The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
99 Chauncy Street, Boston, MA 02111

CHARLES D. BAKER
Governor

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Lieutenant Governor

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Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

Circular Letter: DHCQ16-9-661

TO: Chief Executive Officers, Acute Care Hospitals

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

SUBJECT: UPDATED Guidelines for Certification of Acuity Tools pursuant to 958 CMR 8.00, "Patient Assignment Limits for Registered Nurses in Intensive Care Units in Acute Hospitals"

DATE: September 30, 2016

This Circular Letter updates Circular Letter 15-11-647, issued November 24, 2015, by reiterating the deadlines for certifications of Acuity Tools for Neonatal Intensive Care Units (NICUs) and all Acute Care Hospitals that are not academic medical centers, and reporting on the certification of ICU Acuity Tools for all academic medical center ICUs (except for NICUs).

Background

On June 30, 2014, Chapter 155 of the Acts of 2014, An Act relative to patient limits in all hospital intensive care units, was signed into law, creating Section 231 of Chapter 111 of the General Laws. This section establishes patient assignment limits in Acute Care Hospital (ACH) Intensive Care Units (ICU). The law became effective on September 28, 2014, charging the Health Policy Commission (HPC) with promulgating regulations governing the implementation and operation of the law.

On June 10, 2015, the HPC Board approved 958 CMR 8.00 (Attachment B), a regulation outlining the requirements for nurse staffing in ACH ICUs.

The regulations require the Department of Public Health (DPH) to:

- Establish requirements for the certification of ACH Acuity Tools (958 CMR 8.09).

- Certify the Acuity Tools for each ICU no later than (958 CMR 8.12):
    - March 31, 2016: For each ACH that is an academic medical center, excluding their NICUs; or
    - January 31, 2017: For all other ACHs, and NICUs in academic medical centers.
- Specify the form and manner for ACHs to report staff nurse-to-patient ratios by ICU to DPH, which each ACH shall subsequently post on its website or as specified by the HPC (958 CMR 8.10).
- At its discretion, request an ACH to provide DPH its records regarding the development or selection of its Acuity Tool (958 CMR 8.08(1)).

The regulation outlines the requirements that an ACH must adhere to when staffing its ICUs, including the following:

- In all ICUs, the patient assignment for each staff nurse shall be one or two ICU patients, depending on the stability of the ICU Patient, as assessed pursuant to 958 CMR 8.05.
- The maximum patient assignment for each staff nurse may not exceed two ICU Patients.
- Each ACH shall develop or select an Acuity Tool for each ICU that meets the requirements of the regulation in order to:
    - Support the determination of whether an 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
    - Address the unique care needs and circumstances of the patient population in, and physical environment of, each ICU at the ACH.
- Each ACH shall establish and document the process for development or selection of the Acuity Tool to be deployed in each ICU. The written records related to the development or selection of the Acuity Tool shall be retained by the Hospital for a minimum of 10 years and be provided to DPH and HPC upon request.
- Each ACH shall develop written policies and procedures for the implementation of the Acuity Tool to be deployed in each ICU.

<u>Definition of ICU</u>

958 CMR 8.02 includes defined terms such as “Intensive Care Unit”, “Indicators of staff nurse Workload”, and “Clinical Indicators of Patient Stability”. The definition of Intensive Care Unit refers to existing DPH and Federal regulations, stating that the unit,

> "…meets the Medicare requirements in 42 CFR 413.53(d) for intensive care type inpatient hospital units, licensed by the Department, and shall include intensive care unit, coronary care unit, burn unit, pediatric intensive care unit and neonatal intensive care unit, as defined in 105 CMR 130.020: Definitions, however named by the Acute Hospital, and any such unit in a hospital operated by the Commonwealth."

Therefore, even if a hospital does not refer to a specific unit as an "ICU", if it is licensed by DPH as such, it is subject to this regulation as an ICU.

