

**MINUTES OF THE QUALITY IMPROVEMENT AND PATIENT PROTECTION
COMMITTEE**

Meeting of May 20, 2015

MASSACHUSETTS HEALTH POLICY COMMISSION

**THE QUALITY IMPROVEMENT AND PATIENT PROTECTION COMMITTEE OF THE
MASSACHUSETTS HEALTH POLICY COMMISSION
HEALTH POLICY COMMISSION
50 MILK STREET, 8TH FLOOR
BOSTON, MA 02114**

Docket: Wednesday, May 20, 2015 9:30-11:00 AM

PROCEEDINGS

The Massachusetts Health Policy Commission's Quality Improvement and Patient Protection (QIPP) Committee held a meeting on Wednesday, May 20, 2015 at the Health Policy Commission, 50 Milk Street, 8th Floor, Boston, MA 02109.

Committee members present were Dr. Wendy Everett (Acting Chair); Mr. Martin Cohen; Ms. Veronica Turner; Dr. Carole Allen; and Ms. Alice Moore, designee for Ms. Marylou Sudders, Secretary of Health and Human Services.

Dr. Everett reviewed the day's agenda. She stated that the Committee would discuss both the proposed updates to Office of Patient Protection regulations and the recommended final regulation for nurse staffing ratios in intensive care units (ICUs).

Item 1: Approval of minutes

Dr. Everett asked for any changes to the meeting minutes from March 4, 2015. Seeing none, she made a motion to approve the minutes. Ms. Turner seconded the motion. The motion passed with five votes in the affirmative.

Item 2: Discussion of proposed updates to the Office of Patient Protection Regulations

Ms. Jenifer Bosco, Director of the Office of Patient Protection (OPP), presented proposed updates to OPP regulations. She noted that these proposed updates would ensure consistency with recent changes to Massachusetts law and further consumer protection. Ms. Bosco noted that she would review the changes to both regulations.

First, Ms. Bosco discussed changes to 958 CMR 3.00. She stated that this regulation governs health insurance claims for consumers. Ms. Bosco noted that there were inconsistencies between the provisions around medical necessity criteria in Chapter 224 and those in state law. She stated that the proposed updates to the OPP regulation would clarify expanded access to proprietary and non-proprietary medical necessity criteria.

Ms. Bosco then reviewed changes to 958 CMR 4.00, which governs open enrollment waivers. She noted that these updates are required to ensure that the regulation conforms

with the Affordable Care Act (ACA) and Massachusetts law. Ms. Bosco noted that the most significant change is to the definition of an eligible individual. She reiterated that the proposed updates would not significantly change the waiver process.

Ms. Bosco provided a summary of the proposed changes to the medical necessity criteria regulation. She highlighted that the change would clarify that the non-proprietary criteria should be accessible to the public, while proprietary criteria should be disclosed to insurers, prospective insurers and their health care providers. She continued to say that the requester must identify particular treatments and services that relate to the criteria.

Ms. Bosco presented a summary of the proposed changes to the open enrollment waiver regulation. She stated that a few definitions changed to ensure consistency with the ACA and Massachusetts law.

Ms. Bosco reviewed the timeline for amending the regulations. She stated that the HPC would hold a public hearing on July 8, 2015 and accept public comment through August.

Dr. Everett asked the Committee for a motion to approve and advance the proposed regulations to the full Commission. Dr. Allen made the motion. Dr. Everett seconded. Four Committee members voted in the affirmative. There were no votes in opposition or abstention.

Item 3: Discussion of recommended final regulation for the nurse staffing ratios in intensive care units

Dr. Everett thanked stakeholders and members of the public for their input as the HPC drafted a regulation governing nurse staffing in hospital ICUs. She stated that the HPC has come to a resolution on a majority of the issues, but will further discuss the definition of an ICU.

Mr. Seltz thanked everyone who has engaged with the HPC in this process and introduced Ms. Lois Johnson, General Counsel.

Ms. Johnson presented the HPC's final recommended regulation governing nurse staffing ratios. She presented the arc of the regulatory development process. She stated that the HPC has prioritized extensive stakeholder engagement throughout the process with significant outreach to and input from hospitals, nurses, experts, the Department of Public Health (DPH), and others.

Ms. Johnson stated that over 225 people attended either the Boston or Worcester public hearing on the regulation. She noted that forty-five people testified at the hearings and an additional 48 submitted written comment. She stated that these comments focused on the acuity tool, the definition of ICU, the timeline for certification, the role and composition of the advisory committee, and patient assignment.

Ms. Johnson discussed key HPC considerations when developing the final regulation. She said that the recommended final regulation attempts to balance the statutory goal of safe patient-centered care with the flexibility necessary for hospitals to address unique circumstances affecting each ICU. For that reason, the regulation establishes guidelines for the selection and development of the appropriate acuity tool.

Ms. Johnson spoke of the importance of the ICU nurse in the ICU care team, and highlighted the role of the ICU nurse in the implementation of this law.

Ms. Johnson reviewed the HPC's consideration of administrative burden, most notably, hospital reporting obligations. She said that the final regulation would require reasonable reporting and record keeping to support compliance to minimize burden, where possible.

Finally, Ms. Johnson described the role of DPH in the implementation of the law. She said that, as the HPC developed the final recommended regulation, staff and commissioners were mindful of the companion role of DPH.

Ms. Johnson stated that, following public input, the HPC changed the name of the regulation from "Registered Nurse-to-Patient Ratio in Intensive Care Units" to "Patient Assignment Limits for Registered Nurses in Intensive Care Units."

Ms. Johnson stated that the HPC received much comment on whether the law required a default nurse to patient ratio of 1:1 or 1:2. She reiterated that the ratio in the final recommended regulation is 1:1 or 1:2, depending on the stability of the patient. She further emphasized that the ratio is a unit wide ratio.

Ms. Johnson addressed concerns about the language "at all times" in the regulation. She stated that the HPC removed this language to allow for the day-to-day implementation of the law to be addressed at the hospital and unit level.

When describing the assessment of patient stability, Ms. Johnson stated that the regulation charges the nurse to use the acuity tool and his or her own judgement. She also said that, based on comments by the nurses, the HPC added a reference to other relevant laws governing nurses.

Ms. Johnson stated that the HPC did not change the nurse manager's role in resolving a disagreement between the acuity tool and the staff nurse's assessment of patient stability. She also stated that the HPC did not change the frequency of assessments, adding that more frequent assessments may be required by certain hospitals.

Ms. Kate McCann, HPC Associate Counsel, reviewed the HPC's recommendations on the advisory committee and acuity tool. She noted that the regulation requires that the advisory committee include at least 50% direct care staff nurses working in ICUs where the acuity tool will be deployed. She also stated that hospitals must have representation from each ICU in which they plan to use the acuity tool.

Ms. McCann reviewed clarifying edits to the required elements of the acuity tool. She noted that these edits reflect the intent to allow flexibility in acuity tool design for each ICU.

Ms. McCann addressed the administrative burden of the records retention requirements regarding acuity tool development. She also stated that, based on consultation with DPH, the HPC did not recommend amending the 10 year retention requirement.

Dr. Everett asked for clarification on whether the 10 year retention was a DPH requirement. Ms. McCann responded that it was DPH's recommendation for this regulation.

Ms. McCann reviewed clarifying edits to record requirements for staffing compliance. She stated that the HPC does not recommend specifying the results of the acuity assessment in the patient record. She added that acute hospitals should maintain the flexibility to determine the appropriate documentation and retention, as long as it is consistent with state and federal law regarding personally identifiable health information.

Ms. McCann stated that the HPC's regulation provides DPH with flexibility to develop its certification and compliance requirements.

Ms. Lisa Snellings, HPC Assistant General Counsel, discussed specific quality measures identified by stakeholders. She noted that the HPC wanted to ensure that the quality measures are evidence-based, standardized, validated, nationally accepted, and measureable. Ms. Snellings stated that the HPC considered quality measures that are currently reported in Massachusetts hospitals and the extent to which those measures are collected. She stated that the HPC also considered whether the quality measures are nursing sensitive and how they would apply across ICUs.

Ms. Snellings stated that, from the 11 quality measures initially identified, four were proposed for further public comment at the March 4 QIPP meeting. The measures were (1) catheter associated urinary tract infection - CAUTI, (2) central line associated blood stream infection - CLABSI, (3) all patient falls with and without injury, and (4) hospital acquired pressure ulcers.

Ms. Snellings stated that a majority of stakeholders agreed with CAUTI, CLABSI, and hospital-acquired pressure ulcers. Stakeholders believed that including only patient falls with injury was a more sensitive quality measurement.

Ms. Johnson stated that the section requiring hospitals to create a staffing plan, based on the implementation of the acuity tool and compliance with staffing requirements, had been recommended for removal because it was unnecessary based on other compliance obligations in the regulation.

