

**State Board of Health
Minutes
September 17, 2015 – 9:00 a.m.
Perimeter Center, 9960 Mayland Drive
Richmond, Virginia 23233**

Members present: Bruce Edwards, Chair; Brad Beall; Theresa Brosche; Tommy East; Jim Edmondson; Megan Getter; Linda Hines; Wendy Klein, MD; Hank Kuhlman; Benita Miller, DDS; Faye Prichard; John Seeds, MD; Jim Shuler, DVM; Amy Vest; and Mary Margaret Whipple

VDH staff present: Dr. Marissa Levine, State Health Commissioner; Bob Hicks, Deputy Commissioner for Community Health Services; Dr. David Trump, Chief Deputy Commissioner; Joe Hilbert, Director of Governmental and Regulatory Affairs; Catherine West, Administrative Assistant; Cathy Peppers, Administrative Assistant; Maribeth Brewster, Risk Communications Manager; Matt LiPani, Public Information Officer; Erik Bodin, Director, Office of Licensure and Certification; Susan Puglisi, Policy Analyst, Office of Licensure and Certification; Steve Harrison, Director, Office of Radiological Health; Stan Orchel, X-Ray Program Supervisor, Office of Radiological Health; Dr. Adrienne McFadden, Director, Office of Minority Health and Health Equity; LaNisha Childs, Field Operations Coordinator, Office of Epidemiology; and Tangye Harris, Senior Epidemiologist, Office of Epidemiology

Others Present: Cindy Bailey, Robin Kurz, Allyson Tysinger, and Sarah Allen, Office of the Attorney General; Cindy Davis, Deputy Director, Virginia Department of Housing and Community Development; Ron Clements, Assistant Director of Building Inspections, Chesterfield County Government

Call to Order

Mr. Edwards called the meeting to order at 9:00 a.m. Ms. Getter led those in attendance in the pledge of allegiance.

Welcome and Introductions

Mr. Edwards welcomed the large turnout of members of the public to the meeting, located in both Boardroom 2 and Boardroom 1. He also reminded the public to maintain appropriate decorum during the meeting. In particular, Mr. Edwards asked the audience to be polite during the meeting, and to please refrain from waving of hands and signs. Mr. Edwards said that members of the audience would be given an opportunity to display their signs during the public comment period. Mr. Edwards stated that those members of the public that are disruptive during the meeting will be escorted out by security. He also indicated that due to the large number of action items on the Board's meeting agenda, there will be two public comment periods.

Following introductions, Mr. Hilbert reviewed the agenda and the items contained in the Board's notebooks. The agenda was approved by unanimous consent.

Approval of Minutes

A motion was made and seconded to approve the draft minutes of the June 4, 2015 Board meeting. Ms. Getter noted two corrections that needed to be made. First, in the last line of the fourth paragraph on page four, add the characters “-220” between “412” and “C” to correct the citation for the Virginia Administrative Code. The end of the sentence now reads “. . . infection prevention (12VAC5-412-220 C).” Second, in the third line of the last paragraph on page seven, remove the word “other” between the words “to” and “regulatory” as well as the word “not” between the words “requirements” and “covered” so that the line now reads “. . . related to regulatory requirements covered by the variance. Mr. Bodin said that any” The amended minutes were approved by unanimous consent.

Commissioner’s Report

Dr. Levine began the Commissioner’s report to the Board with the introduction of the “agency stars” for the meeting: LaNisha Childs and Tangye Harris, both with the Office of Epidemiology.

Dr. Levine then provided the Board with an update on the development of Virginia’s Plan for Well-Being, which will be Virginia’s State Health Improvement Plan. The plan is still being drafted, with a key first step being the development of metrics. Dr. Levine said that those metrics will be shared with the Board in the near future, and will be presented to the General Assembly’s Joint Commission on Health Care on October 7. Dr. Levine told the Board that this is very important work for VDH, and that the Board’s continued input and feedback would be greatly appreciated.

Next, Dr. Levine briefed the Board concerning healthcare-associated infections (HAI). New state reporting requirements for hospitals will take effect on September 25, as the result of regulatory amendments previously approved by the Board. Hospitals already required by CMS to report HAIs, but reporting will now be streamlined and more informative.

Dr. Levine then provided an update concerning the newborn screening program. As a result of regulations recently promulgated by the Board, the newborn screening program has expanded to include screening for critical congenital heart disease.

Dr. Levine ended the Commissioner’s report by providing an update on a recent VDH key personnel change: Dr. Ted Tweel is the new District Director for the Three Rivers Health District.

There was a brief discussion concerning newborn screening in the event of home births. There was also discussion concerning the extent to which VDH monitors the frequency of different types of medical procedures, such as surgeries.

Matrix of Pending Regulatory Actions

Mr. Hilbert reviewed the summary of all pending VDH regulatory actions. Since the June 2015 meeting, there have been two regulatory actions that the Commissioner has taken on behalf of the Board while the Board was not in session. These actions are:

- Emergency Medical Services Regulations (12VAC5-31) – Approval of final exempt amendments; and
- Regulations for the Licensure of Nursing Facilities (12VAC5-371-191) – Approval of the withdrawal of pending fast track amendments pertaining to the implementation of electronic monitoring in nursing homes. After publication of the fast track amendments, several stakeholders advised VDH that certain provisions in the regulatory text go beyond provisions of the 2004 guidelines. VDH agrees and plans to initiate a new fast track regulatory action that is more consistent with the 2004 guidelines.

Mr. Hilbert advised the Board that there are three periodic reviews in progress:

- Regulations Governing Do Not Resuscitate Orders (12VAC5-381);
- Rules and Regulations Governing Campgrounds (12VAC5-450); and
- Rules and Regulations Governing the Construction of Migrant Labor Camps (12VAC5-501).

Abortion Facility Licensure Overview and Status Report

Mr. Bodin provided the Board with the abortion facility licensure status report. Mr. Bodin told the Board that there is a change to the information contained on slide two with regard to the number of licensed abortion facilities. One facility, which has a variance, will be closing due to the retirement of the owner. This reduces the number of licensed facilities to 17 and the number of facilities with a variance to 12. One complaint involving a licensed facility was received just prior to the Board meeting, and an additional complaint for the same facility was received since the June 2015 Board meeting (for a total of two complaints). Those complaints were investigated and the allegations were unsubstantiated. An additional complaint has been received and is being scheduled for survey. In addition, a facility self-reported a situation to VDH which will be scheduled for survey.

