

**State Board of Health Nominating Committee
Minutes
June 15, 2012 – 8:30 a.m.
Perimeter Center, 9960 Mayland Drive
Richmond, Virginia 23233**

Members present: Dr. Bhushan Pandya, Paul Clements, and Gail Taylor

VDH staff present: Dr. Karen Remley, State Health Commissioner

The members discussed the slate of officers to recommend to the Board. The meeting adjourned at 8:50 a.m.

**State Board of Health
Minutes
June 15, 2012 – 9:00 a.m.
Perimeter Center, 9960 Mayland Drive
Richmond, Virginia 23233**

Members present: Bruce Edwards, Chair; Paul Clements; Kay Curling (left meeting at 12:15 pm); Eric Deaton; Dr. John deTriquet; Jim Edmondson; Dr. Steven Escobar; Dr. Anna Jeng; Dr. Mary McCluskey; Dr. Bhushan Pandya (left meeting at 10:15 am); Dr. Cathy Slusher; Gail Taylor; and Amy Vest

Members absent: Dr. Charles Johnson and Dr. Bennie Marshall

VDH staff present: Dr. Karen Remley, State Health Commissioner; Jeff Lake, Deputy Commissioner for Community Health Services; Dr. Marissa Levine, Deputy Commissioner for Public Health and Preparedness; Joan Martin, Deputy Commissioner for Administration; Catherine West, Administrative Assistant; Donna Tiller, Administrative Assistant; Susie Horn, Research Assistant; Doug Harris, Adjudication Officer; Gary Brown, Director, Office of Emergency Medical Services; Suzi Silverstein, Director, Office of Risk Communication and Education; Maribeth Brewster, Risk Communications Manager; Dr. David Trump, Director, Office of Epidemiology; Bob Hicks, Director, Office of Environmental Health Services; Allen Knapp, Director, Division of Onsite Sewage, Water Programs, Environmental Engineering and Marina Programs; Steve Harrison, Director, Division of Radiological Health; Dana Sikon, Office of the Chief Medical Examiner; and Dale Kitchen, Office of Drinking Water

Others Present: Allyson Tysinger, Robin Kurz, and Karri Atwood, Attorney General's Office; Jim Stewart, Commissioner, Virginia Department of Behavioral Health and Developmental Services; John Pezzoli, Assistant Commissioner, Virginia Department of Behavioral Health and Developmental Services

Call to Order

Mr. Edwards convened the meeting at 9:05 a.m.

Approval of Minutes

A motion was made and seconded to approve the draft minutes of the March 23, 2012 Board meeting. Mr. Edmondson requested that Katherine Greenier's comments during the public comment period for the March meeting be amended as follows: "As the Board and VDH are directed to compile a list of facilities that provide free ultrasounds, under House Bill 462, the Board and Department must only include in that list facilities overseen by licensed physicians. Many crisis pregnancy centers that are not directed by licensed physicians provide free ultrasounds but they should not be included on the list because HB462 mandates the ultrasound be conducted under the oversight of a physician". VDH staff will make that correction. The minutes were approved as corrected.

Commissioner's Report

Dr. Remley introduced Dr. David Trump, new Director of the VDH Office of Epidemiology. Dr. Remley also introduced VDH's two "agency stars": Dana Sikon with the Office of the Chief Medical Examiner, and Dale Kitchen, with the Office of Drinking Water-Lexington Field Office.

Dr. Remley provided the Commissioner's report to the Board. The report addressed the following topics:

- Emergency Medical Services Medication Shortage,
- VDH response to Navy jet crash in Virginia Beach,
- Health Information Exchange,
- All Payer Claims Database,
- Vital Records Index,
- Uranium Mining and Milling,
- HB462 – Informed Consent for Abortion,
- Access to Dental Care,
- Critical Congenital Heart Disease Demonstration Project,
- Response and Treatment of Anaphylaxis in the School Setting HB1107/SB656,
- FY11 Audit Results,
- Critical Drug/Vaccine Purchases,
- Certificate of Public Need Litigation,
- Infant Mortality,
- Preterm and Late Preterm Births,
- Teen Pregnancy,
- Plan First Enrollment, and
- Abortion Facility Survey Progress.

In response to a question by Dr. Slusher, there was a brief discussion by Dr. Dempsey concerning the different types of contraceptives covered by the Plan First Medicaid family planning program.

Dr. Jeng then commented concerning the importance of teen pregnancy prevention efforts. Dr. Jeng also requested an update from VDH at the September meeting concerning uranium mining and milling, to include a discussion of health and environmental risk assessment.

Public Health Accreditation Update

Mr. Czarda provided an update concerning VDH's efforts to obtain accreditation from the Public Health Accreditation Board. The accreditation process is lengthy, and focuses on the 10 essential public health services. VDH has formed an accreditation team and is starting to gather the necessary documentation.

In response to a question by Mr. Edmondson, there was a discussion concerning the various accreditation domains. There was also a discussion concerning the extent to which direct health care services are provided by VDH and its local health departments and how that has changed over time.

Report of the Nominating Committee

Dr. Pandya provided the report of the Nominating Committee. The committee was comprised of Dr. Pandya, Paul Clements, and Gail Taylor. The Nominating Committee recommended the following slate of Board officers for the year beginning July 1, 2012 and ending June 30, 2013:

Chairman – Bruce Edwards

Vice-Chairman – Paul Clements

Executive Committee Member – Eric Deaton

Executive Committee Member – Dr. Steve Escobar

Mr. Edwards opened the floor for other nominations. Hearing no other nominations, the Board received the Nominating Committee report as a motion to approve the slate of officers. The slate of officers was approved unanimously.

Recognition for Dr. Bhushan Pandya

Mr. Edwards recognized Dr. Pandya and told the Board that this was Dr. Pandya's last Board meeting, as he has served two four-year terms and is not eligible for reappointment. Dr. Remley read a Certificate of Recognition expressing gratitude for Dr. Pandya's service on the Board. Dr. Pandya told the Board that he was very grateful for the opportunity to serve on the Board, and that his membership on the Board had been a great experience. He was very complimentary of his fellow Board members and of VDH staff. Following these remarks, Dr. Pandya left the Board meeting.

Matrix of Pending Regulatory Actions

Dr. Remley reviewed the summary of all pending VDH regulatory actions. Since the March 2012 meeting, there have not been any regulatory actions that Dr. Remley approved on the Board's behalf while the Board was not in session.

Public Comment

After a brief break, Mr. Edwards reminded the Board that, pursuant to the Board's by-laws, the Board meeting was to be conducted pursuant to Robert's Rules of Order. Mr. Edwards then reviewed Robert's Rules of Order with the Board. As part of this review, Mr. Edwards reminded the Board that a second to a motion should only be made if appropriate (i.e., the member intends to vote for the motion). Mr. Edwards also advised the Board that upon a motion to call the pending question, a majority vote can stop any further discussion on a pending matter.

Mr. Edwards then discussed the rules and procedures by which the public comment period would be conducted. Each individual has a maximum of two minutes in which to address the Board. Each speaker is to relinquish the podium when their two minutes have expired. Mr. Edwards said that it is important that everyone who wishes to address the Board has the opportunity to speak, but it is also important to maintain proper decorum.

Mr. Edwards recommended to the Board that, unless a Board member had an objection, the length of the public comment period be extended from the standard 20 minutes to one hour, and then after one hour to reevaluate to determine whether a further extension of time was warranted. In response, Mr. Edmondson suggested extending the length of the public comment period to 1½ hours, which would be until 12:00 noon. The Board, by unanimous consent, agreed to extend the length of the public comment period to 1½ hours. At noon, the Board, by unanimous consent, approved further extending the public comment period to allow seven additional individuals who had signed up to speak to address the Board.

Fifty-six citizens spoke during the public comment period. One individual spoke in support of the proposed guidelines regarding mammography services with respect to breast density. Forty-seven individuals spoke in opposition to all or part of the Proposed Regulations for Licensure of Abortion Facilities. Eight individuals spoke in support of the Proposed Regulations for Licensure of Abortion Facilities.

The individuals who spoke in opposition to the proposed abortion facility regulations stated several concerns. Many of these individuals expressed opposition to the design and construction provisions contained in the proposed regulations. These individuals stated that construction requirements are not related to patient safety, and that the decision to include these provisions in the proposed regulations is inappropriate. These individuals further stated that existing health care facilities have been "grandfathered" by the Board of Health in prior regulatory actions, and that no other entities such as the offices of plastic surgeons or dentists are required to comply with such regulations. Other individuals expressed more general opposition to any regulation of these facilities.

The individuals who spoke in support of the proposed abortion facility regulations stated that the regulations are common sense provisions. These individuals also stated their concern about two abortion facilities in Virginia that are owned by Dr. Stephen Brigham. These individuals also stated that several physicians employed by Virginia abortion facilities have had malpractice claims and had their medical licenses suspended at various times.

Lunch Presentation

Dr. Remley introduced Jim Stewart, Commissioner of the Virginia Department of Behavioral Health and Developmental Services. Mr. Stewart provided an overview of the agency and the services it provides. Mr. Stewart told the Board that Virginia's publicly funded behavioral health system is comprised of public and private providers, and that community services boards (CSBs) are a key point of entry into the system in localities across the Commonwealth.

In response to questions from Board members, there was a discussion concerning how the system is funded, systemic efforts to transition from institutional care to community-based care, substance abuse treatment, crisis response, link between behavioral health system and law enforcement, emergency care for victims of domestic violence, services for children and adolescents, and effectiveness of state hospital services.

Regulatory Action Items

Sanitary Regulations for Marinas and Boat Moorings (12VAC5-570) – Proposed Amendments

Mr. Hicks presented the proposed amendments. He told the Board that these regulations have been in effect since 1968, but were last revised in 1990 and need to be updated. VDH regulates about 1,000 marina facilities and other places where boats are moored. Mr. Hicks introduced Mr. Knapp, who provided a more detailed explanation of the proposed regulatory action. Mr. Knapp said that the regulations provide for adequate sanitary conditions at marinas and other places where boats are moored. The proposed amendments add a third category of regulated entities, boat access facilities. Since 1990, there have been many changes in the marina industry (e.g., increase in water-based recreation, houseboats, living on boats in marinas, increases in dry storage, additional marina services). These changes, coupled with the increased importance of protecting water quality, shellfish harvesting, and other water related activities important to Virginia's economy, point to the need to update the regulations. The proposed amendments were approved unanimously by a show of hands.

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

Mr. Edwards reminded the Board of the legislative mandate for regulations established by SB924 of 2011. Mr. Edwards also described the next steps in the state regulatory process, should the Board approve the proposed regulations. Mr. Bodin presented the proposed regulations to the Board. Mr. Bodin told the Board that the proposed regulations were quite similar in substance to the emergency regulations that are currently in effect. Mr. Bodin said that there were some differences between the emergency regulations and the proposed regulations, most of which were intended to make the proposed regulations more consistent in language and format with other health care facility regulations administered by VDH. He explained the specific differences between the emergency regulations and the proposed regulations. This proposed regulatory action also includes two amendments to 12VAC5-410, Regulations for the Licensure of Hospitals. Mr. Deaton moved to adopt 12VAC5-410 as amended and 12VAC5-412. The motion was seconded by Dr. Slusher. Mr. Edwards asked the Board if there was any discussion concerning the motion.

Mr. Edmondson said that he supports the concept of regulation of abortion facilities, but that he does not support the proposed regulations that have been presented to the Board. Mr. Edmondson said that the Board has the power to approve regulations that are different from those that have been drafted and presented by VDH. Mr. Edmondson said that the Board has a legitimate obligation to promote the health and safety of abortion facility patients. Mr. Edmondson also said that he believes that there are inaccuracies in the Agency Background Document (TH-02), and that the document is flawed. Mr. Edmondson said that the Board needs to rethink how that document is created. Mr. Edmondson said that the Board does not have to take the advice of the Attorney General's Office, although VDH staff must take such advice. Mr. Edmondson said that the Board has its own constitutional responsibilities. He also said that the Board has the authority to differentiate between existing and new facilities. Mr. Edmondson said that it was his hope that the Board did not intend to change the regulations for outpatient and inpatient hospitals so that they are consistent with these proposed regulations. Mr. Edmondson said the regulations are seriously flawed, and that they are not consistent with other health care facility regulations administered by VDH. Mr. Edmondson said that the proposed regulations set precedents that are not in the best interest of the Commonwealth.

Dr. Jeng made a motion to amend 12VAC5-412-370 by replacing the following language: "Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001." with "All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation." For the sentence that begins "Entities operating as of the effective date . . . , Dr. Jeng's motion further deleted the language at the end of the sentence: "if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure".

12VAC5-412-370 would now read as follows:

"All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A

building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation.

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings.”

The motion was seconded by Mr. Edmondson. Ms. Tysinger referenced § 32.1-127.001 of the Code of Virginia, enacted by the General Assembly in 2005, which states that “Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health.”

Ms. Tysinger then advised the Board that the proposed amendment is in violation of the Code of Virginia and that the Board does not have the statutory authority to make the amendment. Ms. Tysinger also advised the Board that all abortion facilities should be considered new facilities, because they have not been previously regulated or licensed.

Dr. Jeng responded by referring to the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, and by referring to guidance issued to hospitals by the VDH Office of Licensure and Certification, which states that the Guidelines only apply to new construction of buildings and major addition. Dr. Jeng also referred to a provision from the VDH Hospital Licensure Regulations, 12VAC5-410-650, which states that the Uniform Statewide Building Code (USCB), and local building and zoning ordinances, takes precedence over 2010 Guidelines for Design and Construction of Health Care Facilities. Dr. Jeng said that the Board has the duty and authority to make the proposed Regulations for Licensure of Abortion Facilities consistent with this current provision of the hospital licensure regulations.

In response, Ms. Tysinger stated that § 32.1-127.001 is not limited to new construction. Ms. Tysinger also advised the Board that the hospital licensure regulations will have to be amended because of inconsistencies with § 32.1-127.001.

Mr. Edmondson responded that the statute does not specifically say that it applies to existing structures. He also said that the Board should rely on the obviousness of the language if the language is not clear. Mr. Edmondson said that he supports Dr. Jeng’s observation, and that the Board should ignore the advice from the Attorney General’s Office.

Mr. Clements stated that it is important to look at the big picture. He said that the advice provided by the Office of the Attorney General is based on its interpretation of the law, but that the Board does not have to agree with that interpretation.

Ms. Vest, referring to photographs of certain existing clinics that had previously been submitted to the Board, stated that she cannot support proposed regulations that do not apply to existing buildings.

Dr. Jeng said that she supports regulatory provisions pertaining to issues such as hygiene, toilets, and fire safety, but she considers the required retrofitting of existing buildings to be inappropriate.

There was a brief discussion between Mr. Edmondson and Ms. Vest concerning the extent to which appropriate ventilation in a facility needs to be addressed through design and construction requirements as opposed to other non-structural requirements.

Mr. Edwards said that, in his view, since these buildings have never been licensed as a facility, they should be considered a new facility. Mr. Edwards stated that the design and construction requirements are a critical component of the proposed regulations.

Mr. Bodin told the Board that the USCB applies to all manner of buildings. Mr. Edmondson said that local ordinances frequently exceed the requirements of state codes.

There was a brief discussion between Ms. Vest and Dr. Jeng concerning whether the USCB addressed issues and topics that are addressed in the 2010 Guidelines for Design and Construction of Health Care Facilities .

The Chair called for a roll-call vote on this motion, 7 in favor (Mr. Clements, Dr. deTriquet, Mr. Edmondson, Dr. Escobar, Dr. Jeng, Dr. McCluskey, and Dr. Slusher), 4 in opposition (Mr. Deaton, Mr. Edwards, Ms. Taylor, and Ms. Vest). This amendment was adopted.

Mr. Edmondson told the Board that the emergency regulations require that a facility's application for initial licensure be accompanied by a copy of the facility's certificate of use and occupancy. Mr. Edmondson proposed amending 12VAC5-412-50.C by adding the following language to the end of the sentence: "or a statement from the facility's architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy". Dr. Jeng seconded the motion. Ms. Tysinger advised the Board that a facility license could not be issued until an occupancy certificate is issued.

Mr. Deaton made a secondary motion to add the word "certified" before the word "architect". Mr. Edmondson agreed that this was a good addition and Dr. Jeng seconded the motion. The Chair called for a roll-call vote, 9 in favor (Mr. Clements, Mr. Deaton, Mr. Edmondson, Mr. Edwards, Dr. Escobar, Dr. Jeng, Dr. McCluskey, Dr. Slusher, and Ms. Taylor), 2 in opposition (Dr. deTriquet and Ms. Vest). The secondary amendment was adopted. The Chair then called a roll-call vote on the primary amendment, 8 in favor (Mr. Clements, Mr. Deaton, Mr. Edmondson, Mr. Edwards, Dr. Escobar, Dr. Jeng, Dr. McCluskey, and Ms. Taylor), 3 in opposition (Dr. deTriquet, Dr. Slusher, and Ms. Vest). This amendment was adopted.

Mr. Edmondson made a motion to change the number of days in 12VAC5-412-50.E from 30 days to 10 days. This section refers to the number of days until the scheduling of the initial on-

site licensure survey once the facility notifies OLC that it is ready for the initial on-site survey. Dr. Jeng seconded. Ms. Vest asked how this time period compares with that found in VDH's other health care facility regulations. Ms. Tysinger responded by saying that she was not sure. Dr. Escobar asked what the impetus is for 30 days.

Mr. Bodin responded that 30 days gives OLC time to complete tasks necessary to schedule and plan for the initial on-site survey. Mr. Bodin also said that 30 days is still a difficult deadline for OLC to meet. Mr. Edmondson said that he is concerned that 30 days will result in a drawn out process. He would like to shorten the period of time that a facility is complete but not in use. Mr. Bodin said that a shortened 10 day timeframe would create expectations that will be very difficult to meet given competing priorities within OLC. Mr. Bodin said this will result in disappointment among the facilities when those expectations are not realized.

Mr. Edmondson withdrew his motion with the unanimous consent of the Board.

There was a discussion concerning 12VAC5-412-60.A. Mr. Edmondson asked if this section refers to compliance with the regulations now or with some change to the regulations that may happen in the future. Mr. Bodin responded that the section refers to the regulation that is in effect at the time of licensing or renewal. Mr. Edmondson then asked if the last sentence of 12VAC5-412-60 is redundant. Ms. Tysinger responded that the Commissioner cannot issue a license unless the facility is in compliance.

Mr. Edmondson made a motion to delete the last sentence of 12VAC5-412-60.A that starts, "Renewal applications shall only be granted . . ." and ends ". . . substantial compliance with this chapter". Dr. McCluskey seconded the motion. Mr. Clements stated that, with the removal of that sentence, it appears to him as if a facility could pay the licensure renewal fee but not be inspected. Dr. Remley said that the sentence promotes clarity and follows the Code of Virginia. Mr. Edmondson withdrew his amendment with the unanimous consent of the Board.

Mr. Edmondson discussed whether to replace the second sentence of 12VAC5-412-60.B with the following: "If an application is submitted after the 60-day deadline, then a renewal, if granted, will be delayed by as many calendar days as the length of the delay in submission, in which case the facility will not be allowed to operate during the delay. If the application is more than 30 days late, then the facility will have to re-apply for licensure." There was a discussion concerning the fact that 12VAC5-412-60.B is consistent with the provisions of other VDH health care facility regulations. This section of the proposed amendments was not amended by the Board.

Mr. Edmondson made a motion to add the words "or permanent" before the word "variance" in the first sentence of 12VAC5-412-80.A, and to further delete the word "temporary" wherever it appeared in 12VAC5-412-80. The motion was seconded by Dr. Jeng. Ms. Tysinger advised the Board that it is authorized by the Code of Virginia to issue "reasonable" variances to its regulations. Ms. Tysinger also advised the Board that the Office of the Attorney General's interpretation of the statute was that the Board could grant a temporary, one-time variance to provide a facility with time to come into compliance with the regulations.

Mr. Deaton asked if temporary variances have a time limit. Dr. Remley responded by saying that it depends. VDH would follow a careful, common sense approach in considering the issuance of variances, taking into consideration actual conditions. At a maximum, a variance would be good for the duration of the license; however, a variance could be issued for a time period shorter than the duration of a license. When a license comes up for renewal, the continued need for the variance would be reassessed. Dr. Remley emphasized to the Board that she follows a very thoughtful process prior to issuing a variance to any VDH regulation. Dr. Remley told the Board that she has not issued a variance to any health care facility. Mr. Edwards said that the Board should be careful not to encumber the Commissioner's ability to handle discretionary matters.

Mr. Edmondson made a motion for a secondary amendment, to add the following sentence after the first sentence of the 12VAC5-412-80.A, "In no event shall a temporary variance exceed the term of the license." This motion was seconded by Mr. Deaton. This motion was approved unanimously by the Board by a show of hands.

Mr. Edmondson then withdrew his motion for the primary amendment with the unanimous consent of the Board.

Dr. Jeng made a motion to delete the words "Pursuant to § 32.1-25 of the Code of Virginia, . . ." from the beginning of 12VAC5-412-90. She further moved that the words "who displays a valid identification" be inserted after the words "Virginia Department of Health" and the words "during normal business hours" be inserted after the words "into the premises . . ." She further moved that the word "may" in the second sentence that begins "Any such employee . . ." be deleted and the words "has the right to" be inserted in its place. The motion was seconded by Mr. Edmondson. There was a discussion among Mr. Clements, Mr. Deaton and Mr. Edmondson concerning whether or not it was necessary to specify that an inspector only had the right to enter a facility premises during normal business hours. Dr. Remley told the Board that OLC inspectors would not come to a facility during an unreasonable time, and would come during normal business hours for the facility.

There was discussion concerning valid identification of OLC inspectors. Mr. Edmondson said that abortion facility staff are concerned about intruders. Mr. Edmondson asked how the Board can make sure that facilities have the right to demand to see valid identification of OLC inspectors. Dr. Remley responded by saying that OLC inspectors are required to show identification when they arrive at a facility. Dr. Remley also said that if OLC inspectors fail to display valid identification, facility staff have the right not to allow the OLC inspector to enter the facility. Dr. Remley told the Board that all of the abortion facilities on-site surveys that have been conducted to date have been performed by senior, experienced medical facility inspectors.

Ms. Tysinger advised the Board that the citation to § 32.1-25 in this section of the proposed regulations is the statutory citation that gives the Commissioner the authority to enter and inspect facilities upon the display of proper credentials.

The Chair called for a roll-call vote on the motion, 2 in favor (Mr. Edmondson and Dr. