INDEX to the video/audio from QIPP 5/20/15 :

0:00:00 Intro by Chair, Dr. Wendy Everett – attendees: Veronica Turner of SEIU 1199, Undersecretary of HHS Alice Moore (designee for Marylou Sudders), Martin Cohen CEO of Metro West Foundation, Dr. Carole Allen, David Seltz Executive Director of HPC, Lois Johnson HPC Counsel.

3:06 Start of Committee discussion of Final Regulations – reveals that

4:50 Wendy reveals they have not come to a resolution of what is the definition of an Intensive Care Unit

6:00 David Seltz – housekeeping and gratitude and thanks – introduces Lois Johnson, General Counsel, Kate McCann and Lisa Snellings also counsels with HPC

7:58 Lois Johnson begins her presentation on the regulations – pages numbers refer to slide presentation -- http://www.mass.gov/anf/docs/hpc/quipp/20150520-qipp-may-20-presentation.pdf

9:20 pages 13, 14 Arc of regulatory development process

11:13 Frames discussion – key considerations include Recognition of Hospital/ICU Differences,

Role of ICU Staff Nurses, Consideration of Administrative Burden, Role of DPH

Will not be "overly prescriptive" about acuity tools, "meaningful opportunity" for staff ICU nurses, "seeks to minimize burden where possible", "companion role of DPH – will oversee staffing compliance", and "excluding issues not specifically addressed in the statute"

13:55 – page 16 – 958 CMR 8.00 – change of title to "patient assignment limits…" also mentions moved definitions of clinical indicators, indicators of workload, and critical environmental factors to definition section 8.02

15:18 – page 17 – 8.04 -- One of the areas of comment, that we received, was whether the law requires the regulation to incorporate a default nurse to patient ratio of one to one -- that is the assignment of one nurse to one patient. The statute states that 'the patient assignment for the registered nurse shall be one to one or one to two depending on the stability of the patient'. We received several comments asserting that this language was intended to require a default one to one staffing assignment, with a one to two assignment only permitted where the patient is stable enough upon assessment to require less intensive nursing care. We do not recommend a change to the regulation on this point. The regulation does reflect the statutory language of one to one or one to two and does not otherwise require acute care hospitals to implement a default nursing assignment of one nurse to one patient in ICUs. That said, a one to one ratio should result in appropriate circumstances based on the assessment of patient stability with the staff nurse and the acuity tool. Nothing in the regulation would prohibit a hospital from implementing a tool that uses one to one as a baseline staffing approach in a given ICU with particularly higher acuity patients or particular environmental factors that warrant it."

16:50 – page 18 – the statue "clearly requires" unit-wide applicability of the staffing limit requirements

18:4 page 19 -- Application of Limit “at all times” and “at any time” –8.04, “it was not intended to impose unreasonable requirements that impede daily dynamic patient care workflow in the ICU and accordingly, we do recommend removing the language “at all times during a shift” or “at any time during a shift” from the regulation. This will allow the day-to-day implementation of the law’s requirements to be addressed at the hospital and unit level. Expectations for break coverage, for example, can be addressed in the hospitals’ policies and procedures and implementation of this law. DPH may also consider issuing guidance on this issue, especially for how hospitals might, as a practical matter, assure compliance while addressing this particular issue.”

21:11 page 20 – Assessment of Patient Stability y –8.05(1)

25:40 page 21 -- Assessment of Patient Stability – 8.05(2) – what happens if there is a disagreement in the assessment of patient stability

25:15 page 23 – Frequency of Patient Assessment – 8.05(3)

26:50 Kate McCann – page 24 - Development or Selection and Implementation of the Acuity Tool -- “The statute precludes the HPC from recommending a change to the advisory nature of the committee. However, based on extensive public comments, and to reinforce the role of the staff nurses in the selection or development of the acuity tool, we do recommend amending the composition of the to include at least 50% direct care staff nurses working in the ICU in which the acuity tool will be deployed.”

29:50 – page 25 – Required Elements of the Acuity Tool –8.07

31:27 – pages 26, 27 -- Records of Compliance for Certification Purposes –8.08(1) and (2)

34:50 – page 28 -- Acuity Tool Certification and Compliance -- 8.09 – giving flexibility to DPH

35:26 – page 29 -- Public Reporting on Nurse Staffing Compliance –8.10 – removed requirement of detailed report of each instance of a violation, did not add a requirement to notify patients or post the law in waiting rooms, “as that is outside the regulatory scope.”

37:01 – page 30 -- Collection and Reporting of Quality Measures –8.11

38:10 – Lisa Snellings -- page 31-- Identification of Quality Measures -- 8.11 --The HPC recommends the following four quality measures:

(1) CLABSI – NQF #0139
(2) CAUTI – NQF #0138
(3) Pressure Ulcers – NQF #0201; and
(4) Patient Falls with Injury – NQF #0202

41:34 – Lois Johnson -- page 32 -- Certification Timeline -- 8.12

- Academic medical centers (as the term is used by CHIA) must comply with DPH's requirements for certification of Acuity Tools by March 31, 2016, or as otherwise specified in DPH's requirements for certification
- All other Acute Hospitals must comply with DPH's requirements for certification of Acuity Tools by September 30, 2016, or as otherwise specified in DPH's requirements for certification