At the June 2015 meeting, there was a discussion concerning how the results of abortion facility inspections compare with other types of facilities that are inspected by VDH. Mr. Bodin told the Board that VDH has not completed that comparison but that a quick check of the numbers for the 3½ years that abortion facilities have been regulated is comparable to the same time period for ambulatory surgery centers.

Mr. Bodin also told the Board that, while there is not a legal requirement for OLC staff to report suspected crimes identified during facility inspections, he has instructed his staff that—as professionals—they are expected to adhere to a higher ethical and moral standard to report such incidents.

There was a brief discussion concerning the fact that OLC's use of the term "unsubstantiated" with regard to facility complaints could mean that the allegation could have been true at the time the complaint was filed, but was corrected prior OLC arriving at the facility to investigate the complaint.

There was additional discussion concerning facility citations for incomplete medical records; that all facilities have written transfer agreements with hospitals, that only one facility performs only medication abortions, and the process that VDH surveyors follow to ensure that abortion facility staff comply with continuing education requirements. Mr. Edmondson asked Mr. Bodin, based on the facility inspections that have been performed, if he had any reason to believe that the clinics have unusual mortality or morbidity. Mr. Bodin responded that nothing VDH has seen thus far would indicate that is the case.

Ms. Getter requested that VDH better define the term "unsubstantiated" with respect to the investigation of facility complaints as she does not believe that its meaning is clear. Mr. Bodin said that VDH would try to do so, but also explained that one of the difficulties is that VDH investigates what the conditions are at the time of the survey, which may not be the same as the conditions at the time of the event which triggered a complaint. Ms. Getter said that "no evidence found to substantiate the claim" would be better wording. Mr. Bodin responded that that wording may be something to consider.

Ms. Getter asked if the OLC ever shut down a hospital or outpatient facility or revoked a license in response to a deficiency or series of deficiencies. Mr. Bodin said no, but also explained that if OLC identifies a situation in which the facility's patients are in immediate jeopardy, the OLC inspectors remain in the facility until the immediate jeopardy problem is corrected. Ms. Getter asked if OLC tracks the instances where that has occurred. Mr. Bodin said yes, it is recorded in the CMS database but he did not know how easily that data can be queried and retrieved from the database. Ms. Getter asked Mr. Bodin to confirm that any abortion facility deficiency over an "F" on the VDH severity index would trigger a revisit. Mr. Bodin said that was correct, and that VDH has never identified a deficiency as being over an F during an abortion facility inspection.

Mr. Bodin told the Board that under the current regulations, there is no difference between surgical and medication abortion providers, so no change in the license is needed if a facility decided to stop performing medication only abortions and start performing surgical abortions, or vice versa. However, if the regulations are amended as proposed, there would be a difference and a license may need to be reissued to reflect the change in capability, after evaluation by OLC to ensure that the facility is meeting the requirements of the regulation. This would not be treated as a new license.

Public Comment Period 1

Mr. Edwards outlined the procedure for the first public comment period. This public comment period, as stated on the agenda, would cover the topics of the Regulations for Licensure of Abortion Facilities; Regulations for the Licensure of Hospitals in Virginia; Regulations for Licensure of Nursing Facilities; and related topics. In order to maximize the number of people

that can speak, Mr. Edwards said that Mr. Hilbert would call the name of the speaker and an on-deck name for the next speaker. Mr. Edwards further stated that there are two sets of sign-in sheets for the public comment period; one for Boardroom 2 and one for Boardroom 1. Mr. Edwards explained that names would be called from the sheets for Boardroom 2 first and then if time allows, from the sheets for Boardroom 1. Mr. Edwards asked that speakers comply with the two-minute time limit. He also stated that any person signed up to speak could cede their time slot to another individual. Finally, he asked that speakers not be unduly repetitive of what other speakers have already said.

Mr. Edwards said that the chair would entertain a motion to extend the time for the public comment period in order for the Board to hear from as many individuals who have signed up to speak as possible. Mr. Edmondson moved that the comment period be extended from the standard 20 minutes to 60 minutes. Mr. East seconded the motion. The motion was adopted unanimously by a voice vote.

Delegate Kirk Cox and 29 other individuals spoke during the public comment period. Twenty-eight individuals spoke in support of the proposed amendments to the Regulations for Licensure of Abortion Facilities. One individual spoke in opposition to the proposed amendments to the Regulations for Licensure of Abortion Facilities.

Delegate Cox commented that the issue of abortion draws passionate voices from both sides of the aisle. He said that the debate over abortion was brought back into the spotlight by recent videos, which are appalling. He told the Board that the General Assembly has requested an investigation, but the Governor has said that investigation is not necessary because of strong regulations. He told the Board that the intent of the legislation mandating the regulations (SB924 of 2011) is not ambiguous, by requiring that facilities performing five or more first trimester abortions per month be classified as a type of hospital. Delegate Cox told the Board that by voting to roll back the regulations, it is circumventing the intent of the General Assembly.

The individuals who spoke in support of the proposed amendments to the abortion facility regulations expressed several concerns. Many individuals stated that construction requirements are not related to patient safety, and of their approval of proposed amendments to these requirements. In addition, many individuals commented that the current regulations are not based on medical evidence and urged revisions to the regulations.

The individual who spoke in support of the current abortion facility regulations stated she is pro-life and that abortion is murder.

Mr. Edwards asked Ms. Getter to go into Board Room 1 to observe the public in that room. He then asked that those individuals that did not have an opportunity to speak who support the proposed amendments to the regulations to stand. He then asked that group to be seated and asked that those individuals that did not have an opportunity to speak who oppose the proposed amendments to the regulations to stand. He then asked that group to be seated. Finally, he indicated that those having signs could carefully hold up the signs for the Board to look at. He then declared public comment period 1 to be ended and asked that the signs be put back down. Mr. Edwards thanked the members of the audience for their input.

Regulatory Action Items

Rules and Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) – Proposed Amendments

After a brief break, Mr. Bodin presented the proposed amendments. The proposed amendments are in response to a petition for rulemaking to bring the regulations into alignment with § 32.1-127.001 with regard to architectural drawings and specifications requirements for hospitals. Two regulatory panels were convened during the process of drafting the proposed language. The proposed amendments update five sections of the regulations that address building design and construction. The proposed amendments update references, the titles of the guidelines, and provide clarity. The proposed amendments change the phrase “according to” to “consistent with” to better reflect how the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, published by the Facility Guidelines Institute (FGI), work in conjunction with the Virginia Uniform Statewide Building Code. The proposed amendments also reflect changes for consistency with wording in other facility regulations. Finally, the proposed amendments also remove sections that fall under the purview of the Department of Housing and Community Development (DHCD). Mr. East moved that the proposed amendments be approved with Dr. Klein seconding the motion.

