included in the patient record. Any information recorded in an acuity tool developed in accordance with the ICU staffing law should be considered an extension of the staff nurse’s documentation and part of the patient’s record. This will ensure that any information recorded by the staff nurse as part of the patient assessment is not able to be altered by anyone else. Any disagreement between the staff nurses on the unit and the nurse manager about the nurse-to-patient assignment that results in a change from the staff nurse recommended nurse-to-patient assignment should also be recorded as part of the patient’s record. This is good patient practice as well as a mechanism of enforcement by allowing disclosure for people to question the industry.

Finally, we applaud the Health Policy Commission for including language explicitly stating that the limits established under this law are in effect at all times. The law does not provide for any exceptions.

We deeply appreciate the work of the HPC. We are aware of the challenge of getting this “right.” The MNA, as the primary organization moving this law forward to protect patients, shares your desire for and commitment to that outcome. We will continue to work with you to achieve the right regulations, understanding that any one of us or our loved ones will likely be directly impacted by the law and the regulations implementing the law.

Should you have any questions regarding this testimony, or the changes proposed in the attached document, please do not hesitate to contact me.

PROPOSED REGULATION
Approved by HPC Quality Improvement and Patient Protection Committee
1-6-15

| 958 CMR 8.00: REGISTERED NURSE-TO-PATIENT RATIO-LIMIT IN INTENSIVE CARE UNITS
IN ACUTE HOSPITALS

Section

- 8.01: General Provisions
- 8.02: Definitions
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8.01: General Provisions

| Scope and Purpose: 958 CMR 8.00 governs the implementation of M.G.L. c. 111, §231, which establishes a Registered Nurse-to-patient ~~ratio-limit of one-to-one or one-to-two~~ in Intensive Care Units in Acute Hospitals licensed by the Massachusetts Department of Public Health and in hospitals operated by the Commonwealth of Massachusetts.

8.02: Definitions

As used in 958 CMR 8.00 the following words mean:

Acute Hospital. The teaching hospital of the University of Massachusetts Medical School, any hospital licensed by the Department of Public Health pursuant to M.G.L. c. 111, § 51 or hospital operated by the Commonwealth, and which contains a majority of medical-surgical, pediatric, obstetric, and maternity beds as defined by the Department.

Acuity Tool. A decision support tool using a method for assessing patient stability for the ICU Patient according to a defined set of indicators, and used in the determination of a Patient Assignment.

Commission. The Health Policy Commission established in M.G.L. c. 6D.

Department. The Massachusetts Department of Public Health established in M.G.L. c. 111.

Intensive Care Unit (“ICU”). 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 the 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, and licensed by the Department, including coronary care unit, burn unit, pediatric intensive care unit and neonatal intensive care unit, as defined in 105 CMR 130.020, however named by the Acute Hospital; and an ICU service or beds in a hospital operated by the Commonwealth.

ICU Patient. A patient occupying a bed in an ICU.

Nurse Manager. A nurse with management responsibility for nursing services for the ICU.

Patient Assignment. The assignment of a Staff Nurse to care for ~~one or two specified~~ ICU Patient(s)-~~for a Shift~~, consistent with the education, experience and demonstrated competence of the Staff Nurse, the needs of the ICU Patient, and the requirements of 958 CMR 8.00.

Registered Nurse. A nurse who meets the criteria for licensure under M.G.L. c. 112, § 74 and 244 CMR 8.00, and who holds a valid license from the Massachusetts Board of Registration in Nursing to engage in the practice of nursing in Massachusetts as a Registered Nurse.

Staff Nurse. A Registered Nurse providing direct patient care in an ICU who is not a Nurse Manager.

~~Shift. A designated period of work time within the ICU.~~

Acuity Tool Committee. A group of staff nurses and other staff to work in consultation with the acute care hospital on the development/selection and implementation of the acuity tool, which shall be composed of at least 50 percent Registered Nurses who are direct care ICU staff nurses, representatives of nursing management, and other appropriate ancillary and medical staff.

