MINUTES OF THE

HEALTH CARE ADMINISTRATION BOARD

THURSDAY, JANUARY 13, 2011

BOARD MEMBERS PRESENT:

DEVON L. GRAF, DHSS
HOLLY GAENZLE, DHSS
MICHAEL BAKER, CHAIR
JUDY PERSICHILLI, (present via telephone)
TASSOS EFSTRATIADES, (present via telephone)
CHRISTINE STEARNS, MEMBER
MARY WACHTER, MEMBER
MARY KAY ROBERTS, (present via telephone)

EXCUSED:

GREGORY MARKS, MEMBER
ELLSWORTH HAVENS, MEMBER
JOSEPH ROTH, MEMBER

ALSO PRESENT:

JOHN GONTARSKI
GENEVIEVE RAGANELLI

STAFF:

MICHELE STARK

CALL TO ORDER:

Michael Baker, Chair, opened the meeting on Thursday, January 13, 2011, located at the New Jersey Department of Health and Senior Services, John Fitch Plaza, Market and Warren Streets, 1st Floor, Auditorium, Trenton, NJ.

MOTION SUMMARY

1. Approval of the Minutes – September 16, 2010
   Motion – T. Efstradiades, M. Baker, Second

2. Approval of the Notice of Adoption
   Hospital Licensing Standards
   Codified at N.J.A.C. 8:43G

3. Adjournment (voice vote)

JANUARY 13, 2011 HEALTH CARE ADMINISTRATION BOARD

VOTING RECORD

VOTING BOARD MEMBER	ROLL	1	2
Mr. Graf	X	A	Y
Ms. Gaenzel	X	Y	Y
Mr. Baker	X	Y	Y
Ms. Roberts	X	Y	Y
Mr. Havens	-	-	-
Mr. Efstratiades	X	Y	-
Mr. Marks	-	-	-
Ms. Persichilli	X	A	N
Mr. Roth	-	-	-
Ms. Stearns	X	Y	Y
Ms. Wachter	X	Y	N
TOTAL TOTAL Absent	8 3-(-)	6-Y 2-A 0-N 3-(-)	5-Y 0-A 2-N 4-(-)

KEY: Y=YESN=NO A=ABSTAIN (-) ABSENT

DETAILED MINUTES TAKEN FROM TRANSCRIPT OF JANUARY 13, 2011 ATTACHED

MS. STARK: This is a formal meeting of the Healthcare Administration Board. Adequate notice of this meeting has been published in accordance with provisions of Chapter 231, Public Law 1975 C-10:4.10 of the State of New Jersey entitled Open Public Meetings Act. Notice was sent to the Secretary of State, who posted the notice in a public place. Notices were forwarded to 17 New Jersey newspapers, two New York newspapers, two wire services, two Philadelphia newspapers, and the New Jersey Public Broadcasting Television Station.

I will now call roll.

Mr. Graf?
MR. GRAF: Present.
MS. STARK: Ms. Gaenzle?
MS. GAENZLE: Present.
MS. STARK: Mr. Marks? Absent.
Ms. Persichilli?
MS. PERSICHILLI: Present.
MS. STARK: Mr. Havens? Excused.
Mr. Roth? Excused.
MS. STARK: Mr. Efstratiades?
MR. EFSTRATIADES: Present.
MS. STARK: Ms. Stearns?
MS. STEARNS: Present.
MS. STARK: Ms. Wachter?
MS. WACHTER: Here.
MS. STARK: Ms. Roberts?
MS. ROBERTS: Here.
MS. STARK: Mr. Baker?
MR. BAKER: Here.
MS. STARK: Eight members of the Board are present, which is a quorum.

MR. BAKER: Thank you very much. I have no report. We do have the minutes from September, and there was a correction that you caught and you E-mailed everyone. Does anyone have any other comments or corrections in the minutes? If not, I'd entertain a motion to approve the minutes with the correction that we received by E-mail, I believe yesterday.

MR. EFSTRATIADES: So moved.
MR. BAKER: Is there a second? I will second.
MS. STARK: Mr. Graf?
MR. GRAF: Abstain.
MS. STARK: Ms. Gaenzle?
MS. GAENZLE: Approved.
MS. STARK: Mr. Marks? He's absent.
Ms. Persichilli?
MS. PERSICHILLI: Abstain.
MS. STARK: Mr. Efstratiades?
MR. EFSTRATIADES: Yes.
MS. STARK: Ms. Stearns?
MS. STEARNS: Yes.
MS. STARK: Ms. Wachter?
MS. WACHTER: Abstain.
MS. STARK: Ms. Roberts?
MS. ROBERTS: Yes
MS. STARK: Mr. Baker?
MR. BAKER: Yes.
MS. STARK: Motion carries.

MR. BAKER: Thank you. For a Commissioner's report, I'd first like to welcome Mr. Graf to the Board and see if there's any report you have for us today?

MR. GRAF: Thank you, Mr. Chairman. I have no formal report, other than to introduce myself. My name is Devon Graf. I am the new Director of the Office of Legal and Regulatory Compliance for Commissioner Alaigh. And I look forward to working with this Board and the members on it. So thank you very much.

MR. BAKER: Thank you. The first item of new business is the new hospital licensing standards. John, are you going to be presenting?

MR. GONTARSKI: Thank you. Thank you, Mr. Chairman, members of the Board, guests. The Department is today proposing final publication of a Notice of Readoption with Amendments of the Licensing Standards Governing Hospital Services, N.J.A.C. 843G. The chapter is scheduled to expire next week, actually, January 18th in accordance with the administrative rule. Readoption is taken to maintain existing regulatory policies regarding hospital services. It's a readoption with amendments and will continue to provide regulatory framework necessary for the Department to ensure a high level of quality care from hospital services.

While the proposal calls for readoption of existing rules with numerous technical changes, it does attempt to respond to a substantive and controversial issue regarding the need for direct anesthesiologist supervision of certified nurse anesthetists, or the old term, which is expected to -- which, as expected, generated some degree of controversy.

The proposed amendments would correct outdated contact information, update patient rights to conform to existing law, and namely, such things as New Jersey Smoke Free Air Act and Domestic Partnership Act, and the New Jersey civil union law; also update tuberculosis screening standards, update referenced CDC infection control standards, update physical plants standards, and establish hospital inspection process that permits hospital CEO attestation and CMS-approved accreditation in lieu of biannual inspections by the Department staff.

The Department anticipates that the readoption of the rules and amendments would continue to provide the uniformity and consistency in the delivery of hospital care state-wide and continue to ensure the quality of services provided by hospital programs through effective oversight and appropriate enforcement.

Specifically, readoption of the rules with amendments would continue to establish requirements for the licensing of hospitals in New Jersey, as well as continued renewal of such a license. However, additional standards apply to hospital licensure, so that the hospital licensing standards are consistent with licensure requirements established for most healthcare facilities and services in New Jersey. For instance, these rules would continue to establish standards that are in addition to or exceed Medicare standards for employee health, especially those personnel who have direct patient contact, patient rights, infection control programs. In addition, the licensing rules would continue to specify the fees that must be obtained to obtain initial license and license renewal, as well as inspection fees.

In response to the Petition for rulemaking, submitted by the New Jersey Association of Nurse Anesthetists, the Department proposed amendments to the anesthesia services requirements, set forth at N.J.A.C. 843G-6.3(e), which would permit certified nurse anesthetists to administer anesthetic agents without immediate anesthesiologist supervision. The Department received hundreds of comments regarding the issue prompting a public hearing and extended comment period to assure that all interested parties are able to comment on the proposal. The Department is making substantive and technical changes that would not require additional public comment or notice as a result of the comments that were received.

The proposal was initially published in the August 16th, 2010 New Jersey Register. And as I indicated, due to the number of comments received on the proposed amendments, particularly at subchapter six, the anesthesia subchapter, the summary of public comments and agency responses was divided into two sections, the first section providing a summary of public comments and responses have a bearing on the proposed readoption of amendments, with the exception of subchapter six, and the second part provides a summary of the comments and responses bearing on subchapter six. Persons commenting at the public hearing, which was largely commenting on subchapter six, testified exclusively with respect to subchapter six. Therefore, the Department identifies those commenters and the responses to their testimony in part two of the notice. In some cases, persons are identified twice because they are commenting on both part one and part two.

With respect to part one, the Department received comments from a total of 115 commenters. Commenters addressing part one, the readoption of amendments, other than subchapter six, largely addressed issues regarding the elimination of the biannual inspections and the absence of staffing ratios for medical surgical payers. The Department's response to those many comments begin on page 21 of the notice. And just briefly summarized, the Department indicated that the proposed amendments eliminated biannual inspections, would enable the facility survey program and the Department to concentrate its efforts on investigations of licensed healthcare facilities, focused hospital surveys following a complaint investigation and monitoring surveys and licensed healthcare facilities that declare financial difficulties or have strike activity. And this would make the most efficient use of the facility survey program's limited resources and hasten responses to complaints, including those complaints regarding staffing issues; also reiterated that it has the authority to enforce a facility's self-directed acuity system, which was the subject of many complaints, and that the Department lacks jurisdiction to determine which acuity system is appropriate for use by facilities since there are many acuity systems that are acknowledged to be reasonable for a hospital's use.

The Department also acknowledged the importance of maintaining appropriate staffing levels to assure quality healthcare services and that the rules proposed for readoption would continue to require minimum staffing ratios for such critical areas as cardiac surgery, intensive and intermediate care, critical care, intermediate care, or step down, normal care newborn nursery, intermediate care nursery, pediatric intensive care and psychiatric services; also pointing out that in all of those cases these critical services are just nurse staffing based, again, on patient acuity levels because one of the rules listed above provide minimum standards. Ultimately, service directors must exercise clinical judgment with respect to staffing levels to ensure patient safety.