Ms. Brosche asked who is authority having jurisdiction (AHJ) in Virginia. Mr. Bodin responded that the AHJ is the State Health Commissioner with regard to the FGI Guidelines. Ms. Brosche also asked if Mr. Bodin could provide examples of situations that would pose a distinct hazard to life and require renovations, repairs, or modifications. Mr. Bodin responded that he could not, as such would need to be evaluated on a case-by-case basis. Mr. Bodin also said that to speculate as to specific examples may create false assurances that may be applied to similar, but not exact, situations.

There was a discussion concerning several aspects of the proposed amendments, including architectural certification of drawings and specifications for new construction, and approval of the FGI guidelines by major medical associations, and application of the FGI guidelines in the event in the change of use or function of a structure. There was additional discussion concerning the difference in meaning between the terms “alteration,” “renovation,” “repair,” and “addition.” Dr. Miller suggested that the terms “rehabilitation” or “major repair” would be more accurate for inclusion in the regulations. Ms. Getter asked if the FGI guidelines contain a definition for “renovation.” Dr. Levine responded that there is a renovation section in the FGI guidelines.

Ms. Getter made a motion to change the word “and” to “or” in the first sentence of 12VAC5-410-445 A on page two of the proposed amendments. Dr. Seeds seconded the motion. Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

There was then a discussion regarding certificates of occupancy for facilities. Mr. Kuhlman asked if there are any licensed abortion facilities that do not have a certificate of occupancy. Mr. Bodin said that all of the facilities have a certificate of occupancy issued by the building official

of the locality in which the facility is located. Mr. Kuhlman stated that, according to recent media reports concerning Freedom of Information Act requests submitted to local building officials, several of the facilities did not have a certificate of occupancy. Mr. Bodin responded that, during the initial licensure survey for each facility, the OLC inspector verified the presence of a certificate of occupancy in each facility. Ms. Davis, with DHCD, told the Board that the lack of certificates of occupancy in certain jurisdictions could be due to records retention practices in those offices.

Ms. Getter made a motion to restore 12VAC5-410-650 B and 12VAC5-410-1350 B. Both of these subsections were recommended for removal in the proposed amendments. Both sections refer to the inspection and approval of buildings by the appropriate building regulatory entity. Ms. Vest seconded the motion. There was a discussion about what type of construction this section refers to, and that VDH proposes removal because it does not control the inspection process or issuance of a certificate of occupancy; rather, it falls under the purview of the local building officials. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Getter made a motion to add the word “Uniform” between the words “Virginia” and “Statewide” in the fourth sentence of the third paragraph of 12VAC5-410-650 as well as the fourth sentence of the second paragraph of 12VAC5-410-760. She further moved to add the word “to” after the word “conform” in the fourth sentence of 12VAC5-410-1350. These sections are on pages four and five of the proposed amendments. Mr. Edmondson seconded the motion.

Ms. Prichard asked that VDH staff be directed to make these types of wordsmithing corrections to the proposed amendments rather than making motions to make non-substantive changes. Ms. Bailey commented that the Commissioner can act for the Board when the Board is not in session to approve those changes. Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

There being no further discussion, Mr. Edwards then called for a vote on the main motion to approve the proposed amendments as amended during the foregoing discussions. The proposed amendments were approved unanimously by a roll call vote.

Regulations for the Licensure of Nursing Facilities (12VAC5-371) – Proposed Amendments

Mr. Bodin presented the proposed amendments. The proposed amendments are in response to a petition for rulemaking to bring the regulations into alignment with § 32.1-127.001 with regard to architectural drawings and specifications requirements for nursing facilities. The proposed amendments update two sections of the regulations that address building design and construction. The proposed amendments update references, the titles of the guidelines, and provide clarity. The proposed amendments change the phrase “according to” to “consistent with” to better reflect how the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, published by FGI, work in conjunction with the Virginia Uniform

Statewide Building Code. The proposed amendments also reflect changes for consistency with wording in other facility regulations. Finally, the proposed amendments also remove sections that fall under the purview of the DHCD. Dr. Klein moved that the proposed amendments be approved with Mr. East seconding the motion.

Ms. Brosche made a motion to add a comma after the word “renovations”, remove the next word “or”, and add a comma and the words “or repairs” after the word “alterations” in the first line of 12VAC5-371-410 so that the sentence reads: “A. All construction of new buildings and additions, renovations, alterations, or repairs of existing . . .” Ms. Getter seconded the motion. Ms. Brosche indicated that this change will make this section consistent with its counterpart section in the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

Ms. Brosche made a motion to add a sentence to the end of the paragraph for 12VAC5-371-410 B that states “The certification shall be forwarded to the OLC.” Ms. Vest seconded the motion. Ms. Brosche indicated that this change will make this section consistent with its counterpart section in the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

There being no further discussion, Mr. Edwards then called for a vote on the main motion to approve the proposed amendments as amended during the foregoing discussions. The proposed amendments were approved unanimously by a roll call vote.

Lunch

Mr. Edwards queried the Board about taking a break, picking up lunch, and working through lunch on the next agenda item. The Board approved by unanimous consent to take this course of action.

Regulations for Licensure of Abortion Facilities (12VAC5-412) – Proposed Amendments

Dr. Levine presented the proposed amendments. She stated that, since the June 4th Board meeting, VDH had received additional proposed amendments to the regulations from various interested parties. However, after consultation with the Office of the Attorney General (OAG), all but three of the additional proposed amendments were not included as part of VDH’s recommended amendments since they were determined to be outside the scope of the Notice of Intended Regulatory Action (NOIRA). Three of the additional proposed amendments, based on consultation with the OAG, are considered technical amendments and therefore can be considered to be within the scope of the NOIRA. Dr. Levine stated that the Board does not have the authority to repeal the regulations because they are mandated by the Code of Virginia. VDH convened two regulatory panels, one for medical issues and another for building design and construction issues, to provide recommendations for proposed amendments to the regulations.

The current regulations will stay in effect until any approved proposed amendments go through the entire regulatory development process. The proposed amendments cover the following areas:

Definitions

Technical change. Addition of the terms medication induced abortion and surgical abortion in order to tailor the facility design and construction guidelines more precisely to the requirements of each facility. Change in the definition of first trimester.

Classification

Repeal the section as it is unnecessary due to Code requirements and this section of the regulations is more stringent than the Code requirements.