8.03: Applicability

958 CMR 8.00 applies to Acute Hospitals licensed by the Department to provide ICU service(s) or with licensed ICU beds, and to hospitals operated by the Commonwealth and authorized to provide ICU service(s) or with ICU beds.

8.04: Staff Nurse Patient Assignment in Intensive Care Units

- (1) In all ICUs, the Patient Assignment for each ICU Staff 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 at all times, one or two ICU Patients at all times during a Shift.
- (2) The maximum Patient Assignment for each Staff Nurse may not exceed two ICU Patients at any time ~~during a Shift.~~
- (3) Nothing in 958 CMR 8.00 prohibits a Patient Assignment of more than one Staff Nurse for an ICU Patient.

8.05: Assessment of Patient Stability and Determination of Patient Assignment

- (1) For purposes of determining ~~a~~ Patient Assignment, the Staff Nurse assigned to care for the ICU Patient shall assess the stability of the ICU Patient utilizing:
 - (a) The exercise of sound nursing assessment and judgment within the parameters of the Staff Nurse's continuing education and experience. The Acuity Tool developed or selected by the Acute Hospital and certified by the Department, pursuant to 958 CMR 8.00; and
 - (b) The Acuity Tool developed or selected by the Acute Hospital and certified by the Department, pursuant to 958 CMR 8.00.~~The exercise of sound nursing assessment and judgment within the parameters of the Staff Nurse's continuing education and experience.~~
- (2) If the Staff Nurse assigned to care for the ICU Patients in the ICU determines within the exercise and scope of sound nursing assessment and judgment within the parameters of the Staff Nurse's Nurses' continuing education and experience that the ICU Patient's Patients' stability requires a different Registered Nurse-to-patient ratio-limit than that indicated by the Acuity Tool, the Nurse Manager or the Nurse Manager's designee shall be consulted to assist in resolve-resolving the disagreement between the Acuity Tool and the Staff Nurse's Nurses' assessment, ~~in consultation as appropriate with the other Staff Nurses on the unit and taking into account critical environmental factors such as nursing skill mix and patient census on the unit, and shall determine the appropriate Patient Assignment.~~
- (3) The Staff Nurse assigned to care for the ICU Patient shall assess the stability of the ICU Patient using the Acuity Tool at a minimum:
 - (a) Upon the ICU Patient's Patients' admission or transfer to the ICU;
 - (b) Once ~~during a Shift~~every four hours; and
 - (c) When a substantial event or change in a patient's condition or treatment occurs;
 - (d) At other intervals or circumstances as specified in the Acute Hospital's policies and procedures established pursuant to 958 CMR 8.07(6).
 - (e) The Staff Nurses' assessment of the patient and resulting patient assignment shall be documented by the Staff Nurse in the patient's record, as will instances when there is a disagreement between the Staff Nurses' assessment and the Acuity Tool.

8.06: Development or Selection and Implementation of the Acuity Tool

(1) Each Acute Hospital shall develop or select an Acuity Tool for each ICU that meets the requirements of 958 CMR 8.00, in order to:

(a) Support the determination of whether each ICU Patient requires care by ~~one or more~~ Registered Nurses, ~~and or by a Registered Nurse assigned to care for no more than two ICU Patients; and~~ when a patient is sufficiently stable to no longer require 1:1 care by a Registered Nurse.

(b) Address the unique care needs and circumstances of the patient population in and physical environment of each ICU at the Acute Hospital.