CHIA lists only six hospitals as Academic Medical Centers: Beth Israel Deaconess Medical Center, Boston Medical Center, Brigham and Women's Hospital, Massachusetts General Hospital, Tufts Medical Center and UMass Memorial Medical Center – CHIA definition: "AMCs are a subset of teaching hospitals. AMCs are characterized by (1) extensive research and teaching programs and (2) extensive resources for tertiary and quaternary care, and are (3) principal teaching hospitals for their respective medical schools and (4) full service hospitals with case mix intensity greater than 5% above the statewide average." http://chiamass.gov/massachusetts-acute-hospital-cohort-profiles/#cohortlist

43:45 Wendy Everett – asks commissioners if they have questions for Lois, Kate, or Lisa…

44:27 Carole Allen – particularly glad that the "at all times" language was removed as it "was bothering me right from the get go"

46:14 Veronica Turner – Asks Lois about the deletion of the environmental factors, specifically other support staff… Lois answers that intent was not to delete, but rather to move that into 8.02 as a defined term. (But readers should note that the HPC has segregated the Critical Environmental Factors from the required scoring of the acuity tool 8.07 (3). But 8.08 (1) (c) includes a requirement of reporting "how Critical Environmental Factors… were taken into account in the selection and method for scoring of the indicators." This is confusing and unhelpful.)

47:30 Alice Moore thanks staff and chair for changes that are "a nice way of balancing the very different interests here."

48:18 Martin Cohen gives commends staff and then asks "Have we had discussion with DPH about their ability to actually enforce these standards?" Lois Johnson answers that they want to "maximize deference to DPH as to how it will effectuate that". Alice Moore, the law clearly gives the department certification and compliance…

49:48 Wendy Everett – page 33, 34 – as part of the motion to approve and advance final regulation the committee with recommend further discussion of the definition of "intensive care units" – we will discuss but not make a final decision…

51:30 – page 20 -- Definition of Intensive Care Unit – 8.02

51:51 – Lois Johnson – gives framework, reviews language of referenced statute 105 CMR 020, we adopted an inclusive definition that, in consultation with DPH, is "consistent with DPH's own interpretation of its licensure regulation and regulatory approach to intensive care services". Mentions

MHA, ONL, individual hospital commenters trying to exclude all but adult intensive care units – on "legal grounds" and policy and operation considerations especially in NICUs…

57:40 Wendy Everett –Identifies three domains for focusing the committee's discussion relative to the definition of which ICUs should be included/excluded from the application of the law… First legal interpretations, second there are important policy issues both for the nurses and for the hospitals, and third "Govenor Baker and Secretary Lepore have been very clear with us that they are extremely concerned about the cost implications."

59:48 Veronica Turner asks Lois for clarification of the way the law defines various units

1:02:00 Lois Johnson "The reason I think initially we felt and still feel that it is a sound interpretation to be all inclusive is that because the term "intensive care unit" is included the very title of a NICU and a PICU and a Cardiac Care Unit is defined as an "intensive care unit" that serves cardiac patients."

1:03:02 Alice Moore notes that the Governor and Lepore may look at and change the DPH regulation involved, but she generally concurs with Lois Johnson about the current regulation supports being inclusive, "Those units are still very specifically referred to as intensive care units, still very specifically applied to critical care and specialized staffing and specialized physicians necessary in the units, at times 24-7. Again those aren't necessarily equally applicable to each type of unit but they are intensive care units, they are there at least under the DPH definitions to provide for critical care and therefore separating out specific units may be a difficult task."

1:05:42 Carole Allen "We have a principle in medicine, do no harm, first do no harm… so I think we hav to be very cautious not to put in regulations that may create undue burden or may undo good processes that we already have in place. And I do think we do have the opportunity to use some time to implement these things… the thing that most concerns me are NICUs… from all the testimony that we've heard, from my own personal experience as a pediatrician, I'm having great difficulty understanding how NICUs can actually fit into this regulation… they [American Academy of Pediatrics guidelines for neonatal care] already spell out what the standard of care should be in a NICU, and for us to override that and put in our own, is really presumptuous and could be dangerous… I feel very strongly that we should go slow and exclude NICUs at this time until we've had some experience with ICUs in general."

1:09:15 Wendy Everett "Although the legislation said "Intensive Care Units" there is a sophistication, as we all know, to intensive care units, particularly in NICUs, and there is a huge difference between a Level 1 NICU and a Level 4 NICU. Which is not something that we necessarily expect a senate president, in any state, to be knowledgeable about or understand. So I think part of our role in promulgating proposed regulations is to help educate the people who will be implementing those where there are subtleties. And I'm not saying they are across the board.

1:10:07 Martin Cohen "So I get the arguments that Carole so eloquently stated. But I went back and looked at the statute and the word that trips me up is "all". And I don't know if we've gone back and looked at what the legislative intent was and whether that was included. Was that meant to just be adult? Or was it meant to include these others as well? I think it's hard to know just looking back but I

also then worry about when you exempt one, do we then have a cascading effect with pediatrice intensive care units, burn units, and so forth?"

1:11:06 Veronica Turner, Lois Johnson, Wendy Everett, Carole Allen – discuss the issue of non-critically ill infants physicaly located in the NICU… and co-located Level 2 and Level3 NICUs

1:14:53 – page 34 – Wendy Everett calls for motion and vote – passes with 4 Ayes, 1 abstention (Martin Cohen)