Violation of this chapter or applicable law; denial, revocation, or suspension of license.

Amend this section to include guidance issued by the Virginia Department of Health Office of Licensure and Certification.

Patient services; patient counseling

Remove an unnecessary restriction not required by the Code. Clarify the requirements of parental consent. Ensure all requirements of parental consent are within the regulations. Make additional technical changes which are in line with medical best practices.

Medical testing and laboratory services

Remove an unnecessary documentation requirement. Reformatting. Incorporate additional best practice standards. Remove an unnecessary mandate, which will allow the patient and physician to work together to determine the best course of action. Insert a new requirement which will allow tracking of lab results.

Anesthesia Service

Incorporate additional best practice standards. Add a documentation requirement.

Emergency Services

Align these provisions more precisely with medical best practices. Remove an unnecessary provision that is not required due to federal requirements.

Facility Design and Construction

Update the design and construction requirements; bring into alignment with the opinion issued by Attorney General Mark Herring, issued to the Commissioner on May 4, 2015.

Documents Incorporated by Reference

Update those documents incorporated by reference to reflect the most current publications.

Ms. Whipple moved that the proposed amendments be approved with Dr. Miller seconding the motion.

There was a discussion that in the original NOIRA that the Board approved in December 2014, the scope was very narrow in terms of the regulatory sections that would be reviewed for

proposed changes. The proposed amendments contain revisions that are technical in nature, to three additional regulatory sections that were not in the NOIRA. Ms. Bailey advised the Board that the three additional sections are allowed to be included in the NOIRA. Some members of the Board expressed concern that the public should have had an opportunity to comment on these three additional areas as part of the NOIRA. Dr. Levine and Ms. Bailey advised the Board that, as the regulatory process is a three-stage process and that the amendments before the Board today are only proposed amendments, there will be additional opportunity for the public to comment during the 60 day public comment period following publication of the proposed amendments and, in addition, the final amendments will come before the Board for review and approval at a future meeting.

There was a discussion that an area identified in the NOIRA at the Board's December 2014 meeting concerning the administration, storage, and dispensing of drugs is not included in the proposed amendments. Dr. Levine advised the Board that further review of this section of the regulations indicated that an amendment was not needed. Statutory and regulatory authority for that topic resides with the Board of Pharmacy and it is VDH's procedure to refer any issues related to medications and providers it finds during a survey of abortion facilities to the Board of Pharmacy. Mr. Bodin told the Board that communication between VDH and the Department of Health Professions (DHP) has improved and that there is now a requirement that DHP report findings back to other agencies that have referred concerns to them. VDH's inspection procedure has not changed. There was continued discussion that facilities and its providers have to be in compliance with all laws and regulations that govern them, whether those laws and regulations are with VDH or other enforcement entities (such as DHP for providers). Dr. Levine told the Board that there is a broad responsibility for a facility to be in compliance with applicable federal, state, local statutes and regulations as outlined in the general section of the current regulations.

There was a discussion about the wording of the definition of "first trimester" in 12VAC5-412-10 to include a reference to the required ultrasound that must be performed 24 hours prior to an abortion in accordance with § 18.2-76 of the Code of Virginia. During the discussion, Dr. Levine and Ms. Bailey indicated to the Board that providers must comply with this requirement and therefore it did not have to be included in the regulations. There was further discussion about the exceptions that are outlined in § 18.2-76 of the Code of Virginia. Dr. Seeds told the Board that an ultrasound is more accurate in determining gestational age than a clinical examination and that having the reference included in the regulations clarifies the obligation. Dr. Seeds made a motion that the following words be removed from the definition of first trimester in 12VAC5-412-10: "based on an appropriate clinical estimate by an appropriately trained licensed provider working within the scope of his license," and add the following after the word "conception": "as determined in compliance with § 18.2-76 of the Code of Virginia." The sentence now reads: "'First trimester' means the first 12 weeks from conception as determined in compliance with § 18.2-76 of the Code of Virginia." Mr. Beall seconded the motion. Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

Dr. Seeds moved that the definition of "trimester" be removed from 12VAC5-412-10. Ms. Brosche seconded the motion. Dr. Seeds informed the Board that a trimester is not 12 weeks but

rather three months. Because a normal pregnancy is 40 weeks, you cannot evenly divide 40 by 3. He indicated that this definition should be removed because it is inaccurate and not necessary. There was a discussion between the Board members on what a trimester is and that this definition does not impact any other part of the regulations. Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

Dr. Seeds moved that the wording in 12VAC5-412-230 A be changed to be consistent with the definition of first trimester in 12VAC5-412-10. Mr. Beall seconded the motion. There was a discussion that changing the language in this section of the regulations does not preclude a licensed provider other than a physician from determining if a patient is in the first trimester. Ms. Brosche shared information that had been received by her from the Department of Health Professions, in regards to the type of licensed provided that can perform the “appropriate clinical estimate” as referenced in 12VAC5-412-230 A; and the type of “qualified medical professional trained in sonography” that can perform the ultrasound imaging to determine gestational age, as referenced in § 18.2-76 B. The sentence now reads “A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy as determined in compliance with § 18.2-76 of the Code of Virginia.” Mr. Edwards called for a vote on this motion to amend the proposed amendments as presented by VDH. The motion was approved unanimously by a voice vote.

There was a request that the proposed amendments be reviewed section by section.

Mr. Beall made a motion to include §§ 32.1-125.2, 32.1-126.1, 32.1-126.3, 32.1-127.1:03, 32.1-127.1:05, and 32.1-137.02 with the sections listed in 12VAC5-412-130 that would result in suspension or revocation of a facility’s license if violated. Ms. Getter seconded the motion. There was discussion that the current wording of 12VAC5-412-130 is overly broad. Mr. Beall said that his intent was to make the list more complete. Dr. Levine explained that the amendment as proposed by VDH lists only the statutory sections that are relevant to VDH’s authority. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Getter made a motion to remove VDH’s proposed amendment in 12VAC5-412-130 A and 12VAC5-412-130 B so that the sections will remain as they are in the current regulations. Mr. Beall seconded the motion. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Getter made motion to add language to 12VAC5-412-130 A regarding civil penalties. Specifically, in line 5 of that section, after the words “department may”, add a subsection 1 to read: “1. Petition the court to impose a civil penalty pursuant to § 32.1-27 of the Code of Virginia; or”. Further, to create a second subsection, insert “2.” before the words “deny, suspend, or revoke . . .” Ms. Vest seconded the motion. There was discussion that this proposed change is unnecessary as the provision is already in the Code of Virginia and VDH can request that the Office of the Attorney General file an action on behalf of VDH. Mr. Edwards called for

a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was five ayes, nine nays, and one abstention. The motion failed.