(2) Each Acute Hospital shall develop, implement and document the process for development or selection and implementation of the Acuity Tool to be deployed in each ICU, which shall include but not be limited to the following required elements:

(a) Formation of ~~an advisory~~ a committee ~~to make recommendations to work in consultation with~~ the Acute Hospital on the development or selection and implementation of the Acuity Tool, which committee shall be composed of at least 50 percent Registered Nurses ~~who are not Nurse Managers, who are direct care ICU Staff Nurses, a majority of whom are Staff Nurses, and other members selected by the hospital including but not limited to~~ representatives of nursing management, and other appropriate ancillary and medical staff. Where members of the committee are represented by a certified collective bargaining agent, the collective bargaining agent will be responsible for the selection of members to the committee.;

(b) A process for the ~~advisory~~ committee to address ~~and make recommendations on~~ the elements of the Acuity Tool and other considerations for its implementation including but not limited to the following:

1. The presence of defined set of indicators to be ~~assessed~~ identified by the Acuity Tool, including clinical indicators of patient stability and other indicators of Staff Nurse workload as set forth in 8.07(4) that would allow the safe assignment of a second patient by a nurse.;

2. ~~Scores to be assigned to each indicator~~ The Acuity Tool shall identify the presence of each indicator.;

3. ~~How scores are tabulated and used in the determination of whether each ICU Patient requires care by one or more Staff Nurses, or by a Staff Nurse assigned to care for no more than two ICU Patients; and~~ Indicators present are tabulated and used in the determination of whether each ICU Patient requires care by one or more Staff Nurses, or when a patient is sufficiently stable to no longer require 1:1 care.

4. Critical environmental factors relevant to the particular ICU and that may affect the ability of ICU Staff Nurses to care for ~~one or two~~ a second ICU Patients that should be addressed in the selection or development of the Acuity Tool, such as:

(i) Physical environment of the unit, including visibility of patient/monitoring equipment;

(ii) Nursing skill mix, competency and familiarity with the ICU;

(iii) Availability of patient care equipment and technology; and

(iv) Availability of ancillary and support staff in the ICU (e.g., pharmacist, IV team/respiratory therapist, nurse practitioner, clinical nurse specialist, physician assistant, unit secretary, sitters, aides/technicians, staff to operate patient care equipment and technology, patient transport services, travel team/coverage);

(v) Availability of an integrated electronic documentation system:

- (c) A process for ICU Staff Nurses and Nurse Managers to test, validate and ~~recommend-adopt~~ any revision to the Acuity Tool prior to implementation;
 - (d) A process for the Acute Hospital to address and respond to ~~recommendations of the the advisory~~ committee regarding the selection, development or revision of the Acuity Tool pursuant to 958 CMR 8.06;
 - (e) Development and implementation of policies and procedures for assessment of patient stability and determination of the appropriate Patient Assignment in any ICU in the Acute Hospital, consistent with the requirements of 958 CMR 8.00; and
 - (f) A process for periodic review and evaluation of the implementation of the Acuity Tool, which at a minimum, shall be conducted annually by the committee.
- (3) Nothing in 958 CMR 8.06 shall restrict or limit any additional obligation of an Acute Hospital to bargain with a labor organization under applicable law, regulation or collective bargaining agreement.

8.07: Required Elements of the Acuity Tool

Each Acute Hospital shall develop or select an Acuity Tool that meets the following minimum requirements:

- (1) The Acuity Tool shall be in writing either in electronic or hardcopy format;
- (2) The Acuity Tool shall be tailored to the unique care needs and circumstances of the patient population in any ICU in which the Acuity Tool is deployed;
- (3) The Acuity Tool shall include a method for ~~scoring~~ defining clinical indicators of patient stability and other indicators of Staff Nurse workload as required in 8.07 (4)(a) and (b); and
- (4) The Acuity Tool shall include a defined set of indicators incorporating:
 - (a) Clinical Indicators of Patient Stability related to physiological status and clinical complexity and related scheduled procedures, medications and therapeutic supports appropriate to the ICU Patient population in the ICU in which the Acuity Tool will be deployed in clinical domains ~~such as~~ which include but are not limited to:

1. Respiratory;
2. Cardiac;
3. Surgical;
4. Neurological;
5. Gastrointestinal;
6. Skin; [Integument](#)
7. Orthopedic;
8. Reproductive;
9. Hematologic;
10. Renal;
11. Metabolic/endocrine;
12. Immune;

[13. Behavioral health/substance abuse;](#) and

(b) Other indicators of [ICU](#) Staff Nurse workload associated with caring for the ICU Patient appropriate to the ICU Patient population in the ICU in which the Acuity Tool will be deployed such as:

1. Patient age, including gestational age as applicable, and cognitive/functional ability;
2. Patient and family communication skills and cultural/linguistic characteristics;
3. Need for patient and family education;
4. Family and other support for the patient;
5. Need for care coordination; and
6. Transitional care and discharge planning required for the patient.