The existing rules proposed for readoption already require hospitals to establish joint staffing committees, develop methods to maintain safe nursing staff levels, to formulate contingency plans and provide proper orientation for floating nurses and provide adequate ancillary care are already established in the licensing rules. Rather than prescribe strict ratios without regard to the particular situation of each hospital, the rules proposed for readoption require each hospital to achieve patient safety through its establishment of staffing levels and contingency plans, while at the same time allowing each hospital to determine and establish those levels and plans within the context of its particular organizational structure and clinical circumstances.

Again, reiterating the elimination of biannual inspections will enable the Department to expand its licensing oversight by providing more timely complaint investigations, including those involving nurse staffing and staff posting requirements. However, unlike routine facility inspections in which the Department surveyors can share potential deficiencies with the facility at the completion of a visit, complaint investigations often contained confidential patient information and Department surveyors cannot share the facility staff or collective bargaining agents during the investigation process. This, again, was in response to several comments about access to documents where complaints are being investigated.

Commenters also raised appropriate issues regarding stroke team membership with the definition of hospitals. That was recommended by our Stroke Advisory Panel. Licensed signatories, in terms of

licensing application, questioning who -- whether there would be an alternative to the chief executive officer who can sign off on the licensing application or not. And such substantive issues as psychiatric licensing requirements, which the Department has acknowledged for some time now are -- need updating, and the Department is in the process of dealing with that, so mental health services. There were no changes with respect to those comments, but the Department will be looking at those issues that were raised by the commenters.

With respect to comments regarding subchapter six, part two of the notice, the Department received 343, by my count, individual comments. Those comments are listed on pages 37 and 59 of the adoption notice. Again, the comment is largely centered on the level of supervision to be required of the new terminology of the APN anesthesia professional. Many commenters opposed the amendments that eliminate references to physician supervision of CRNAs and adding references to APN anesthesia subject to protocol, and assert that such an elimination would be detrimental and compromise patient care and pose a threat to patient safety. The commenters emphasized the fact that anesthesiologists undergo more education and have greater technical skills, clinical expertise and medical training, and that would prepare them to think critically and make medical judgments, particularly in life-threatening situations.
They're also required, during that training, to handle high-risk patients, participate in Fellowships and have exposure to care for the sickest of patients requiring close supervision --

MR. BAKER: For the record, Ms. Stearns is now here in person and not on the phone.
Sorry, John. Please continue.

MR. GONTARSKI: Supervised by anesthesiologists, in terms of the commenters opposed to the amendments, better protects patients when complications occur. They note that patient surveys show the patients want physicians to advise them with anesthesia and not nurses. And they also question studies that find no difference in outcomes between anesthesiologists and APN anesthesia personnel as fundamentally flawed and scientifically unreliable.

And they note that 36 states preclude independent practice of APN anesthesia, including the neighboring states of Pennsylvania, Delaware and New York; also commenting that some patients may elect to obtain care in these other states if the Department were to adopt the proposed amendments. And also, stating that changing the title of CRNAs to APN anesthesia does not change their skills, capabilities or need for physician supervision in hospital operating rooms.

The Department's response to the many commenters on this issue state that they appear to object to the action of the New Jersey Board of Nursing eliminating references to physician supervision as CRNAs and establish a standard for APN anesthesia subject to protocols. The comments and concerns are matters of consideration by the professional licensing boards of the Division of Consumer Affairs of the Department of Law and Public Safety in determining appropriate authorized scopes of practice of the professionals they respectively license and are certified. Thus, the commenter's concerns exceed the scope of the proposed ruling.

The Department -- in addressing the issue of joint protocols, the Department did consider the need for clarifying language. The Department stated in its response to comments regarding the joint protocol that just as the Department intends to -- the proposed amendments at subchapter six to refer to the authority, the Board of Nursing, the regulated practice of the professionals under its jurisdiction likewise intends to propose amendments to defer to the comparable jurisdiction vested in the Board of Medical Examiners. The commenter – several commenters accurately notes the current applicability of the rules the BME promulgated at N.J.A.C. 13:35-6.6, standards for joint protocols between advanced practice nurses and collaborating physicians.

The Department inadvertently omitted a cross-reference to this rule in its rule at N.J.A.C. 843G-6.3 to accompany the cross references to the joint protocol to the Board of Nursing. The Department agrees that the Board of Medical Examiners would apply to collaborating physicians in their execution of and compliance with joint protocols, regardless of whether the Department's rule at 6.3 would cross-reference it.

The Department further states that the commenter correctly understands that N.J.A.C. 843G-6.3(e)3 (h)3 and (j)3 are proposed amendments to establish that a joint protocol between APN anesthesia and a collaborating anesthesiologist is required; the anesthesiologist be available to consult electronically during the perioperative period and to be present during induction, emergency and critical change in status. The Department defers to the BME and the Board of Nursing as part of these respective agencies exercise the jurisdiction to establish the minimum requirements of the joint protocols between the professionals they respectively license. These responses are on pages 75 and 76 of the notice.

Again, further, in response to commenters nine through 12, the Department indicated that -- the comments related to the presence of an anesthesiologist during the performance of anesthesia suggest of that the proposed amendments at N.J.A.C. 843G-6.3(e)3, (h)3 and (j)3 described the required content of a joint protocol are subject to misinterpretation. Therefore, in response to the commenter's request for clarification, the Department will make a change on adoption to delete the phrase address section governing and to add the term require and reorganize those subsections to improve readability by breaking some of the clauses into subparagraphs and paragraphs. That is basically the one change that the Department is proposing in response to comments in part two of the notice.

And the Department at this time requests that the Board consider readoption of N.J.A.C. 843G with amendments and with the change indicated in the notice.

MR. BAKER: Thank you, Mr. Gontarski. Before getting to any questions on the Section 6.3, do the Board members have questions on any of the other sections of the proposed regulations?

MS. PERSICHILLI: Even though I have to drop off at ten to give a report, I've read the material, and the only question I have is the definition of a substantive change. It seems to me that the term require is substantive, as compared to what we were dealing with prior to that particular change. So that is my comment. I am concerned about that. Quite frankly, I see it as a step backwards, rather than a step forward.

MR. BAKER: Thank you, Judy. If there aren't any questions on any other section, John, I was going to ask you dealing specifically with section 6.3, go through the specific changes from what was originally published, and then now both in language and the practical effect.

MR. GONTARSKI: Genevieve, identify yourself.

MS. RAGANELLI: My name is Genevieve Raganelli with the Office of Legal and Regulatory Compliance, and I work under section --subsection six.

MR. BAKER: Thank you, Genevieve. What I'm trying figure out, both the actual changes, the language changes between the original publication and now what's been approved for publication, and then the net effect as the Department sees it.

MS. RAGANELLI: Section N.J.A.C. 8:43G-6.3(e), (h) and (j), they each have similar language, so I will just say it once. At (e)3 we are deleting the reference -- the sentence, and the sentence reads: A general or major regional anesthesia shall be administered and monitored only by the following, and at item three under that section E reads: An APN anesthesia, in accordance with the joint protocol established in accordance with N.J.A.C. 13:37-6.3, standards for joint protocols between advanced practice nurses and collaborating anesthesiologists, which joint protocol shall, and instead of the phrase address sections governing the, we're going to say shall require the availability of an anesthesiologist to

consult with the APN anesthesia on site, on call or by electron means, and the presence of an anesthesiologist during induction, emergence and critical change in status.

And I am informed that this has been preliminarily reviewed by the Office of Administrative Law, and they agree with us that it is a non -- it is a change that does not require additional public notice and comment, and that it is an accurate reflection of the Department's original intention. As you can see, the phrase joint protocol shall address sections governing is something of a clumsy formulation, so it was simply an effort to articulate that we would require the presence -- the availability of anesthesiologists in the perioperative period to consult and during induction, emergence and critical change in status, the anesthesiologist would be -- the presence of an anesthesiologist would be required.

MR. BAKER: That is physical presence, electronic presence? What type of presence is required?

MS. RAGANELLI: Presence is --

MR. BAKER: How is that defined?

MS. RAGANELLI: We did not propose a definition of presence. It's something we could do in the future. We note there is an existing definition of presence within the context of the existing definition of supervision, but we don't want to use -- obviously, we don't want to use the definition of supervision because of the words to that definition. But in part, that term reads immediately available to proceed to the site of the operation. But that is one option we would assume that would -- presence would be inferred from that definition; however, that is something we could propose in the future.

MR. BAKER: Do any other Board members have questions?

MS. WACHTER: I have questions about -- we'll talk presence since we were just talking about that. The standard definition of presence to most people would mean that the person would need to be in the room. I realize that that's not clearly defined, and it sounds like the Department has not decided on what definition of presence, or if a definition of presence needs to be determined. But I think that that change or that use of that word is ambiguous enough that it will create lots of questions in the actual practice setting. So that's one comment that I have about presence and since -- as my question was going to be how do you define it. I would say when I compared the existing rules, specifically looking at the section related to conscious sedation, the administration of conscious sedation, and that is at 8:43G-3. --6.3(h). And the current rule reads that anesthetic agents used for conscious sedation shall be administered only by the following. Number two says: Under the supervision of a physician who has privileges in accordance with medical staff bylaws to administer and supervise anesthetic agents used for conscious sedation who is immediately available. And then it says: I, a certified registered nurse anesthetist.