Ms. Getter made a motion to add language to 12VAC5-412-130 to create a new subsection B to deny a license to a facility. Mr. Beall seconded the motion. The new subsection B would read: “The department may deny a license to: 1. A corporate applicant if the corporate entity has an owner, director, or officer: a. Whose conduct caused the revocation of a prior license; or b. Who held the same or similar position in another corporate entity which had its license revoked; 2. An individual applicant: a. Whose conduct caused the revocation of a prior license; or b. Who held a position as owner, director, or officer in a corporate entity which had its license revoked; 3. An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.” Adding the new subsection B would then renumber the existing subsections to C, D, and E. Ms. Bailey advised the Board did not have statutory authority to deny a license as proposed by the amendment. Mr. Edwards ruled the motion was out of order.

The Board approved a short break by unanimous consent.

After the break, Ms. Brosche made a motion to remove VDH’s proposed amendment to repeal 12VAC5-412-30 so that the section will remain as it is in the current regulation. She further moved to add the words “pursuant to § 32.-127” after the word “hospital”. Ms. Prichard seconded the motion. Ms. Vest made a secondary motion to add the letter “B” to “32.1-127” so that the statutory citation reference would be correct. Mr. Beall seconded the secondary motion. There was a discussion that this is the only reference to classification in the regulations and retaining the section would make the regulations consistent with the hospital regulations. Mr. Edwards called for a vote by show of hands on the secondary motion to amend the proposed amendments as presented by VDH. The vote was nine ayes and six nays. The secondary motion was approved. Mr. Edwards then called for a vote by show of hands on the primary motion as amended by the secondary motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Vest made a motion to amend 12VAC5-412-230 D by adding the following words “the licensed physician performing the abortion shall be currently licensed in advanced resuscitative techniques and” after the words “are being performed” in the first line of this subsection. She further moved that the words “a staff member currently certified to perform cardiopulmonary resuscitation” be removed. Finally, she moved that the following sentence be added to the end of the subsection: “All staff members assisting in the abortion shall be currently certified in basic cardiopulmonary resuscitation.” 12VAC5-412-230 D would read “When abortions are being performed, the licensed physician performing the abortion shall be currently licensed in advanced resuscitative techniques and shall be available on site for emergency care. All staff members assisting in the abortion shall be currently certified in basic cardiopulmonary resuscitation.” Ms. Brosche seconded the motion.

There was a discussion about the importance that a physician performing the abortion be able to respond appropriately if an emergency arises. There was further discussion that this is re-stating the standards of care, that this is covered by the regulations of the Board of Medicine, that activities by health care practitioners are referred to the appropriate licensing Board, and that this

proposed change is unnecessary and duplicative. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Mr. Beall made a motion to remove VDH's proposed amendment in 12VAC5-412-230 E in the last sentence of that subsection so that it would remain as it is currently in the regulations with respect to the words "and post abortion counseling." Mr. Kuhlman seconded the motion. There was a discussion that the amendment as proposed by VDH is taking out some key wording. There was further discussion that there is reference to counseling in parts of that section. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was seven ayes and eight nays. The motion failed.

Ms. Getter made a motion to move the words "appropriate counseling" in the second sentence of 12VAC5-412-230 E after the words "instruction in the abortion procedure," and insert the "and" between "procedure" and "appropriate". The line would read ". . . she understands, instruction in the abortion procedure and appropriate counseling, and shall. . . ." Dr. Seeds seconded the motion. There was a discussion that the informed consent section covers counseling before an abortion is performed, that this proposed change would add clarity, that the proposed change is getting into practice protocols, and that the counseling should not be only about the abortion care as this change would indicate. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Mr. Beall made a motion to amend 12VAC5-412-230 F to add the words "excessive bleeding, and/or acute unrelieved pain" after the word "develop" in the last line of that subsection. Dr. Seeds seconded the motion. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was seven ayes and eight nays. The motion failed.

Ms. Getter told the Board that 12VAC5-410-1270 E (hospital regulations) contains a provision for making family planning information available to patients receiving an abortion. Dr. Levine advised the Board that that section pertains to outpatient surgical hospitals and that abortion facilities do not fall under that category. Dr. Miller commented that the Board had just voted on a motion about providing family planning counseling. Ms. Getter made a motion to remove the words "or referral for" in the third sentence of 12VAC5-412-230 E. There being no second, this motion failed.

Ms. Getter made a motion to add the words "and subject to a \$2,500 civil penalty" after the word "Virginia" in the last sentence of 12VAC5-412-230 C. Ms. Vest seconded the motion. Ms. Getter indicated that facilities are not being penalized for citations during inspections. Ms. Bailey advised that it is not under VDH's purview to enforce § 18.2-76 of the Code of Virginia. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was five ayes, nine nays, and one abstention. The motion failed.

Ms. Vest made a motion to remove VDH's proposed amendment in 12VAC5-412-240 A 3 so that the subsection remains as it is in the current regulations. Mr. Beall seconded the motion. There was a discussion that the facilities have been screening for sexually transmitted diseases and this requirement has not been burdensome. There was further discussion that VDH does want patients to be assessed for risk and tested when appropriate but to be less prescriptive in the regulations about how that is accomplished. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Getter made a motion to strike VDH's proposed amendment to 12 VAC5-412-240C and replace it with the following new language: ". . . the patient shall be evaluated in order to assess for risk of an ectopic implantation in early pregnancy. Each facility must have a written protocol to evaluate ectopic pregnancy. All relevant staff at the site must be familiar with the protocol, including referrals as appropriate. A plan for when and how to seek emergency medical attention must be reviewed and documented. Resolution of the pregnancy must be verified, tracked, and logged. Patient follow-up must continue until one of the following has been documented: 1) The diagnosis of ectopic pregnancy has been excluded, 2) Clinical resolution of an ectopic pregnancy has been ensured, or 3) Transfer of care to an appropriate provider has been made." Mr. Beall seconded the motion.

Ms. Getter told the Board that her proposed amendment is based on the recommendation of the National Abortion Federation. There was discussion concerning the relevance and very prescriptive nature of the proposed amendment. Dr. Seeds said that the amendment proposed by VDH falls short of the standard of care. Dr. Klein stated that VDH's proposed amendment was based on the recommendation of a physician regulatory advisory panel. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Brosche made a motion to amend 12VAC5-412-250 C, by inserting "and shall be documented in the patient's medical record," after the word "administration." The motion was seconded by Ms. Vest. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was eleven ayes and four nays. The motion passed.