Certification of Acuity Tools

DPH is responsible for certifying each Acuity Tool and hospital compliance (958 CMR 8.09). Specifically, the regulation states that the Acuity Tool must meet 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 the ICU in which the Acuity Tool is deployed;

3) The Acuity Tool shall include a method for scoring a defined set of indicators, which shall include Clinical Indicators of Patient Stability and other Indicators of staff nurse Workload; and

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

DPH has established a process by which to determine each ACH's compliance with these minimum requirements. As of March 31, 2016, the Department certified ICU Acuity Tools for all ICUs (except for neonatal ICUs (NICU)) at each of the ACHs that are academic medical centers. All other ACHs and ACHs that are academic medical centers and have NICUs must comply with the Department's certification process and requirements for each ICU Acuity Tool by the dates below:

1) Each ACH that is an academic medical center must comply with certification requirements for each **NICU** by no later than **January 31, 2017**.

2) All other ACHs must comply with certification requirements for each ICU by no later than **January 31, 2017**.

To comply with the requirements of the regulation, DPH has developed a "Certification Checklist" (Attachment A) that will be used when evaluating each Acuity Tool.

When a hospital submits its proposed Acuity Tool, it will be reviewed by the Bureau of Health Care Safety and Quality (Bureau) according to the Certification Checklist. After its first review, the Bureau may provide an ACH the opportunity to refine and/or enhance its Acuity Tool and

resubmit it for final review, prior to certification. The following process and timeline for submission, review and certification of Acuity Tools will be utilized:

September 30, 2016
– Additional DPH guidance issued for Acuity Tools of academic medical center NICUs and all other ACH ICUs.
October 1, 2016
– Academic medical centers may submit Acuity Tools for all NICUs; and
– All other ACHs may submit Acuity Tools for all ICUs.
November 30, 2016
– First review of Acuity Tools complete; resubmission begins.
December 31, 2016
– Final review of Acuity Tools begins.
January 31, 2017
– Complete certification of all ICU Acuity Tools.

Submission of Acuity Tools

All ACHs must submit an Acuity Tool for each of their ICUs, as defined in 958 CMR 8.00, by reference to 42 CFR 413.53(d), and 105 CMR 130.020. An Acuity Tool must be submitted to DPH as a scanned document or file that is attached using the Health Care Facility Reporting System (HCFRS). Submissions should select the report type as "ICU Staffing Report".

Waivers from these requirements are not available.

ACH Reporting of Staff Nurse-to-Patient Ratios

As of September 28, 2014, the effective date of Section 231 of Chapter 111 of the General Laws, ACHs are required to report staff nurse-to-patient ratios by ICU to DPH, in the form and manner specified by DPH. The following guidance clarifies this reporting requirement.

Beginning April 1, 2016, each ACH must submit a quarterly report through HCFRS using the report type code "ICU Staffing Report". This report must include the following information for each licensed ICU operated by the ACH in the prior quarter: (1) the average daily patient census; (2) the average daily staff nurse census; and (3) the average daily staff nurse-to-patient ratio, which is found by dividing (1) the average daily patient census, by (2) the average daily staff nurse census.

- For example: If an ICU maintains a daily average of 5 staff nurses and 5 patients (a 1:1 daily staff nurse-to-patient ratio) for half of the days between January 1, 2016 and March 31, 2015, and maintains a daily average of 5 nurses and 10 patients (a 1:2 daily staff nurse-to-patient ratio) for the other half of those days, the following would be reported as the average daily totals for the quarter:
    - average daily patient census – 7.5
    - average daily staff nurse census – 5
    - average daily staff nurse-to-patient ratio – 1:1.5

These reports must be made available on the ACH's website within 7 days of reporting to DPH, and must be maintained on the website for 3 years from submission.

Please note, for reporting purposes, a patient occupying a bed in an ICU, must be included in the average daily patient census as an ICU patient, even if the patient does not require intensive care and occupies the bed for reasons other than intensive care needs.

Complaint Review

If the Bureau's Complaint Unit receives complaints on the utilization of a hospital's Acuity Tool and corresponding staffing levels, the Bureau has the authority to investigate that complaint. During this investigation, the Bureau would review the hospital's Acuity Tool and documentation related to usage of the Acuity Tool as part of the investigation process. If the documentation indicates that the hospital has failed to comply with its statutory obligations or has failed to provide appropriate care to its patients, the Bureau has the authority to take action against the hospital's license.