So to me, the current -- for just conscious sedation administration in a hospital right now, a certified registered nurse anesthetist can provide conscious sedation with supervision by a physician credentialed in anesthesia. The new rules suggest -- let me make sure I have the new rule in front of me -- that it needs to be – that the -- let me reread this. In accordance with N.J.A.C. -- standards for joint protocols between
advanced practice nurse and collaborating anesthesiologist, which joint protocols shall address sections governing the availability of an anesthesiologist to consult with the APN on site through electronic presence and anesthesiologist during induction, emergence and critical changes in status. This, I believe, is the rule that was proposed back in July.

And the current rule that's being proposed requires that an anesthesiologist be present during the administration of conscious sedation, during induction, emergence and critical change in status. And I think if there is any justification that this is a substantial change, it is in this section. I would say that having been a critical care nurse that spent eight years working throughout an acute care tertiary teaching institution in the State of New Jersey, and I, myself, have provided conscious sedation many, many times in my career, the conscious sedation is provided at many different areas of the hospital all

day long. It's in the radiation -- interventional radiology labs. It's in the special test labs. It is in the cardiac cath labs. It's in the ORs. It's in the ICUs at a minimum. Emergency Departments -- there is no -- there's no possible way that an anesthesiologist can be present during the induction, emergence and changes in critical status for conscious sedation throughout the hospital. So I would say to me it just doesn't even seem that if this was going to be implemented -- if approved and implemented, there's no way it could ever be implemented. I think it's a major substantial change to the rule. So that would be one of my arguments on the issue of substantial change.

I'd also suggest that there's substantial change with the word required. The joint protocol regulations, specifically at 13:37-6.3(c) read: The content of a joint protocol under B above shall address. That language shall address is listed right from the joint protocol regulations and was included in the initial proposed rule in July of 2010. The word required, in my opinion, absolutely represents a substantial change. A joint protocol was created with only the intent to address prescribing of medications and devices.

In the letter drafted and submitted to the HCAB on July 12th by Senator Joseph Vitale, who is the sponsor of the enabling statute legislation that allowed for the drafting of joint protocols, he specifically states, and I read: As sponsor of public law 2004, chapter 122, let me be clear that both the spirit and intent of the law was to ensure that all APNs, no matter their specialty, have the autonomy to practice as independent professionals who are required to have a joint protocol with a collaborating physician for prescribing purposes only. APNs are not to be supervised by physicians. I realize that the proposal, both the one in July and the one that we're reviewing today, removes the language supervision, but I think that the word presence, having not been defined, can certainly be interpreted to mean supervision.

I have got a few other comments, but I can probably hold so that I'm not hogging the entire time here and let some other people present some other parts of the testimony.

MR. BAKER: While Mary is going through her papers and gathering her thoughts, does anyone else have any comments?

MS. RAGANELLI: Was I allowed an opportunity to respond?

MR. BAKER: We'll do it in the order. Judy, are you still there? We may have lost her, then. You can respond.

MS. RAGANELLI: With respect to the comment on conscious sedation, it is my understanding that this would not represent a departure -- the concept of presence would not represent the departure from existing practice. Presence is -- it's my understanding that in certain situations an operating suite could have, for example, four different salons and the one anesthesiologist is present -- considered present for purposes of all four procedures that are ongoing. So it's my understanding that this would not be a departure from an existing practice; that the concept of presence in that sense would not be a departure.

MS. WACHTER: What about when there aren't enough anesthesiologists in the hospital to be in the upwards of potentially 15 locations in the hospital where conscious sedation is taking place all at one time?

MS. RAGANELLI: Well, within the existing definition that you mentioned in the section that we're proposing for deletion from the supervision of CRNAs, the concept of presence generally means immediately available to proceed to the area, not necessarily in the room. So if a physician were in one area, they could proceed to the other.

The other comment we received from a number of commenters is that there's always an anesthesiologist present in a hospital.

MS. WACHTER: I can tell from you my practice that there's not been an anesthesiologist available in areas where conscious sedation is provided. And I would also wonder if you can comment about the change from that fact that with conscious sedation that there's definitely a change from the original proposed -- the rule that exists now, which is a physician credentialed in anesthesia versus present supervision, whatever you want to call it, to now, which is an anesthesiologist.

MS. RAGANELLI: Are you saying there's a difference between a physician credentialed in anesthesia and an anesthesiologist?

MS. WACHTER: Well, there is. There's definitely that difference. And then there's a difference between the current existing rule, the rule that was proposed in July, and the rule that we're reviewing today.

MR. BAKER: So I can be clear, we know there's a difference, and you're saying in the original one it was credentialed in anesthesia, and the current proposed for adoption it says anesthesiologist?

MS. WACHTER: Yes.

MS. RAGANELLI: We're not making that change on adoption. That is as proposed. There's no change.

MS. WACHTER: The proposal in July definitely took out the language that said physician credentialed in anesthesia.

MS. RAGANELLI: To be the person with whom the joint protocol must be established, is that what you're referring to?

MS. WACHTER: Correct. But now it says -- when you change it to say require the presence, the word require the presence of an anesthesiologist during induction, emergence and change in status for a patient receiving conscious sedation. In the practice setting, do you feel that that is a substantial change?

MS. RAGANELLI: No, because it's our -- it's the Department's position that address sections governing that has the same meaning as required. In other words, that each protocol shall contain these provisions.

MS. WACHTER: We respectfully disagree because in practice, in the actual setting where care is being delivered and conscious sedation is being delivered, it is a substantial change from what I believe was proposed in July to what I believe -- and the existing rule.

MS. RAGANELLI: Well, we're not changing the term anesthesiologist to physician credentialed in anesthesia or vice versa. The term used in the existing rule is anesthesiologist.

MS. WACHTER: But in practice, when this would get implemented, because the term presence is not clearly defined, and if I'm a hospital administrator, I would think that presence means they need to be there in the room when it's being delivered. And if that's the case, I think that it is a substantial departure from current practice and makes the practice of conscious sedation deliver even more restrictive than it currently exists right now. It was my understanding that the change proposed in July was meant to actually reflect changes in the Board of Nursing rules, which acknowledge that advanced practice nurses in anesthesia are practicing as advanced practice nurses who have the ability to provide care within the full scope of their training and education. And I think that this is reverting back to an actual more restrictive rule than the current existing rule as it exists.

MR. BAKER: Any other members have comments? Devon?

MR. GRAF: One, I guess, absent any change, the word presence would be part of this adoption because wasn't that part of the proposal? We're not inserting the word presence at this time; isn't that correct?

MS. RAGANELLI: That is correct. The existing rule as proposed reads: Which joint protocol shall address sections governing the presence of an anesthesiologist during induction, emergence and critical change in status. And the proposed amendment would change it to which joint protocol shall require the presence of an anesthesiologist during induction, emergence and critical change in status.

MR. GRAF: So at this time we're not inserting the issue of presence. That was present back in July when this was first proposed. So I recognize your concern, but I guess we're looking at this as an adoption, and maybe that's something that needs to be further reviewed for other rulemaking. I think that can be done, but I think at this time -- we have a little timing issue because our rules will, if they're not adopted, will expire this month. And so there is – there has been a concern of getting these on board.

The other question which I have is who is -- I mean, at this point you said it was an informal consultation that we have had with the -- that the Department has had with OAL. So at this point, OAL is the final arbiter of what is substantive; isn't that correct?

MS. RAGANELLI: My understanding is that if OAL believes it's a substantive change, the Office of Administrative Law generally obtains an opinion from the Office of the Attorney General, which will then advise them whether it's their position.

MR. BAKER: I just know we usually get advice from our DAG, who represents the Board on those issues. And I'm not so much concerned with the language, but I guess folks might think I'm a little more on the doctor side of things than on the nurse side of things on these issues. But I am concerned that in the past when we have asked for minor changes, what we have thought of minor changes, the DAG and the Department has always said that's substantive. So I want to be sure that we don't adopt something that is readily challenged and overturned.

But we still have more comments from people and we may need to have an executive session to consult with counsel and figure out what appropriate legal advice is for the Board.

MS. WACHTER: My knowledge of the joint protocol -- I will give you an example. If there's an advanced practice nurse anesthesia working in collaboration with an anesthesiologist, for example, and the rule, as proposed in July, was the final rule, let's say, shall address for conscious sedation, let's say the APN is providing conscious sedation in the interventional radiology lab in the basement of a hospital, which is where they're usually located, the joint protocol could say when addressing presence of the anesthesiologist that presence is required by the anesthesiologist for the following cases, patients who are critically ill on ventilators, patients who are level-three trauma. They could specify in the joint protocol between the physician and the anesthesiologist, between the anesthesiologist and the APN, which types of patients might -- want the need to have the presence of the anesthesiologist.

However, it could say for routine interventional radiology procedures, the anesthesiologist does not need to be in the room with the nurse anesthetist providing the conscious sedation; that the anesthesiologist could remain in the OR suite, which could be on the third or fourth floor of the hospital, and if they're needed, they could be called down. The way the rule is now written to say that the presence is required does not allow that flexibility between the two practitioners to determine when the presence is required or not. So that's what I would argue the difference is between the word required, which does not give any leeway to the practitioners. It is required. So however it is defined, it is required. It is not shall address.

MS. RAGANELLI: If we were to define presence to mean what it means in the existing rule in the definition of supervision, the last clause of the definition of supervision is that the presence means immediately available to proceed to the area. Would that be something that would resolve your question?

MS. WACHTER: Well, it would certainly further define what presence means.

MS. RAGANELLI: But would that resolve your question about now that they don't have to be in the room, necessarily, but they need to be in the suite, for example?

MS. WACHTER: It would definitely make it -- would further clarify that, like, where the anesthesiologist needs to be physically located in the administration of the conscious sedation.

MS. RAGANELLI: With Devon's permission, maybe we could ask if that is proposed or make an adoption.