Ms. Vest moved to add three subdivisions to 12VAC5-412-250 B. The proposed language reads: "1. Deep sedation, general anesthesia or a major conductive block shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist. 2. Moderate sedation/conscious sedation may be administered by the operating doctor with the assistance of and monitoring by a licensed nurse, a physician assistant or a licensed intern or resident. 3. Any doctor who administers office-based anesthesia without the use of an anesthesiologist or certified registered nurse anesthetist shall obtain four hours of continuing education in anesthesia each biennium." Mr. Kuhlman seconded the motion.

There was a discussion concerning risks associated with use of anesthesia and the importance of patient safety. There was additional discussion that the regulations already require compliance with the office-based anesthesia regulations of the Board of Medicine. The Board also discussed

the process by which OLC ensures that its facility inspection surveyor workbooks accurately and completely reflect all regulatory requirements. Mr. Bodin said that OLC could expand the surveyor workbook so that it includes the documents that are incorporated by reference (i.e., Board of Medicine office-based anesthesia regulations) into the abortion facility regulations. Dr. Seeds requested that the updated workbook be shared with the Board at the December meeting. Mr. Bodin responded that he would make that presentation in December. There was further discussion concerning the need to hold facilities accountable for deficiencies cited during inspections. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Brosche then told the Board that she would not be presenting an additional amendment she had prepared for the office-based anesthesia section of the regulation because of the information Mr. Bodin provided during the meeting, about expanding the surveyor workbook to include the office-based anesthesia regulation and other regulatory requirements.

Ms. Getter made a motion to amend 12VAC5-412- 250 B, after the word “shall”, strike “be directed by and under the supervision of a physician licensed in Virginia” and insert “be administered by a physician licensed in Virginia in accordance with 12VAC25-20-10.” There being no second, this motion failed.

Ms. Brosche made a motion to reinsert all of the stricken language in the first two sentences of 12VAC5-412-290 C. Mr. Beall seconded the motion. Dr. Levine told the Board that the Board of Medicine office-based anesthesia regulations contain a transfer agreement requirement, and VDH’s proposed amendments do not change that requirement. Mr. Beall said that, since the Commissioner has not granted any variances to this regulatory requirement, reinserting the requirement does not appear to be problematic. There was discussion concerning EMTALA requirements. There was also discussion about the difference between EMTALA and transfer agreements; and Ms. Brosche shared that the wording in this section, that is being proposed for removal, is supported by other state regulations. Mr. Edwards called for a vote by show of hands on the motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Whipple made a motion to revise the proposed amendments to 12VAC5-412-370. Specifically, she moved that the words “alterations” and “repairs” be removed in the first sentence of 12VAC5-412-370 A and add the words “major renovations” between the words “additions” and “to existing buildings”. She also moved that the word “with” in sentence two of subsection A be removed. Further, she moved that in subsection A, remove the words “In addition, abortion facilities” in line four and insert the words “All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility” before the words “that perform only surgical.” Further, she moved that in line 6 of subsection A, remove the words “3.1 and” between the words “sections” and “3.8.” Further, in line 11 of subsection A, remove the words “Part 1 and section 3.1 of Part 3” after the words “and constructed consistent with” and before the words “of the 2014 Guidelines” and replace those words with “Part 1, sections 1.1, 1.3, and 1.4.” Finally, she moved that in subsection A, add a new paragraph between the paragraphs that begin “All construction of new buildings. . .” and the

paragraph that begins “Architectural drawings and specifications. . .” that reads “Abortion procedures may take place in a procedure room, as detailed in section 3.8-3.1, except that minimum square footage requirements for procedure rooms used for the provision of surgical abortion do not need to be greater than 120 square feet, with a minimum room dimension of 10 feet and a minimum clear dimension of 3 feet at each side and at the foot of the bed. Rooms designed in accordance with section 3.8-3.2 are not required for abortion facilities. Section 3.7-3.6.13.1(2) shall not apply to facilities that do not have a room designed in accordance with section 3.8-3.2.”

The first paragraph of 12VAC5-412-3701 A now reads:

“A. All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall conform to state and local codes, zoning ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility that perform only surgical abortions or a combination of surgical and medication induced abortions shall be designed and constructed consistent with Part 1 and section 3.8 of Part 3 of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute, pursuant to § 32.1-127.001 of the Code of Virginia. Abortion facilities that perform only medication induced abortions shall be designed and constructed consistent with Part 1 sections 1.1, 1.3 and 1.4 of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute.”

Mr. Edmondson seconded the motion.

Ms. Whipple told the Board that the intent of her proposed amendment is to provide for the “grandfathering” of existing facilities, to make clear that these provisions are for new facilities or major renovations, and to make the regulations less burdensome.

Ms. Bailey told the Board that it had the statutory authority to approve the proposed amendments.

At that point, at the request of Mr. Edwards, Ms. Vest made a motion to table the pending motion. Mr. East seconded the motion, and the motion was approved by unanimous consent.

The Board then took a short break.

Upon completion of the break, Ms. Vest moved to take the pending motion from the table. Ms. Prichard seconded the motion. The motion was approved unanimously by voice vote.

There was a discussion concerning the substance of Ms. Whipple’s proposed amendment. Dr. Seeds noted that the proposed amendment strikes the reference to section 3.1 of the 2014 FGI guidelines. Ms. Whipple stated that the proposed amendment includes section 3.8, which refers back to section 3.1. Dr. Levine said that section 3.1 is the foundational section of the FGI guidelines for outpatient facilities. Ms. Whipple said that section 3.1 was not needed in the regulations, while Dr. Seeds said that striking 3.1 affects the rest of the paragraph. Mr. Beall

expressed concern about striking provisions that had been recommended by the building regulatory advisory panel. Ms. Getter asked why the Board would want to exclude minimum requirements in section 3.1.

Mr. Edmondson stated that many parts of section 3.1 are not relevant. There was additional discussion concerning the substance and merits of Ms. Whipple's proposed amendment. Ms. Getter requested to hear from Mr. Clements, at which point Dr. Levine explained that Mr. Clements' expertise was with the Virginia Uniform Statewide Building Code, and not the FGI guidelines. Mr. Clements told the Board that use of the term "renovation" was problematic in that it is not a term used by the building code. Mr. Edmondson responded that the word "repair" is not found in the building codes with which he is familiar. Ms. Whipple then reminded the Board that the proposed amendment would still need to go through the executive branch review process. Mr. Edwards called for a roll-call vote on this motion to amend the proposed amendments as presented by VDH. The vote was nine ayes (Mr. East, Mr. Edmondson, Mr. Edwards, Ms. Hines, Dr. Klein, Dr. Miller, Ms. Prichard, Dr. Shuler, and Ms. Whipple) and six nays (Mr. Beall, Ms. Brosche, Ms. Getter, Mr. Kuhlman, Dr. Seeds, and Ms. Vest). The motion was approved.

Dr. Seeds moved that the last paragraph of 12VAC5-412-370 A be restored in VDH's proposed amendment so that part of the subsection remains as it is in the current regulations. Ms. Vest seconded the motion. There was a discussion concerning the number of abortion facilities that have received a variance pertaining to the requirements of this section, and how many variances have been granted to abortion facilities operated by Planned Parenthood. There was additional discussion concerning the extent to which this regulatory section poses a burden to abortion facilities. There was further discussion concerning the Attorney General's Opinion and the FGI guidelines. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and nine nays. The motion failed.

Ms. Getter asked if VDH had issued guidance concerning the differing regulatory requirements for medical and surgical abortions. Dr. Levine said that such guidance would be developed once the regulatory amendments take effect. Mr. Getter asked if the separation of medical and surgical abortions would affect any other part of the regulations. Dr. Levine responded that the separation would only affect the building design and construction requirements. There was discussion concerning the failure rate for medication abortions.

Mr. Edmondson made a motion to call the pending question. The motion was seconded by Ms. Whipple. Mr. Edwards then called for a roll call vote on the motion to call the pending question. The vote was nine ayes (Mr. East, Mr. Edmondson, Mr. Edwards, Ms. Hines, Dr. Klein, Dr. Miller, Ms. Prichard, Dr. Shuler, and Ms. Whipple) and six nays (Mr. Beall, Ms. Brosche, Ms. Getter, Mr. Kuhlman, Dr. Seeds, and Ms. Vest). The motion failed as passage required a two-thirds vote of the Board.

Ms. Getter expressed continued concerns about the complication/failure rate of medication abortions. Dr. Levine commented that the Board's discussion was focusing on standard of care issues, while the proposed amendments focus on building design and construction requirements.

Ms. Getter told the Board that the decision to separate medication from surgical abortions has implications for other sections of the regulations, beyond merely the design and construction provisions. There was further discussion concerning medical abortion complication rates.

Ms. Getter made a motion to remove the distinction between medical and surgical abortions. Ms. Vest seconded the motion. There was further discussion concerning the standard of care for medication abortions. Mr. Edwards called for a roll-call vote on this motion to amend the proposed amendments as presented by VDH. The vote was five ayes (Mr. Beall, Ms. Brosche, Ms. Getter, Mr. Kuhlman, and Ms. Vest) and ten nays (Mr. East, Mr. Edmondson, Mr. Edwards, Ms. Hines, Dr. Klein, Dr. Miller, Ms. Prichard, Dr. Seeds, Dr. Shuler, and Ms. Whipple). The motion failed.

Ms. Getter inquired concerning the rationale for striking the reference to section 3.7 of the FGI in 12VAC5-412-370 A, with respect to surgical abortions. Dr. Levine responded that section 3.8, relating to procedure rooms, was not part of the 2010 FGI guidelines but it is now part of the 2014 FGI guidelines—which is why it was included in the proposed amendments.

Ms. Getter made a motion to reinsert “alterations” and “repairs,” and to strike “major renovations” from 12VAC5-412-370 A. Mr. Edwards said that the Board had already voted on that, and ruled the motion out of order.

There was a brief discussion concerning Roberts Rules of Order.

There being no further discussion, Mr. Edwards then called for a vote on the main motion to approve the proposed amendments as amended during the foregoing discussions. The vote was nine ayes (Mr. East, Mr. Edmondson, Mr. Edwards, Ms. Hines, Dr. Klein, Dr. Miller, Ms. Prichard, Dr. Shuler, and Ms. Whipple) and six nays (Mr. Beall, Ms. Brosche, Ms. Getter, Mr. Kuhlman, Dr. Seeds, and Ms. Vest). The proposed amendments were approved.

Public Comment Period 2

Mr. Edwards outlined the procedure for the second public comment period. This public comment period, as stated on the agenda, would cover any topics not previously identified in Public Comment Period 1. Mr. Edwards asked that speakers comply with the two-minute time limit. He also asked that speakers not be unduly repetitive of what other speakers have already said.

Eleven individuals provided comments to the Board. All of the comments pertained to the Board agenda item: Emergency Regulations and Notice of Intended Regulatory Action – Virginia’s Rules and Regulations Governing Cooperative Agreements 12VAC5-221.

Stephanie Wilkinson from the U.S. Federal Trade Commission (FTC) requested that the Commissioner share information with FTC during her review of any application for a cooperative agreement. Ms. Lindsay Berry, representing Anthem, said that the regulations would have a significant impact on Anthem, and that most states are not equipped to provide the necessary level of regulatory oversight envisioned by the regulations. Mr. Robert Barratta,

representing America's Health Insurance Plans, said that it is impossible to provide the necessary level of regulatory oversight envisioned by the regulations. Representatives from Mountain States Health Alliance and Wellmont Health System expressed general support for the emergency regulations. However, they requested that provisions requiring a Plan of Separation to be included with the application for a cooperative agreement, and authorizing the Commissioner to condition a Letter Authorizing Cooperative Agreement on inclusion of a cap on the negotiated case-mix adjusted revenue per discharge by payer by product, be stricken. Representatives of hospitals, and health care providers, in Southwest Virginia also expressed general support for the regulations. Doug Gray, representing the Virginia Association of Health Plans, expressed support for the Commissioner's authority to condition a Letter Authorizing Cooperative Agreement on inclusion of a cap on the negotiated case-mix adjusted revenue per discharge by payer by product. He told the Board that North Carolina has used a similar provision.

Mr. Edwards declared public comment period 2 ended.

*Virginia's Rules and Regulations Governing Cooperative Agreements (12VAC5-221) –
Emergency Regulations and Notice of Intended Regulatory Action*

Dr. Trump presented the emergency regulations and NOIRA to the Board. He told the Board that the regulatory action is mandated by HB2316 enacted by the 2015 General Assembly. The legislation requires the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applications for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement. The legislation further specified that the regulations must be effective within 280 days of enactment. For that reason, the Board is requested to approve the utilization of the emergency rulemaking process authorized by the Administrative Process Act. The emergency regulations contain provisions pertaining to definitions, a fee schedule, procedures for the Commissioner's request for information, the Commissioner's review, ongoing monitoring, and annual reporting.

Dr. Trump explained that, in drafting the emergency regulations VDH convened a regulatory advisory panel, which met twice. The panel members provided recommendations regarding regulatory language to the State Health Commissioner. VDH reviewed the recommendations of the regulatory advisory panel and regulations for similar programs within other jurisdictions. From that information, VDH created the language which is presented to the Board.

Dr. Trump also told the Board that the Southwest Virginia Health Authority has received a Letter of Intent from Mountain States Health Alliance, and Wellmont Health System, that they intend to submit an application for a Letter Authorizing Cooperative Agreement on or about November 1. The statute authorizes the Southwest Virginia Health Authority to make a recommendation to the Commissioner concerning whether or not a Letter Authorizing Cooperative Agreement should be issued.

Ms. Whipple moved that the emergency regulations/NOIRA be approved. Dr. Miller seconded the motion.

There was discussion concerning the provision authorizing the Commissioner to condition a Letter Authorizing Cooperative Agreement on inclusion of a cap on the negotiated case-mix adjusted revenue per discharge by payer by product. Ms. Whipple said that hospitals in Virginia, particularly those in rural areas, are fiscally-stressed. She also said that the conditioning provision under discussion would not be beneficial to hospitals. Mr. Edmondson asked if Mountain States Health Alliance and Wellmont Health System were both not-for-profit systems. Dr. Levine responded that both of them were not-for-profit.

Ms. Whipple made a motion to add a subsection D to 12VAC5-221-40 that reads “D. If the applicants believe the materials submitted contain proprietary information that are required to remain confidential, such information must be clearly identified and the applicants shall submit duplicate applications, one with full information for the Commissioner’s use and one redacted application available for release to the public.” Mr. Beall seconded the motion.

Ms. Tysinger told the Board that the amendment would apply with respect to the Virginia Freedom of Information Act, to the extent that unredacted information could not be redacted publicly. Ms. Tysinger also said that the proposed amendment basically tracked language in HB2316 and could be defended.

Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was 13 ayes with none opposed. [Note: Ms. Pritchard and Dr. Shuler left the meeting prior to the vote.] The motion was approved.

Ms. Whipple made a motion to amend three sections of 12VAC5-221 with regard to a plan of separation. The first amendment is to 12VAC5-221-10, on page two of the proposed amendments, to the definition of plan of separation. Specifically, remove the words “with an application to return the parties to a pre-consolidation state,” between the words “proposal submitted” and “which includes” and insert the following words in that space: “to the Commissioner, upon notice to a Letter Holder that the Commissioner intends to revoke the approval of a cooperative agreement to the extent necessary to address any anticompetitive conditions then present.” Further, in this section, insert the word “applicable” between the words “separation of any” and “combined” on line 2. The definition now reads: “Plan of Separation’ means the written proposal submitted to the Commissioner, upon notice to a Letter Holder that the Commissioner intends to revoke the approval of a cooperative agreement to the extent necessary to address any anticompetitive conditions then present, which includes a plan for separation of any applicable combined assets, . . .” Ms. Whipple’s second amendment for plan of separation is to 12VAC5-221-70 B 19 on page 7 of the proposed amendments. Ms. Whipple moved that the subdivision 19 as proposed be deleted and replaced with the following: “19. Proposed Process for Separation. The Parties shall provide a description of how they will develop a Plan of Separation to address any anticompetitive conditions identified by the Commissioner as present. The description submitted by the Parties shall set forth the process they will undertake to obtain an independent opinion from a qualified organization that states the proposed Plan of Separation may be operationally implemented without undue disruption to essential health services provided by the Parties.” Finally, Ms. Whipple moved that the proposed 12VAC5-221-110 B language be deleted and replaced with the following: “B. The Parties shall

be required to update the Parties' Proposed Process for Separation annually and submit the updated Proposed Process for Separation to the Department." Mr. Edmondson seconded the motion.

There was discussion concerning how long an applicant would have to submit a Plan of Separation, upon notice from the Commissioner. It was also discussed that Tennessee's regulations governing Certificate of Public Advantage require a Plan of Separation, which is one of the reasons that VDH included the provision. Ms. Getter and Mr. Beall expressed support for continuing to require a Plan of Separation. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was three ayes and 10 nays. The motion failed.

Ms. Whipple made a motion to remove 12VAC5-221-90 C (1), which would eliminate the Commissioner's authority to condition a Letter Authorizing Cooperative Agreement on inclusion of a cap on the negotiated case-mix adjusted revenue per discharge by payer by product. Removing this subdivision will re-number the remaining subdivisions to be 1 through 5. Dr. Miller seconded the motion. Ms. Whipple said that retaining this provision would set a bad precedent, and that there are other ways for the Commissioner to ascertain an applicant's commitment to cost efficiency. There was a brief discussion concerning rate caps in Medicaid and Medicare, as well as concerning Virginia's All-Payer Claims Database. Mr. Edwards called for a vote by show of hands on this motion to amend the proposed amendments as presented by VDH. The vote was six ayes and seven nays. The motion failed.

There being no further discussion, Mr. Edwards then called for a roll-call vote on the main motion to approve the emergency regulations and NOIRA as amended during the foregoing discussions. The emergency regulations and NOIRA were approved unanimously (13 ayes; Ms. Prichard and Dr. Shuler were absent).

By unanimous consent, the Board authorized the Commissioner approve on its behalf the following regulatory action items remaining on the agenda:

Virginia Radiation Protection Regulations 12VAC5-481(Fast track amendments)

Regulations Governing the Virginia Physician Loan Repayment Program 12VAC5-508
(Fast track amendments)

Member Reports

There were no member reports. Mr. Edmondson mentioned that he has discussed with Dr. Levine having an item on a future Board meeting agenda to discuss the public health issue of end of life circumstances.

2016 Proposed Board Meeting Schedule

Mr. Edwards referred to the proposed Board meeting schedule for 2016 as outlined in the members' notebooks: March 17; June 2, June 3, or June 10; September 15 or September 16; and

December 1 or December 9. The members indicated that they prefer the meeting to be held on Thursdays, which would be March 17, June 2, September 15, and December 1. This schedule was approved by unanimous consent.

Adjourn

The meeting adjourned at approximately 8:03 p.m.