If you have any questions about this guidance, please contact the Bureau of Health Care Safety and Quality, Division of Health Care Facility Licensure and Certification, at sherman.lohnes@state.ma.us.

ATTACHMENT A

ICU Nurse Staffing Acuity Tool Certification Checklist

1) Is the Acuity Tool in writing, either in electronic or hardcopy format?

   a. Yes _____ No_____

   b. If yes, what format: Electronic_____ Hardcopy_____

2) Does the Acuity Tool include a method for scoring a defined set of indicators, which shall include Clinical Indicators of Patient Stability and other Indicators of Staff Nurse Workload?

   a. Yes_____ No_____

   b. What type of ICU is the Acuity Tool going to be used in?
   _____ (print ICU type)

   c. If yes, does it include Clinical Indicators of Patient Stability, as defined in regulation? Yes_____ No_____

   If yes, which indicators are included, as defined in regulation:
   1. Physiological status Yes_____ No_____

   2. Clinical complexity Yes_____ No_____

   3. Related scheduled procedures Yes_____ No_____

   4. Medications and therapeutic supports appropriate to the ICU Patient population in the ICU in which the Acuity Tool will be deployed. Yes_____ No_____

   d. If yes, does it include other Indicators of Staff Nurse Workload, as defined in regulation? Yes_____ No_____

   If yes, which indicators are included, as defined in regulation:
   1. Patient age, including gestational age as applicable, and cognitive/functional ability. Yes_____ No_____

   2. Patient and family communication skills and cultural/linguistic characteristics.
   Yes_____ No_____

   3. Need for patient and family education. Yes_____ No_____

   4. Family and other support for the patient. Yes_____ No_____

   5. Need for care coordination. Yes_____ No_____

   6. Transitional care and discharge planning required for the patient. Yes_____ No_____

   e. If yes, does it include Critical Environmental Factors, as defined in regulation? Yes_____ No_____

   If yes, which indicators are included, as defined in regulation:
   1. Physical environment of the ICU. Yes_____ No_____

   2. Nursing skill mix, competency and familiarity with the ICU. Yes_____ No_____

   3. Availability of patient care equipment and technology. Yes_____ No_____

   4. Availability of medical, ancillary and support staff in the ICU. Yes_____ No_____

3) Based on the information provided in sections 1 and 2, is the Acuity Tool tailored to the unique care needs and circumstances of the patient population in the ICU? Yes_____ No_____

ATTACHMENT B

958 CMR 8.00: PATIENT ASSIGNMENT LIMITS FOR REGISTERED NURSES IN INTENSIVE CARE UNITS IN ACUTE HOSPITALS

Section
8.01: General Provisions
8.02: Definitions
8.03: Applicability
8.04: Staff Nurse Patient Assignment in Intensive Care Units
8.05: Assessment of Patient Stability
8.06: Development or Selection and Implementation of the Acuity Tool
8.07: Required Elements of the Acuity Tool
8.08: Records of Compliance
8.09: Acuity Tool Certification and Compliance
8.10: Public Reporting on Nurse Staffing Compliance
8.11: Collection and Reporting of Quality Measures
8.12: Certification Timeline
8.13: Severability

8.01: General Provisions

Scope and Purpose. 958 CMR 8.00 governs the implementation of M.G.L. c. 111, § 231, which establishes Patient Assignment limits for Registered Nurses in Intensive Care Units in Acute Hospitals licensed by the Massachusetts Department of Public Health and in hospitals operated by the Commonwealth of Massachusetts, including the process for selecting or developing the Acuity Tool and required elements of the Acuity Tool.

8.02: Definitions

As used in 958 CMR 8.00 the following words mean:
Acuity Tool. A decision support tool using a method for assessing patient stability for the ICU Patient according to a defined set of indicators (including Clinical Indicators of Patient Stability and Indicators of Staff Nurse Workload), and used in the determination of a Patient Assignment.

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.

Clinical Indicators of Patient Stability. Indicators of ICU Patient stability related to the 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.