MR. GRAF: I don't mean to disagree with what you think is the need. I think what the issue is why we didn't define presence is the fact that the joint protocol should have that flexibility so they can say: In these times, this is what we mean. And the word presence may be different for different types of procedures, as long as it's within that parameter, that they're not on the golf course, but they're readily available. And that's where we were going and why the comments came up and say: What is presence.

The Department didn't want to put a structure because each hospital setting is different. You may have a campus where you're in a building but it still takes you half an hour to get to where you need to be, as opposed to other situations where it's small and you can be wherever you need to be within five minutes. So I believe the context is really going to be governed by the joint protocol, itself, rather than kind of a definition where no matter what, we're still going to have gaps.

MS. WACHTER: So are you thinking that you might consider language that would say, for example, in 8:43G-6.3, let's take (e)3 and then double l, the presence and then potentially, comma, as defined in the joint protocol established between the APN anesthesia and the collaborating anesthesiologist?

MS. RAGANELLI: I don't think that would absolutely be necessary because every -- we don't say for every concept that must be in the joint protocol that -- and as that word is defined. I think it's okay to assume that. To the extent it's not expressed in the rule, it's something that is deferred to the parties to the joint protocol. So I don't know that we absolutely need to say presence, as that term is defined, because then we'd say the -- as that term is defined. We don't need to cross refer to the joint protocol in every situation.

MS. WACHTER: But no where in the rule does the word presence refer back to what the joint protocol says. In fact, it just says that the joint protocol shall require the presence of an anesthesiologist. I don't think it gives any flexibility in the joint protocol.

MS. STEARNS: If I may, based on the comments from the Department, it does seem that the revised language that may have been intended to be more clear about the Department's intent is actually more confusing because it does, in a plain reading, suggest that the Department's intent was to require the physical presence of the anesthesiologist in the room in those particular circumstances versus what I think I heard the Department say that your intent was for the joint protocol to address the circumstances when the presence of the anesthesiologist might be required.

MS. RAGANELLI: I think that was Ms. Wachter's interpretation.

MS. STEARNS: I don't want to put words in you mouth, so maybe you could try to help me understand what the Department means by presence.

MS. RAGANELLI: Rather than me try to wing this, let me read from my response to the comments. I don't want to --

MR. BAKER: If this is your first time before the Board --

MS. RAGANELLI: It's not.

MR. BAKER: You know we like to set a record so that the regulations that we approve are able to be interpreted by the public and those in the industry as to what our intention was.

MS. RAGANELLI: I don't mind at all. We said: Just as the Department intends the proposed amendments at six to defer to the authority of the Board of Nursing to regulate the practices of the professionals under its jurisdiction, the Department also intends to defer to comparable jurisdiction as to the BME. That being said, we omitted to state that the joint protocol has to correspond to the joint protocol rule promulgated by the Board of Nursing, as well as the joint protocol rule promulgated by the Board of Medical Examiners.

The commenter's correct with respect to its understanding of the Department's intention related to anesthesia services in a hospital setting with respect to the concepts of the availability and the presence of collaborating anesthesiologists. The commenter correctly understands N.J.A.C. 8:43G-6.3(e)3, (h)3 and (j)3 as proposed for amendment to establish the joint protocol between an APN anesthesia and the collaborating anesthesiologist is to require that the anesthesiologist be available to consult electronically during the perioperative period and to be present during induction, emergence and critical change in status.

The Department defers to the BME and the Board of Nursing as part of their respective agencies to establish the minimum requirements of a joint protocol between the professionals they respectively license. In an earlier response to comments we state --

MS. STEARNS: Can you tell me what page you're on?

MS. RAGANELLI: That was on page 76. And in an earlier response to comment we state at page 63 and 64, first, that the entire -- that 6.2(a), as proposed for amendment, would require hospital policies and procedures for anesthesia services to be reviewed at least annually and revised as needed to ensure the safety of patients during the administration and conduct of and emergence from anesthesia. It would require the Anesthesia Department to be administered under the overall supervision of a qualified physician director operating under applicable law governing the scope of practice of professionals performing anesthesia services.

We note that the Healthcare Facility Planning Act requires us to establish minimum standards for hospital operations, but we also note that the existing federal regulations governing hospital operations under CMS conditions of participation require the supervision of, quote, nonphysician providers, unquote, of anesthesia services. We anticipate that hospitals – our rules do not have to overlap with that rule, but the existing procedure, which is the hospital board, through its communications with the medical staff organization, will establish who gets credentialed and what is the scope -- what are their privileges within the hospital.

So we really are in a situation where the Board of Nursing has said: You cannot pose extraordinary requirements on advanced practice nurses that happen to have the anesthesia requirement, but at the same time are constrained by the requirement that hospitals establish the protocols for their individual situation, their individual, typical clientele. And this is our best effort to defer to a situation created, we believe, by the Board of Nursing and the Board of Medical Examiners.

MS. WACHTER: The Board of Nursing and Board of Medical Examiners approved the joint protocol rules, as I said, 13:37-6.3, and again, (c) is the section that speaks more broadly about shall address versus require. And I do appreciate in the Department's comments, or responses, rather, that you defer to the Board of Medical Examiners and the Board of Nursing in relationship to the joint protocols. Yet, the proposed language says that there will be a requirement of presence. I think that those two contradict each other.

MS. RAGANELLI: Well, in our deference to the Board of Medical Examiners, their comments begin on page 73, they indicate that they're concerned that the availability of collaborating anesthesiologists on call or by electronic means is unlikely to provide the requisite safety net that the Board of Medical Examiners has felt necessary in the office setting.

MS. WACHTER: But, obviously, the hospital setting and the hospitals are two very different settings, and the BME really only regulates office setting.

MS. RAGANELLI: I'm reading from the wrong section of the comment I wanted to call to your attention. I'm sorry.

MS. WACHTER: That's okay.

MS. RAGANELLI: The Board of Medical Examiners reads: The requirement that the protocol address the presence of an anesthesiologist during induction, emergence and critical change in status to reflect that the anesthesiologist must be on site and immediately available as is presently required under the BME rules. We state in response that that is our understanding. We want them to be present during induction, emergence and critical change in status, and that is how the BME interpreted our statement. So to the extent there was -- they also indicated that to a certain degree the language was confusing, and this was our attempt to clarify that language.

MS. WACHTER: I respect the Department's intent to try to clarify it. Again, I say that the word required versus shall address is a substantial change.

MR. BAKER: Do any other members have comments? Thank you.
Is there anyone -- go ahead.

MS. ROBERTS: I did have a question of the Department. Have you gone to the Governor's Office to seek an extension of next week's expiration?

MS. RAGANELLI: It's not our normal practice to request an extension in anticipation. So no, we have not done that.

MR. BAKER: Let me ask the follow-up. What is the effect, or what is the procedure for getting an extension and what is the effect if you don't?

MS. RAGANELLI: The failure to readopt this chapter will result in there being no rules governing the operation of hospitals in the State.

MR. BAKER: So the practice for an extension then becomes important, and what is that?

MS. RAGANELLI: It would be necessary to, I believe -- what is the expression?

MR. BAKER: Executive order?

MS. RAGANELLI: The governor would need to make a finding of --

MR. GRAF: Emergency situation in which they usually don't say if the Department makes it themselves because of timing issues that's really an emergency. It's very tough standards.

MS. WACHTER: It's my understanding -- could we -- this is a question, actually. Could we adopt all of the rules as proposed with the exception of subchapter – or subsection six, anesthesia? And then there would only need to be the need to get an emergent ruling from the Governor for that one section.

MS. RAGANELLI: The proposal was filed in -- became published August 16th, 2010, which means the proposal remains adoptable until August, 2011. However, the rules expire, so we need to readopt the chapter. Whether you defer certain parts of the proposed amendments, I believe that would be in the discretion of the Commissioner.

MS. WACHTER: Could there be a motion made to adopt the proposal that was made in July of 2010, and then, if the Department – so that there's a rule in place, and then if the Department then feels that they want to change that to make it clearer, they could do that?

MS. RAGANELLI: One of the major problems with that is that our existing rules talk about licensure of a profession that no longer exists, which is the CRNA.

MS. WACHTER: Actually, the proposals in July, 2010, what was brought before this Board, does clarify that CRNA is no longer the language used and it's APN anesthesia.

MS. RAGANELLI: That's what the amendments do. If we were to not adopt the amendments in subchapter six we would continue with the existing rules governing CRNAs.

MS. WACHTER: I'm suggesting that there are two different sets of proposed rules, the rules that were proposed in July of 2010 and the rules that are before us today.

MS. RAGANELLI: Actually, no. The rule that you're referring to as the July was published in August. That's the proposal. And today we are addressing the readoption of that proposal to readopt the chapter. But there's not a second proposal.

MS. WACHTER: I'm sorry. Thanks for that clarification. Could we agree to adopt the rule that was published in the Register in August without the technical changes included in today's proposal?

MS. RAGANELLI: That is not what the Commissioner is proposing to do.

MR. BAKER: That's not what the question is, though. That's not what the question is. Let me make this suggestion. Before we take legal advice in a public hearing, we should probably do that in an executive session.

But if there aren't any other questions of the Commissioners, I'd like to get the public input before we go into executive session. Thank you.

Anyone from the public who would like to be heard on this? We'll start on the left and work over. Please come up. State your name and if you're affiliated with an organization, and please limit your comments to three minutes.

MR. GOODKIND: Good morning. My name is Kenneth Goodkind. I'm a member of the law firm of Flaster Greenberg. Normally, my partner, Alma Saravia, would be here today but she's unavailable because of a medical problem of her own.

I think the focus is not so much on the word presence as required, and the APN law uses the word address. It does not use the word, and that's why the regulation, as proposed back in July, said address. So when we make the change to require, it does, at the very least, create an ambiguity. It is not consistent with the APN law. Under the APN law, all that the joint protocol can do is really address the descriptive authority, and that's what is controlled by the physicians in the joint protocol working in collaboration, in that case, with the APN anesthesia. So I do think it creates worse than ambiguity.

The President of the New Jersey Association of Nurse Anesthetists is also with me today, and that's Robert Shearer, in the back of the room. He can talk, as Mary Wachter did, about the practical effect. You will have hospital administrators not knowing how to proceed, not knowing whether they need to

have anesthesiologists everywhere in the hospital. They could be in 15 different places in the hospital. They will know, if we go back, and I think that was a very constructive suggestion, if we can work with what was adopted and published in August, we'll know where we are. If there needs to be a further change in clarification, that can be done, in fact, under the regulations -- under legislation that was passed this week by both Houses of the legislature.

There's a much more expedited procedure for dealing with those kind of amendments. So that can be accomplished very quickly. But we have something that was the subject of great discussion, great input, studies support, testimony went through the whole process, as you all know, because you passed it and approved it back in July, and I think that's where we want to go.

As for technical amendment issue, with all deference to whoever said it before, what the OAL pronounces, especially orally, is not really subject to deference, and obviously not your counsel, by the courts, but I have with me in my briefcase, but not in three minutes, we can go over a number cases where the Appellate Division has pointed out that that is not the alternative of what the OAL is. There are rules and statutes, and I have those in the briefcase, too, but it is really punctuation, grammar and things like that. Just the very tenor of the comments I've heard today indicates that at least some people think this is going to reap a substantial change on how the system works. It could not have been addressed back in the comments in the fall and in the summer because the words weren't there. So I'd ask you please today to consider going back, I think, again, Mary Wachter's suggestion. Let's work with everyone and have a great deal of consideration, effort and thought for July, and if there needs to be a further change and clarification, do that in the technical amendment. Thank you for your attention.

If Mr. Shearer could speak for a minute, he'll address some of the practical aspects. Thank you very much.

MR. BAKER: Please, also, give your name and affiliation.

MR. SHEARER: Good morning, everybody. My name is Bob Shearer. I'm the President of the New Jersey Association of Nurse Anesthetists. I didn't ultimately raise my hand real quick because I saw a lady raised her hand and I was going to let her come up first.

I work right here in Trenton at Capital Health; five minutes away. I'm sure you have seen the advertisements. There's billboards everywhere, right? I used to work at Jefferson. Let me go backtrack a little bit. I have been a nurse for 20 years. I've been an advanced practice nurse, CRNA, for the last 11. I trained at Hahnemann University. I worked at St. Christopher's Hospital for Children for eight years before going to anesthesia school.

I think we're going to get some more evidence. I know there's been plenty of evidence brought before you guys, as far as our education and training. I just want to comment, maybe give you a picture of the reality of what the day-to-day operations are for us in the OR because, obviously, you guys aren't there. And I think it's part of our job to kind of tell you, or at least show what you goes on. I actually came up with those two neurosurgeons that you see their pictures everywhere. I knew them since residents. They came up here to Capital Health, and they asked me and another CRNA to provide their anesthesia. Nothing against any of the docs we work with, but none of the docs were asked to come. We were asked to come. We give them their anesthesia care 24/7. That's why I'm still in my scrubs. I apologize for not having a suit on today. I am coming off a 24-hour call. So if I seem a little tired, that might be the reason why.

MR. BAKER: You're doing fine.

MR. SHEARER: Thanks. As Ms. Wachter said, on a given day we could be giving anesthesia in an MRI suite, an interventional suite, which we do, an interventional suite. Real quick, I know I only have three minutes, as opposed to just going after aneurysm, this way, cutting through a skull, interventionally, neurosurgeons can go through the groin, catheter, fish wires up in through there, and actually coil the

aneurysm. We're the ones in there wearing led in the dark, keeping these patients asleep, keeping their blood pressure within a small, small range, using titrating medications. There isn't somebody next to me telling me: Give this, give that. Actually, come into Capital Health in Trenton. We're training the anesthesiologists how to do this. So that's the actual -- we're next to the patients. We're heartbeat to heartbeat. We're with these guys. We're right next to them. Whether it's in an MRI suite, there's not a doctor next to me while the patient is asleep in the MRI tube. As you guys know, if anybody's ever had an MRI, it's not like anybody can stay in there with you. So we literally have somebody who is breathing room air that I'm able to sedate to the point where they will hold still for the MRI, and there's not a doctor next to me in case something happens. Because whether it's a doctor or anesthetist, if something happens, just having a doctor there just doesn't mean everything is going to go okay.

The outcomes, again, you're going to hear studies. When we talk about studies, the opposing side isn't going to finance your studies. You finance your studies. And any research that you've ever studied, somebody pays for it. It just doesn't happen. So we're very safe. We have been practicing for 150 years. The evidence is clearly on our side.

As far as the other side goes, we're the most restrictive state in the United States. Why is that? I'm also a committeeman in my town. I'm very proud to live in New Jersey. I got elected the same night as the Governor did. I was actually more happy about him getting elected than myself. And I know that's not what the Governor's about. We're not about more regulation. And I thank you guys for doing this day in and day out. You really make a difference in our careers.

And our members, we're not going to apologize for being the ones in the room day in and day out giving anesthesia. That's the reality of the situation, no matter what people tell you. The other side in the public comments was very anecdotal. There will be blood in the streets. It's absolutely laughable. We came to Trenton to really make a difference because patients were leaving New Jersey to go to Philadelphia, leaving New Jersey to go to New York to have their neurosurgical care done. Now we're keeping those patients here.

I'm on call 24/7; strokes being flown into us all over the State. And we're the ones that are doing the anesthesia. I'm not going to apologize for it. I know you've got to ask yourself why is the reason people are pushing so hard to have that supervision in there. It's about power and money. That's what it's about. I'm just trying to give you a realistic -- I know the lawyers -- you've got to go through the technical part because I don't know that. My job is to kind of show you guys what is going on.

MR. BAKER: Thank you.

MR. SHEARER: Thanks for your time. I probably got extra.

MR. BAKER: Please identify yourself.

MS. BARNETT: Good morning. My name is Pat Barnett. I'm the CEO of the New Jersey State Nurses Association. And we represent the professional nurses in the State of New Jersey, and we were very instrumental in the enactment of the regulation that created the joint protocol, which removes the provision for nurses in the State of New Jersey. I have copies of written testimony and those multiple interventions. But just a couple quick comments I wanted to make.

We do see this not as a explanatory change. We see this as a substantive change, which clearly is very different than the original intent of the language that was proposed and discussed in the hearing here in July and published in August. This does require supervision of APN anesthesia, which is in violation of the State statute that was passed. We feel it is a much more restrictive regulation than the former regulation, which this was to replace in recognition of the APN legislation. So our concern is that we are taking a serious step backwards. New Jersey will be the only state doing that. When you look at other states, they are all loose political ties.

I would like to address Medicare, which was brought up. Medicare addresses the payment of anesthesia, and their regulations have an opt-out clause saying APN anesthesia do not have to be supervised if a state opts out. Sixteen states, plus the District of Columbia, have opt out in the last few years because it is very costly to require supervision. You have something from AARP. AARP testified a number of times. They and their members in the State of New Jersey are opposed to the restrictive regulations and requirement of an anesthesiologist present because it adds two to $300 per case. The State of New Jersey has a terrible budget issue. Two or $300 per case also applies to state employees and Medicaid. That means by having these restrictive practices you increase the costs. This rule is actually more restrictive than the past rule, which requires an APN to supervise up to four nurses and be available within 30 minutes, which means he didn't have to be present.

By having an anesthesiologist present in every single room, including the cath labs, the emergency room, the intensive care unit will increase costs dramatically in this State for patients who are paying through co-pays, employers, whose insurance rates will go up dramatically. And the hospitals will have a nightmare in terms of medical malpractice, because what will happen is if anybody says: You don't have an anesthesiologist in the interventional cath room, you violated the law. Therefore, if my patient has an injury, you are liable. Hospitals will have to be forced to go out and hire significantly larger number of anesthesiologists. And by the way, there are not enough in the State, which means you will force hospitals to close units if they can't have an anesthesiologist present at the time. So this has huge consequence for the State of New Jersey. I'm sorry. The interpretation is required in the room. You can't afford to do it in this State, and physically, you can't do it in the State because you don't have enough anesthesiologists. We see this as a terribly restrictive result. We think it's a terrible step backwards. It flies in the face of the Institute of Medicine report, which just came out. It flies in the face of regulations being enacted in other states by opting out of Medicare supervision. We think New Jersey is going to face a terrible conundrum.

We support what Mary Wachter suggested, which is go with the original regulations and it gives you more time to really look at what the implications of this would be. There's no one here from the Hospital Association. I assume they -- there is. I'm sorry. I'm not sure if they have had a chance to really think of what the cost implications would be of this. But I think this would be a huge problem for the State.

MR. BAKER: Thank you. Anyone else in the public would like to be heard? Hospital Association? We're still in the public portion. No one?

MS. RAGANELLI: Just one point. We are aware of the federal requirement that there be supervision, but we're also aware that there's a federal provision for opt out by the Governor's Office. At this point we don't have any indication whether or not the Governor is going to exercise the determination to opt out of the requirement of supervision, and that's a Medicare/Medicaid requirement. So in as much as it's an existing federal requirement, I don't know that this necessarily makes a difference to the existing law.

MR. BAKER: Thank you.