Ms. Johnson outlined the recommendation for a change in the timeline for acuity tool certification by DPH, with academic medical centers complying with certification requirements by March 31, 2016 and all other hospitals complying with certification

requirements by September 30, 2016. She also recognized the need for DPH input on the timeline because of its companion role in developing the certification procedures.

Ms. Turner asked a clarifying question about the language regarding ancillary staff, which Ms. Johnson answered by indicating location in the regulation.

Mr. Cohen asked about DPH's ability to actually enforce these standards. Ms. Johnson said that the HPC has had conversations with DPH and will allow them to have flexibility in the manner in which they choose to enforce.

Dr. Everett spoke about moving these regulations forward to the full Commission and having the full Commission discuss a final definition for ICU.

Item 4: Discussion of final definition of Intensive Care Unit

Ms. Johnson stated that the definition of ICU in the regulation references the definition section in the DPH hospital licensure regulation. The term ICU is defined in the services section along with specialty ICUs, including coronary care unit (CCU), pediatric intensive care unit (PICU), neonatal intensive care unit (NICU), and burn unit. Ms. Johnson went on to state that the definition in the HPC's regulation was consistent with the definition in the DPH hospital licensure regulation and included CCU, PICU, NICU, and burn unit.

Ms. Johnson said that hospital groups were opposed on legal grounds to the inclusion of CCU, PICU, NICU and burn units because they said such units are separately defined in the services section of the DPH licensure regulation. She continued to say that hospital groups also were opposed on policy and operational grounds to the inclusion of NICUs, arguing that the application would adversely affect the quality of care for neonates. She said that hospital groups argued that due to the unpredictability of volume, some NICUs may not be able to accept emergency transfer patients, or it could result in the separation of mothers from babies.

Ms. Johnson further said that hospital groups voiced similar concerns about why the law should not apply to PICUs, but did not include any clinical, operational, or patient need justifications for the exclusion of CCUs.

She said that other commenters disputed the narrow interpretation of the applicability of the law, saying that the legislation's title was intended to cover all ICUs and noting that the law contains no exceptions or otherwise indicates that it should only apply to adult ICUs.

Ms. Johnson said that HPC staff does recommend further discussion of the definition among the QIPP Committee and at the full Commission meeting. She continued to say that the definition of ICU directly impacts the implementation of this law.

Dr. Everett said that the three areas to consider when determining a definition of ICU are (1) legal, (2) operational issues for the hospitals and the nurses, and (3) Governor Baker and Secretary Lepore's concerns about cost implication.

Ms. Turner asked about the difference in the definitions of ICU, CCU, and NICU in DPH's hospital licensure regulation. Ms. Johnson answered by saying the statute refers to a section of DPH regulation that governs hospital licensure. She continued by saying that in that section of the regulation there is a list of services, one being ICU, which might be read as a broad definition. She added that there are also separate definitions of NICU, PICU, CCU, and burn unit. NICU and PICU have more specific definitions that were added to another section of the regulation at a later date. She continued to say that while a NICU, PICU, CCU and burn unit have separate definitions, they all either have ICU in the name or ICU in the definition.

Ms. Alice Moore said that by nature NICU, PICU, CCU and burn units are ICUs. She continued to say that the law may not be applicable to all units, but reaffirmed that they are all ICUs. She said that separating out specific units may be a difficult task.

Dr. Carole Allen said that it is important to keep the patient perspective in mind when determining the definition of ICU. She said that the law must be careful not to create undue burden or affect good processes already in place. She continued to say that she is most concerned about NICUs because, as a pediatrician, she did not see how NICUs can fit into this regulation. She added that American Academy of Pediatrics and ACOG have already defined the standard level of care, and to override it would be presumptuous and potentially dangerous. She concluded that the regulation should exclude NICUs until there is more experience with ICUs in general.

Mr. Cohen questioned whether the word "all" used in the regulation was meant to mean all adult ICUs or all ICUs. He included that he worried if one unit was excluded, there could be a cascading effect.

Ms. Johnson said that NICUs already have a 1 to 2 ratio for critically ill patients and imposing that unit wide is where worries of increased cost come from. She added that multiple birth babies may be put in an NICU, but each may not be critically ill.

ITEM 5: Vote to Continue Discussion of the Definition of ICU

Ms. Turner made a motion to approve and advance the final regulation to the board for further discussion of the definition of ICUs. Undersecretary Moore seconded the motion. Four members voted in the affirmative. There was one abstention.

ITEM 6: Adjournment

Dr. Everett adjourned the meeting at 12:26PM.