[\(c\) Critical environment factors defined but not limited to Section 4 iv.](#)

(5) The Acute Hospital shall develop written policies and procedures specifying how the resulting Acuity Tool score will be used to support the determination that the ICU Patient requires care by one or more Staff Nurses, or by a Staff Nurse assigned to care for no more than two ICU Patients; and

(6) Other requirements as may be specified in guidance of the Commission.

8.08: Records of Compliance

(1) Development or Selection of Acuity Tool(s). Each Acute Hospital shall document, ~~and~~ retain the Acuity Tool as part of the patient's medical record for a minimum period of ten (10) years and provide to the Department and the Commission upon request, the process it followed for development or selection of the Acuity Tool required by 958 CMR 8.06(2), including but not limited to:

(a) Membership of the ~~advisory~~ committee including name and title;

(b) The rationale for selection or development of ~~an the~~ Acuity Tool ~~including how the Acute Hospital addressed recommendations of the advisory committee and the decision to include or exclude certain clinical indicators of ICU Patient stability and other related indicators of Staff Nurse workload, and how critical environmental factors in 958 CMR 8.06 (2)(b)4 were taken into account in the selection and the method for scoring of the indicators;~~—

(c) Written policies and procedures regarding the implementation of the Acuity Tool required in 958 CMR 8.07(5); and

(d) The process for validating and periodically evaluating the use of the Acuity Tool in each ICU in the Acute Hospital.

(2) Records of Staffing Compliance. Each Acute Hospital shall document and retain for a minimum period of ten (10) years records indicating the results of the assessment of ICU Patient stability and determination of Patient Assignment for each ICU Patient.

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

(1) Each Acute Hospital shall submit the Acuity Tool for each ICU to the Department for certification prior to implementation and periodically as determined by the Department;

~~(2) The Department shall determine whether the Acuity Tool(s) was developed or selected by the Acute Hospital in accordance with the procedures and requirements of 958 CMR 8.00; and—~~

~~(3)~~(2) Acute Hospitals shall comply with the procedures for certification and enforcement as established by the Department through a public process which includes a public hearing.

8.10: Public Reporting on Nurse Staffing Compliance

(1) Each Acute Hospital shall report to the Department, at least quarterly and in the form and manner specified by the Department:

(a) Reports of Staff Nurse-to-patient ratios-limits by ICU; and

(b) Any instance and the reason in which the minimum Staff Nurse to patient ratio of one to two was not maintained by the Acute Hospital. Reporting shall include times where there is a disagreement over the appropriateness of the patient assignment.

(2) Each Acute Hospital shall issue reports quarterly to the public on Staff Nurse-to-patient ratios-limits by ICU on the Acute Hospital's website, and as may be specified in guidance of the Commission.

(3) A copy of the law must be posted and clearly visible in each ICU family waiting area and on the Acute Hospital website. The posting shall include a method for patient/patient advocate/family member to question the determination of acuity and patient assignment.

8.11: Collection and Reporting of Quality Measures

Each Acute Hospital shall:

(1) Report ICU-related quality measures to the Department, as specified in guidance of the Commission;

(2) Report the specified quality measures to the Department, at least annually every 6 months, and in the form and manner specified by the Department; and

(3) Issue reports to the public on the specified quality measures for each ICU, at least annually, on the Acute Hospital's website, and as may be specified in guidance of the Commission.

8.12: Development of ICU Staffing Plan

Each Acute Hospital shall develop and implement a Registered Nurse staffing plan for the ICU in which the Acuity Tool is deployed that incorporates data gathered from implementation of the Acuity Tool.

8.13: Implementation Timeline

Each Acute Hospital shall submit an Acuity Tool for each ICU to the Department for certification no later than October 1, 2015.

8.14: Severability

If any section or portion of 958 CMR 8.00 or the applicability thereof is held invalid or unconstitutional by any court of competent jurisdiction, the remainder of 958 CMR 8.00 or applicability thereof to other persons, entities, or circumstances shall not thereby be affected.

REGULATORY AUTHORITY

958 CMR 8.00: MGL c. 111, § 231.



Statement from the Massachusetts Nurses Association regarding Quality Indicators to be used as a Measurement of Improved ICU Staffing.

Thank you for the opportunity to represent the interests of our ICU bedside nurses and their patients regarding the development of regulations concerning **quality measures** in the proposed regulations 958 CMR 8.00 Registered Nurse-to-Patient Ratio in Intensive Care Units in Acute Hospitals

The Massachusetts Nurses association strongly recommends the use of outcome indicators that have been shown to most strongly reflect ICU staffing and which have been validated on a national level. For the effectiveness of the new acuity ICU staffing standards to be measured accurately in the Commonwealth, the focus must be on outcomes for which the research has demonstrated the most robust statistically significant link to higher staffing levels.

MNA strongly recommends **two indicators- catheter associated urinary tract infections, and patient falls with injury.**

“Patient falls with injury” is a nurse sensitive measure nationally validated by the National Quality Forum (NQF) and Massachusetts hospitals. Because there is no publicly available data for patient falls without injury in Massachusetts hospitals, we cannot evaluate whether research exists to establish a significant correlation with falls to nurse staffing. We strongly suggest that the HPC substitute “falls with injury” for the proposed “ falls without injury” as one of the 5 patient quality indicators.

We also endorse the inclusion of **adult in-patient self-report of pain control and death among surgical patients (failure to rescue).**

Adult self report of pain quality and control is a quality indicator and nationally validated by the Centers for Medicare and Medicaid services. Pain management is often an indicator in ICUs associated with a nurse’s response to patients and a clinical quality measure. Research shows that a patient’s perception of pain control is a robust, statistically significant indicator associated with nurse staffing in Massachusetts hospital ICU’s. Higher percentages of patient’s pain control contribute to faster recovery due to their ability to participate in their care.

Death among Surgical patients with serious but treatable complications (failure to rescue) is also a Patient Safety indicator included in the Hospital Inpatient Quality Reporting Program and nationally validated by AHRQ. (Agency for Health Quality and Research) The indicator measures how often patients died after developing a complication that high quality hospitals identify quickly and treat aggressively. Several serious treatable complications of care listed in death among surgical patients are ones statistically associated with improved nurse staffing, such as pneumonia, deep vein thrombosis/ pulmonary embolism, sepsis, shock/cardiac arrest.

The MNA does not support the inclusion of **CLABSI** (central line-associated blood stream infection) as only a specially qualified group of nurses insert peripheral central catheters and although careful nursing management, such as dressing changes, can help to reduce infections, we do not believe that of the measures available to the Health Policy Commission, this is one that presents one of the stronger correlations between proper ICU staffing and outcomes.

The MNA does not support the inclusion of pressure ulcers, although more frequent nursing intervention can help prevent certain instances of pressure ulceration, there is not a statistically significant correlation with RN staffing in Massachusetts. Skin breakdown can occur due to a number of reasons beyond the control of the nurse and it would be misleading to use pressure ulcers as a measure of the value of improved RN staffing.

In summary MNA recommends the following as the four quality indicators

CAUTI (Catheter Associated UTI), patient falls with injury, pain control, and death among surgical patients (failure to rescue) and does not endorse CLABSI, pressure ulcers or patient falls without injury.