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

Critical Environmental Factors. Factors relevant to the particular ICU in which the Acuity Tool will be deployed that may affect the ability of Staff Nurses to care for one or two ICU Patients, such as: physical environment of the ICU, including visibility of patient/monitoring equipment; nursing skill mix, competency and familiarity with the ICU; availability of patient care equipment and technology; and availability of medical,

ancillary and support staff in the ICU (e.g., physician, 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).

Department. The Massachusetts Department of Public Health established in M.G.L. c. 17, § 1.

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

Indicators of Staff Nurse Workload. Indicators of 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: patient age, including gestational age as applicable, and cognitive/functional ability; patient and family communication skills and cultural/linguistic characteristics; need for patient and family education; family and other support for the patient; need for care coordination; transitional care and discharge planning required for the patient.

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 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, licensed by the Department, and shall include intensive care unit, coronary care unit, burn unit, pediatric intensive care unit and neonatal intensive care unit, as defined in 105 CMR 130.020: Definitions, however named by the Acute Hospital, and any such unit in a hospital operated by the Commonwealth.

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

Patient Assignment
. The assignment of a Staff Nurse to care for specified ICU Patient(s), consistent with the education, experience and demonstrated competence of the Staff Nurse, the needs of the ICU Patient(s), 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:

Licensure Requirements, 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.

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

Staff Nurse. A Registered Nurse providing direct patient care in an ICU.

8.03: Applicability

958 CMR 8.00 applies to Acute Hospitals licensed by the Department to provide service(s) in ICUs, as defined in 958 CMR 8.02, and to hospitals operated by the Commonwealth and authorized to provide ICU service(s).

8.04: Staff Nurse Patient Assignment in Intensive Care Units

(1) In all ICUs, the Patient Assignment for each Staff Nurse shall be one or two ICU Patients depending on the stability of the ICU Patient as assessed pursuant to 958 CMR 8.05.

(2) The maximum Patient Assignment for each Staff Nurse may not exceed two ICU Patients.

(3) Nothing in 958 CMR 8.00 prohibits the assignment of more than one Staff Nurse to an ICU Patient.

8.05: Assessment of Patient Stability

(1) For purposes of implementing 958 CMR 8.04, the Staff Nurse assessing 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; and

(b) The Acuity Tool developed or selected by the Acute Hospital and certified by the Department, pursuant to 958 CMR 8.00.

(2) If the Staff Nurse assessing the ICU Patient determines within the exercise and scope of sound nursing assessment and judgment within the parameters of the Staff Nurse's continuing education and experience that the ICU Patient's stability requires a different Staff Nurse-to-patient ratio than that indicated by the Acuity Tool, the Nurse Manager or the Nurse Manager's designee shall resolve the disagreement between the Acuity Tool and the Staff Nurse's assessment, in consultation as appropriate with the other Staff Nurses in the ICU and taking into account nursing skill mix and patient census in the ICU and other Critical Environmental Factors, and shall determine the appropriate Patient Assignment.

(3) The Staff Nurse assessing the ICU Patient shall assess the stability of the ICU Patient using the Acuity Tool at a minimum:

(a) Upon the ICU Patient's admission or transfer to the ICU;

(b) Once during a Shift; and

(c) At other intervals or circumstances as specified in the Acute Hospital's policies and procedures established pursuant to 958 CMR 8.06(3)(a).

(4) Nothing in 958 CMR 8.05 shall limit the application of relevant state or federal law to Registered Nurses, including M.G.L. c. 112, § 80B, 244 CMR 3.00: Registered Nurse and Licensed Practical Nurse, and 244 CMR 9.00: Standards of Conduct.

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 Staff Nurses, or by a Staff Nurse assigned to care for no more than two ICU Patients; and

(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 establish and document the process for development or selection 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 committee to make recommendations to the Acute Hospital on the development or selection and use of the Acuity Tool to be deployed in each ICU, which committee shall be composed of at least 50% Staff Nurses in the ICU in which the Acuity Tool will be deployed who are not Nurse Managers, together with other members selected by the Acute Hospital including but not limited to representatives of nursing management, and other appropriate ancillary and medical staff;

(b) A process for the advisory committee to make recommendations on the required elements of the Acuity Tool as set forth in 958 CMR 8.07 and other considerations for the use of the Acuity Tool including but not limited to the following:

1. The defined set of indicators to be assessed by the Acuity Tool, including Clinical Indicators of Patient Stability and other Indicators of Staff Nurse Workload;

2. A method for scoring the defined set of indicators and 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

3. Critical Environmental Factors.

(c) A process for Staff Nurses to participate in the testing of, validation of and recommendations for revision to the Acuity Tool prior to implementation; and

(d) A process for the Acute Hospital to address and respond to recommendations of the advisory committee regarding the selection or development and use of the Acuity Tool pursuant to 958 CMR 8.06.
(3) Each Acute Hospital shall develop written policies and procedures for implementation of the Acuity Tool to be deployed in each ICU, which shall include but not be limited to:

(a) Assessment of patient stability and how the resulting Acuity Tool score will be used to support the determination of the appropriate Patient Assignment in the ICU, consistent with the requirements of 958 CMR 8.00; and

(b) Periodic review and evaluation of the implementation of the Acuity Tool.

(4) Within the requirements of 958 CMR 8.06, nothing shall prevent an Acute Hospital with multiple ICUs from seeking administrative efficiency in the development or selection of Acuity Tools by, for example, duplicating non-Staff Nurse members selected by the Acute Hospital pursuant to 958 CMR 8.06(2)(a) on advisory committees or considering a common format or platform for Acuity Tools used in the Acute Hospital.

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 the ICU in which the Acuity Tool is deployed;

(3) The Acuity Tool shall include a method for scoring a defined set of indicators, which shall include Clinical Indicators of Patient Stability and other Indicators of Staff Nurse Workload; and

(4) 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, retain for a minimum period of ten years and provide to the Department and the Commission upon request, the following records related to the development or selection of the Acuity Tool required by 958 CMR 8.06(2):

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

(b) Minutes from meetings of the advisory committee; and

(c) The Acute Hospital's rationale for selection or development of 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 Patient Stability and other related Indicators of Staff Nurse Workload, and how Critical Environmental Factors in 958 CMR 8.06(2)(b)3 were taken into account in the selection and the method for scoring of the indicators.
(2) Staffing Compliance. Each Acute Hospital shall document and retain for a minimum period of ten years the results of the assessment of ICU Patient stability for each ICU Patient and Patient Assignment pursuant to 958 CMR 8.04 and 8.05.

8.09: Acuity Tool Certification and Compliance
Acute Hospitals shall comply with the requirements for certification of an Acuity Tool and compliance with M.G.L. c. 111, § 231 and 958 CMR 8.00, as established by the Department.

8.10: Public Reporting on Nurse Staffing Compliance

(1) Each Acute Hospital shall report to the Department, in the form and manner specified by the Department, reports of Staff Nurse-to-patient ratios by ICU; and

(2) Each Acute Hospital shall post the reports provided to the Department pursuant to 958 CMR 8.10(1) on the Acute Hospital's website, or as may be specified in guidance of the Commission.

8.11: Collection and Reporting of Quality Measures
Each Acute Hospital shall:

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

(2) Report the quality measures for each ICU to the Department in the form and manner specified by the Department; and

(3) Post the reports provided to the Department pursuant to 958 CMR 8.11(2) on the Acute Hospital's website, or as may be specified in guidance of the Commission.

8.12: Certification Timeline

Each Acute Hospital shall comply with the requirements of the Department for certification of an Acuity Tool for each ICU by the dates in 958 CMR 8.12(1) and (2), or as may be otherwise specified in the Department's requirements for certification:

(1) Each Acute Hospital that is an academic medical center, as the term is used by the Center for Health Information and Analysis, shall comply with the requirements of the Department for certification of an Acuity Tool for each neonatal intensive care unit no later than January 31, 2017, and for all other ICUs no later than March 31, 2016.

(2) All other Acute Hospitals shall comply with the requirements of the Department for certification of an Acuity Tool for each ICU no later than January 31, 2017.

8.13: 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.