MS. BARNETT: Can I respond?

MR. BAKER: Certainly. Please keep it brief.

MS. BARNETT: It will be very brief. That opt out only applies to Medicare patients. It does not apply to other patients. It only has to do with payment. It does not have to do with the requirement for supervision, like you are talking about in this regulation.

MR. BAKER: Thank you. Anything further from the public? I will entertain a motion to close the public portion of the hearing.

MS. STEARNS: So moved.

MR. BAKER: Thank you. I think since there are some significant legal and procedural-related questions, I'm going to ask if anyone would like to make a motion to go into executive session so we can discuss the legal issues, and then we will come out publicly again and properly take some form of action. Is there a motion to that effect?

MS. WACHTER: I make a motion to go into executive session.
MS. GAENZLE: Second.
MR. BAKER: Holly seconded.
MS. STARK: Mr. Graf?
MR. GRAF: Yes
MS. STARK: Ms. Gaenzle?
MS. GAENZLE: Yes.
MS. STARK: Mr. Efstratiades?
MR. EFSTRATIADES: Yes.
MS. STARK: Ms. Stearns?
MS. STEARNS: Yes.
MS. STARK: Ms. Wachter?
MS. WACHTER: Yes.
MS. STARK: Ms. Roberts?
MS. ROBERTS: Yes.
MS. STARK: Mr. Baker?
MR. BAKER: Yes.
MS. STARK: Motion carries.

MR. BAKER: Thank you. I'm going to ask the folks in the public and the staff to leave, but I would ask that senior staff people stay nearby in case we need a consult. This will probably take about ten or 15 minutes. Thank you.

(Whereupon, the Board went into executive session at 10:51 a.m.)

(Whereupon, the Board went back into open session at 12:34 p.m.)

MR. BAKER: We are out of executive session and out of adjournment and back into public session. I want to thank everyone for their patience. I want to thank Devon for consulting with counsel and bringing back some guidance and advice to us.

Devon, do you want to begin some discussions about how we might address the concerns put forward by some of the public and some of the commissioners with regard to the proposed change?

MR. GRAF: Certainly. Certainly I thank everyone here for their testimony and the information and the good Board's discussion on the issues, as well as our counsel's advice.

The indication of what is considered substantive or substantive requirement in the proposal is something that's initially determined by the Office of Administrative Law. It's not done by the Department. So therefore – I mean, what we were looking at and suggesting may not be substantive. With the attorneys general's advice, it may be. In order to address the concerns that we have heard, as well as those that have been made in public comments in the adoption notice, itself, we have suggested that the clarification be changed from the way it reads in the three instances from being -- where it says: An APN 18 anesthesia, in accordance with the joint protocol 19 established in accordance with N.J.A.C. 13:37-6.3, comma, standards for joint protocols between advanced practice nurses and collaborating anesthesiologists, comma, which joint protocol shall, in lieu of the word address, we're going to have the word require, but then keep in the language that says: Sections governing the, and then keep in the proposed change to say: One, the availability of an anesthesiologist to consult with the APN anesthesia on site, on call, or by electronic means, semicolon; and two, the presence of an anesthesiologist during induction, emergence and critical changes status. That change basically is removing -- or keeping in the

words – sections governing the. So it's not the direct intent of saying that the protocol would require the presence at all times, but that the protocol must – must have sections in which the availability and presence is detailed and enumerated, as far as the types of cases. The intent of the Department in this case is that we didn't want to have protocols that were void of discussing the availability and the presence. And it is also the intent -- when we discussed presence, it is -- it's some sort of physical presence, whereas the anesthesiologist can be made available physically in cases of emergency situations, especially, rather than being available or present by electronic means or by phone. The Commissioner for public safety purposes, is concerned that an anesthesiologist not be off site and just make the recommendations, especially in extreme cases.

MR. BAKER: So just for clarity, it's not a requirement that the anesthesiologist be present in the room for a procedure, but you want the protocols to be sure that the protocols contain rules about the presence of an anesthesiologist in the building or immediately available somewhere?

MR. GRAF: That's correct. The issue is there's certainly an acknowledgment that not every procedure requires an anesthesiologist to be in the room, and that is really what the purpose of the joint protocols are, to determine to what extent they are. But when an anesthesiologist is -- when they are present, it must be a physical presence. That is the utmost concern. With that, again, that is really a clarification of what the intent of the rule as proposed was.

Where we talk about availability, we said for consult. It could be by these other means, but when we're saying they physically must be present during induction, emergence and change in status, we're talking that they be immediately available physically, not necessarily that they must be present in the room. Again, that's up to the joint protocols to dictate the types of procedures and instances when either – immediate physical presence in the room, in the suite, in the building is appropriate.

MR. BAKER: Any questions or comments from Board members, and then I will be opening this up to the public once again?

MS. WACHTER: I would just state that it's my understanding that currently, let's say in a small community hospital at night, there is not always an anesthesiologist present is my understanding; I could be wrong, but that they're not physically located in the building. And I certainly understand and respect the Commissioner's position that she feels that there should be an anesthesiologist in the building at all times. I'm just stating that I don't think that's current practice in all hospitals everywhere in the State. So it will change a requirement for hospitals, it's my understanding.

MS. PERSICHILLI: I'm going to weigh in here. It's definitely not the practice in smaller organizations.

MS. WACHTER: And it's been probably common practice of quite some time, and I think that's a substantial change to the existing rule. I'm not necessarily saying it's a substantial change from what was proposed in July, but it is a substantial change in hospital policy.

MR. BAKER: Any other comments from Board members? I will open this up to the public once again.

MR. GOODKIND: Kenneth Goodkind, law firm of Flaster Greenberg, and we are counsel to the New Jersey Association of Nurse Anesthetists.

Just on the last point that the two Board members raised, when it is -- it is a substantial change in practice. And let me just cite -- I promised that I wouldn't do this before, but I will just read it very briefly, that the law in New Jersey -- New Jersey Administrative Code, section 1:30-6.3(a) says: Where, following notice of proposal, an agency determines to make changes in the proposed rule, which are so substantial that the changes effectively destroy the value of the original notice, the agency shall give a new notice, a proposal and public an opportunity to be heard, and then I cite from what the case is, or stated another way, considering the rule the agency adopted, the question is whether the proposed notice adequately advised the addressing persons of the agency's adoption. That's from the case in the

adoption of New Jersey Administrative Code 9(a):10-7.8(b), 327 New Jersey super, a 2000 case, New Jersey super 149. I can go on and on with other cites.

But the point is where there is a change, and if the change is something that the hospitals, especially rural hospitals, would not have been aware of, it will considered a substantive amendment and not a technical one that can be promulgated in this fashion. In opinion by the Office of the Administrative Law, it is not dispositive on the issue of whether changes to a proposed rule warrant reproposal or a technical amendment. And one of the decisions there, the one I just cited, as well as In Re, adopted amendments, New Jersey Administrative Code 7:15-8 349, NJ super 320, a 2002 case. So no matter what the Office of Administrative Law may or may not have opined at this point, it is a matter that requires de novo review by the Appellate Division.

The joint protocols, and for perspective here, this proceeding started out back in the summer in respect to rulemaking petitions filed by the New Jersey Association of Nurse Anesthetists. It was not seeking relief, so to speak, or a regulation of the nature of the current one where the anesthesiologist's presence is required. So I would question and I'd ask you to think about it before you take further action.

You are now considering an amendment that is not in accordance with the proposed rulemaking that was started and commenced at the behest of the New Jersey Association of Nurse Anesthetists. So I think there's some question whether it was proper to go forward and expand the regulations to a scope that was not promulgated. There is case law, and this I will not cite to you, but you can't turn a regulation -- you may propose at some point another regulation, and by you, I don't mean you, personally, but this process could not affect changes that were not contemplated by what was requested. And I think that may be where we are here.

A joint protocol -- again, we refer to the law, but they go back as far as 2000. I'm quoting from the Division of Consumer Affairs. But the joint protocols do not place physicians in a supervisory position, and they were never intended to deal with any practice area outside of prescriptive authority.

The last point that I want to make, and I referenced before the APN law, in the joint protocol regulation, which is N.J.A.C. 13:37-6.3, and it does say, as I said before, and I'm looking now at subsection C, and that's where language comes in. The content of a joint protocol, quote, shall address, and a number of things in there, but not what we're talking about. And interestingly, or at least significantly, in subsection D, failure to establish and implement joint protocols consistent with the standards set forth in this section in any violation of a joint protocol by an advanced practice nurse or a physician may be deemed professional misconduct or other grounds for disciplinary sanction within the meaning of various rules.

And the point of that is that since the law says address and we are now looking at a regulation that says required, there's a serious question as to whether or not that is a protocol that is consistent with the law, and not only nurse anesthetists but physicians, anesthesiologists, and even the surgeons who are implementing this because the surgery is taking place as part of their team and under their guidance. People may face the prospect, so you're going to have some concern, unless there's a further clarification that a regulation like this does not violate the other law and subject them to discipline.

So again, I would respect everything you've been doing. You've obviously given this serious thought and consideration, but I do think this is a misstep. If there is any language in here that talks about requirement of the presence of an anesthesiologist and something, frankly, that is the representative nurse anesthetists, and speaking for that association, I don't know how we can find that acceptable and I ask you to reconsider that. Thank you very much.

MR. BAKER: Thank you.

MR. GRAF: If I might, just to discuss, the language saying sections governing would remain in. So it doesn't say that the joint protocols require the presence. It says: Instead of having joint protocols addressing sections governing, it just says: The protocol requires sections governing. So that all we're

doing is making sure that the protocols, themselves, discuss the availability of presence. It is not a change. We have removed that language from -- the proposed amendment before the Board is to remove the direct connection between the word require and the presence. So that way it is up to the joint protocol as to whether and how presence is required and necessary for whatever cases.

MR. GOODKIND: Will you be able to provide us with copies? I'm sure the words are significant and you gave a lot of thought how you worded them, so I want to study the exact language. Will that be available later today?

MR. GRAF: We'll have the change later today.

MR. BAKER: Later today.

MR. GRAF: If you have the draft before you, it's fairly easy to dictate.

MR. BAKER: Go back to the original language from the August publication. The word address comes out and it's replaced by require. And then where the current notice --

MR. GOODKIND: I know the change -- you didn't change anything from what was on the amendment when we came in this morning?

MR. GRAF: No. We are.

MS. RAGANELLI: So I believe the existing amendment on adoption will change address sections governing -- instead of saying address sections governing, it's going to say require sections governing. So require sections governing the availability and the presence.

MR. BAKER: Whereas, what had been proposed just said would require availability and require presence.

MS. RAGANELLI: The change on adoption we originally had said require, delete sections governing require the availability and the presence. Now it just reads require sections governing the availability and the presence. So the only word changing on adoption is address to require.

MR. GRAF: And the renumbering sections is a technical matter.

MR. BAKER: Any other questions or comments by the Board? If not, I guess we have a couple of choices.

MR. GOODKIND: Just to clarify -- it will say, if I have got that down right, if the protocol -- it will require a section that – two things. One, that it addresses presence, and another that addresses availability in certain circumstances?

MR. GRAF: Correct, in line with the proposal as proposed.

MR. GOODKIND: Could it be that the section requiring presence will have just a very limited circumstance where presence is required? I'm asking.

Is that how you intended it, or does it mean there will be sections that must always have --

MR. GRAF: The intent is that the section should discuss when presence is required, not that we're saying that for all situations presence in the room is required. Generally, the Commissioner would like to see that there be presence of an anesthesiologist in the building available at these times, but not necessarily for all cases, for all situations that there must be someone in the room or even someone –

someone should be immediately available, the Commissioner would like, in case there's emergencies, but physically is her concern.

MR. GOODKIND: Hypothetically, could it say presence shall not be required except, and we'll describe some kind of extremely urgent or life-threatening surgery, that will be acceptable? Is that contemplated so the presence will be very limited?

MR. GRAF: Again, it's joint protocols between the anesthesiologist and the APN. So therefore, it should be for the – those performing to determine which cases. I don't want to say the presence as a general matter is not required. That is, again, up to the joint protocols. It's up to the practice of the two professions for which there are two boards that govern that, rather than Public Health interjecting into that argument.

But our purpose is we want to make sure that it is something that is fleshed out between the two professionals during the joint protocols. And when they do say that their presence, that it is someone physically present, not someone who is only on the phone trying to gauge a situation that could be emergent.

MR. GOODKIND: My impression, it seems to me that what this could result in, though, and I will say empowering or entitling the anesthesiologist to dictate when presence is required. Whereas, if you had the word address, they would have to discuss and come to a resolution, the nurse anesthetist and the anesthesiologist. This seems to shift that decision-making power, at least enforce an opportunity, that at least in my view, is inconsistent with the statute that I just read to you that said address. And that would mean if the two professionals disagreed, they addressed it, this would seem to empower one party to the other to dictate that. That's why I think it goes beyond what was requested in rulemaking.

MR. GRAF: Our concern is it shouldn't be left as an open issue. Something of that magnitude should be discussed and worked out between the two parties, that if something is -- we're addressing it, but we're not putting it in there because we disagree, I don't think benefits patient safety. I think it certainly should be, and the Commissioner believes it should be something that is in the joint protocol, discussed for which procedures and --

MR. GOODKIND: Certainly we're all on the same page in advancing the patient safety. The Commissioner has always been that way, and we won't belabor it because you saw all the studies over the summer. But the practice of anesthesiologists is literally a couple hundred times safer than it was 30 years ago. And the incident rates are extremely, extremely low. So we're at a margin here that's quite small. And nurse anesthetists are as qualified as anesthesiologists based on the studies that I have seen to address those emergency situations. The question is, though: Why does the statute not say require those subjects -- require presence to be addressed? The statute and the legislature has spoken and says it just needs to be addressed. It's not required to be in there, and that's where I think the tension is, and that's why what was requested in rulemaking did not go this far. So I think, respectfully, I think the Commissioner's view is one that is not consistent with the statute.

MR. BAKER: Thank you. Would anyone else in the public like to be heard?

MR. SHEARER: Bob Shearer, President, New Jersey Association Nurse Anesthetists. I think basically what will happen then is, okay, Bob, here's your joint protocol. Take it or leave it. That's what will happen, and that will happen all through the State, if this goes through the way it is. The negotiation goes away.

MS. WACHTER: There are layers on that that I understand is not addressed in the responses to the comments. But it was mentioned earlier by, I believe, Pat Barnett is that there is an economic gain by anesthesiologists to require that they be present in the room to supervise, oversee, whatever terminology you want to use, but they can bill Medicare an additional -- between $330 and $485 for standing in a room and watching a nurse anesthetist administer anesthesia. And I have a problem with that because I

think that it really truly clouds their -- or influences their decisions in writing a joint protocol that should be about patient safety only. But when you throw economics into the mix, I think it really has a different influence. It's just something I feel compelled to state on the record.

MR. SHEARER: That, to me, I would think then we need to have a second surgeon standing next to the surgeon in case an emergency arises.

The circulating nurse, does she need a second nurse next to her in case an emergency arises? I mean, it will be take it or leave it. I'm supervising you. I have control. I have the power. Sign it or go try to get a job somewhere else. Thanks.

MR. BAKER: Anyone else in the public? We'll close the public portion for a second time. I guess we have a few options. We could approve as originally presented to us. We can approve with the section amended to reflect -- to add back the original language from August but replace the word address with the word require. We could adjourn the meeting to a date certain, no later than Tuesday of next week and come back and take action on it, or we could -- before the deadline, because I don't think any of us would want the regulations to expire. That would be a bad thing. Or we could do nothing, in which case the regulations would expire. For my part, I don't see a significant, if any, change affect from the word addressing sections -- which shall address sections governing availability and presence, which shall require sections governing the availability and presence. We are not requiring availability.

We're not requiring presence. We're requiring that this document, the protocol, address both those and requiring that it address both of those.

So from a practical standpoint and negotiating standpoint, if the anesthesiologist is going to say: Well, you haven't addressed it, I'm not signing it, I don't see it -- practically a difference in the negotiating standpoint, well, it says you're required to address it and you haven't addressed it. I understand the concerns, but I don't think that the language we're discussing changes it.

I do have some concern that the way that the Commissioner is indicating, through her representative on the Board, that presence in a facility is required under certain circumstances may have a practical impact on the functioning of the facility, and I leave to Mary or Judy, who are experts in that area, to enlighten us further. But I don't think that the language change that's being proposed is substantive, and I will rely on others about the impact of the Commissioner's statement, and then I will entertain motions.

Are there any other comments?

MS. WACHTER: I have concerns that the Commissioner's comments were the implication that a physician needs to be available and that an advanced practice nurse in anesthesia is not educated or trained to manage emergencies. I think that that intense thought philosophy flies in the face of some very recent policy documents that have been released, one in the Journal of Nursing Economics in May and June of 2010, and then another in one of the nation's most reputable health policy journals called Health Affairs, which was issued in August of 2010, which states that there is no harm found when a nurse anesthetist works without the supervision of a physician. The third policy document that has been released since the July meeting is the Institute of Medicine's report on the future of nursing, and which was developed by a very, very broad base of experts in healthcare, including many physicians, that states specifically as one of their top four messages that nurses should be able to practice within the full extent of their training and education, and that it's imperative that policymakers across the country embrace that message and policy and move forward with reflecting that in policy documents that get crafted as they begin to change.

And I just feel very strongly and disappointed, quite frankly, that these major policy documents, studies of thousands of Medicare claims that show no difference in mortality have been virtually ignored in a lot of the responses in the Department's comments, as well as reflected, I believe, in the Commissioner's

concern that a physician is the only one who can manage an emergency. So I just want to make sure I go on record in stating that.

MR. BAKER: Comments from any other members?

MS. PERSICHILLI: Not only do I agree with what Mary just said, my concern is how we're interpreting this language change to mean that there is a collaborative process between the anesthesiologist and the nurse anesthetist to develop the protocol and the intent that the Commissioner has shared with her representative seem to be in conflict. So that causes me some concern because, in fact, I believe in certain circumstances, certainly nurse anesthetists can practice to the full potential of their license and education and practice independently. That doesn't seem to be what the Commissioner's intent is. And my concern is that even if we change the language as it's reviewed, as it's reviewed by the – and from hospital to hospital by any -- by the Department of Health that reviews this type of information, it's open to an interpretation that we did not intend. So we're almost at crossroads at this point in time.

And the other thing that bothers me is that we're talking as if the anesthesiologists and the nurse anesthetists work in a vacuum. These are hospital standards. The governing body of hospitals are responsible for the quality of care that's delivered within their organization. They're also responsible for understanding the level of care and the differences between community hospitals, small, rural hospitals, suburban hospitals, urban hospitals and academic medical centers and what is required to bring the highest quality at the lowest cost to their community. And so protocols would never be developed in a vacuum. And I don't know if the conflict will ever be resolved when there's an economic motivation, and that's what I hear right now, is that this is economically motivated. It's who is present, who can bill, rather than who has the education to do what is right within the limits of their own license.

I think we're at a crossroads here. And I don't think -- I was fine until I heard the intent that seemed to be in conflict with what the actual change from address to require meant. So I suggest we go back to address section governing, the prior language, or I can't support it.

MR. BAKER: Thank you, Judy. Anyone else?
Christine?
Devon?

MR. GRAF: Well, I wanted to respond. One, obviously, the proposal is the proposal. I mean, what was done in August, and certainly the change that we're looking at is, as we believe, not really a change. I think if you put address in there, I don't think that's going to change how the Commissioner views what presence is. I mean, we're not -- again, there is an issue of whether the definition of presence and trying to incorporate that, which we -- obviously, I don't think anyone would agree to a definition of that. That wouldn't be considered substantive requiring reproposal and notification.

So I think the amendment, itself, is fairly innocuous. And I know you're concerned with what I stated as being the Commissioner's feeling about what presence means. I still go back. It's not saying that every procedure requires there to be presence. The issue is when there is presence, what does presence mean to the Commissioner. And presence means to the Commissioner that someone is physically available in order to do that.

So in the joint protocol, if there's a situation and that if there is no presence required in any form, because whatever reason, maybe it's a conscious sedation, it's certainly a low-risk procedure or something, that's not saying that there is requirement that there be an anesthesiologist present in the building during those times. However, if there is something in the protocol to say that there is a significant change, and in the protocol they say the anesthesiologist should become present, then that means that the intent, according to the Commissioner, would be that the person get over to the hospital to assist, to the extent that's feasible. I mean, obviously, you may have an emergency that comes and goes in five minutes, and that's not going to happen.

Again, the joint protocol is what is ruling here, not the -- and that's what the language says, regardless of the presence or how people are interpreting what I'm saying. So I guess I kind of -- hopefully not misstating anything, as far as what it is, so it seems more alarmist than it is, but I don't think there's any intent upon the Commissioner to have a big requirement that there be anesthesiologists 24 hours a day at the facility in case there happens to be an emergency or need. She wants that the joint protocols decide that. The joint protocols should say: If there's no surgery planned, however there's an emergency surgery that has to happen, what happens. And like I said, the availability for consult, you know, does not require presence in the building. However, if there is presence required, she just doesn't want some doctor that's from another state being called up and being asked questions over the phone in those situations, which would be, I think, fairly limited would be why she would prefer having an anesthesiologist on site at that point.

So I hope I clarified. Again, I'm trying not to -- I don't think it's a big change in what we're doing. If it is, or what I'm articulating, I'm probably saying it wrong, then. Because I think her concern is more of how – who is present and why are they present, and that's what I'm clarifying, which again, is really going to be addressed in the joint protocols. And it doesn't alter what the regulation says. And it was only because I was asked as far as where our understanding of a presence means.

Does it mean they have to be in the room at all times? And that's a definite no. Do they have to be in the operating suite? No. Again, it's up to the professionals to decide when is it appropriate, how it is appropriate, and for them to work on that in that mode.

MS. WACHTER: But I think it did say that the Commissioner's intent is that an anesthesiologist must be available on site.

MS. PERSICHILLI: But the regulations state that. I feel like I'm really missing some here, you guys. I mean, I'm grappling with this. I feel like we're only changing the word address to require.

And with all due respect, does it matter what the Commissioner intends? The regulations are going to leave this all up to the protocol. What am I missing?

MS. WACHTER: I disagree, Mary Kay. I think that because the word presence is not defined, the practicing community is going to be looking for the intent of the Commissioner and what she means by the word presence. And if her intention is that the word presence means that there has to be an anesthesiologist physically present in the building, it changes what is required currently and current practice, and I think also flies in the face of a lot of the newly published public policy and research that does not support that; an anesthesiologist is the only one that can manage an emergency.

MR. GRAF: My question is, through the Chair, are you saying that the joint protocols would be written saying that for every procedure there must be presence? Are you saying that's how the nurse anesthetists would be agreeing to the joint protocol? In that case, you're right. But what I'm stating is that -- my view of what a joint protocol is would be delineating certain procedures, certain procedures where they say: Presence isn't required. Well, if presence isn't required, then an anesthesiologist need not be in the building. I think there's certain situations in the joint protocol where they're stating an anesthesiologist should be present, then we're saying presence would mean the person would be on site in some capacity, and then you detail what that means, whether it's available, they could be in an operating suite, they could be doing rounds because it's not that big of a deal, but you don't want them a half hour away, or whether they should be in the room. But again, that should be up to the joint protocols that are drafted.

MS. WACHTER: But it was my understanding that you clarified that the Commissioner's intent of the word presence is that an anesthesiologist would be immediately available on site. And I can give you an example of a small community hospital that would have a patient with an dissecting aortic aneurysm that's rolling through the Emergency Department that needs to be on the operating room table within minutes to save the patient, and the only one in the building is a nurse anesthetist. And it sounds as

though the Commissioner's concerned that she would want an anesthesiologist also to be in the building 24 hours a day to be there to support that emergent case. And I'm saying that I don't think that's appropriate, and I don't think that goes on now, and that's --

MR. GRAF: What I'm stating is what do the joint protocols say about emergency care? The joint protocol talks about that situation and says: Obviously, you've got to induct somebody on an emergent basis, that this is an out of the ordinary type situation, that there is no need because it's not a 24-hour surgicenter, that you're anticipating to have this type of surgery.

What I'm saying is the joint protocol, itself, should address those situations and then say: If there's an emergent situation, if there's a need, then at that point to say: Call up the anesthesiologist and say: You need to be here because there's a problem. But depending on what the diagnosis is, depending on what the situation is, depending on, I think, the practicality of it, whether -- if it's something that can be dealt with in ten minutes and the person lives half an hour away, obviously, there's got to be common sense put into this.

And I think we're deferring to the joint protocol and saying -- when we say joint protocol says that the person must be present, we're not saying that every situation that's the case. But what we're saying is when the joint protocol says the person must be present, we're saying we want them physically on site, but not necessarily every situation is going to require that at these stages that would be feasible. I don't think there's any intent that there has to be a 24-hour anesthesiologist because there may be an emergency. I think for those things that you can gauge and schedule and understand that there's surgeries, then that's a different type of protocol.

MS. WACHTER: So the Commissioner doesn't feel that an anesthesiologist has to be in the hospital 24 hours a day in case there's an emergency that was unexpected?

MR. GRAF: I would say no. I mean, as far as what my communications have been with the Commissioner, she is not stating that. She's not stating there must be 24-hour anesthesiologist available on site, only that this -- again, it depends on the situation. But for a situation where normal surgeries are from eight in the morning until eight at night, and then only emergencies are dictated, then the joint protocols would address that as a separate situation.

MR. BAKER: Christine? Thank you, both.

MS. STEARNS: Well, I just want to start off by saying that patient safety is clearly everyone's top concern, and that I appreciate everyone's discussion today. I have learned a lot, and I think what I take away from this is that the joint protocol is perhaps the best way to try to get there and is critical to all of this.

And I want to raise one concern that, for me, I'm troubled by the potential of this language being interpreted to require physical presence always, and that the potential impact that that could have on hospital costs, the anesthesiologist in the room with the nurse –

MS. WACHTER: Advanced practice nurse.

MS. STEARNS: So I hope that we do watch that issue closely because of the impact that would have on the cost of healthcare or on hospital costs.

But those two things being said, I thought to try to move our discussion along it made sense to make a motion to approve the notice of adoption of the hospital licensing standards codified at N.J.A.C. 8:43G, but with the change on page 100, so that -- which would read -- I don't know how much of it for the record -- I need to read the whole sentence, I guess. An APN, slash, anesthesia in accordance with the joint protocol established in accordance with N.J.A.C. 13:37-6.3, standards for joint protocols between

advanced practice nurses and collaborating anesthesiologists, which joint protocol shall require sections governing, and then the rest of the section as it was presented to the Board.

MR. BAKER: As I understand that, that would also include on page 99 in section (e)3 the same change?

MS. STEARNS: Yes.

MR. BAKER: And on page 100 it's in two sections, both on (n)3, (j)3, which I believe you just read, and in a prior page the same change on (e)3. I will second that. And I want to thank Devon for clarifying, and the Board members for asking the questions and Devon clarifying that this does not indeed, and it is not the Commissioner's intent to require the presence of an anesthesiologist in all procedures, just that on procedures where the protocols indicate the presence is required, that that presence be somewhere in the facility, and that this does not -- is not the intention of the Department to require this in emergent situations, and that it's the protocols that will control that.

Any further discussions?

Can I have a roll call? The other thing that I would ask would be that in the published comments, and I'm not sure how to accomplish it, but that the published comments in response to how this section as amended would be interpreted be written up to reflect the discussions that we have just had.

MR. GRAF: Yes. That change will be made.

MR. BAKER: Thank you.

MS. STARK: Mr. Graf?
MR. GRAF: Yes.
MS. STARK: Ms. Gaenzle?
MS. GAENZLE: Yes.
MS. STARK: Ms. Persichilli?
MS. PERSICHILLI: No.
MS. STARK: Ms. Stearns?
MS. STEARNS: Yes.
MS. STARK: Ms. Wachter?
MS. WACHTER: No.
MS. STARK: Ms. Roberts?
MS. ROBERTS: Yes.
MS. STARK: Mr. Baker?
MR. BAKER: Yes.
MS. STARK: Five yes.

MS. ROBERTS: I know the Department mentioned that at some point maybe consider adding. I will get the rule proposal originally back from August and I don't see a definition of presence there, either, but that might clarify it at the appropriate time.

MR. BAKER: Thank you. Thank you all for your patience and for your fine contributions and comments. I want to thank the public and staff, as well.

We are adjourned.

(Whereupon, the meeting was adjourned at 1:20 p.m.)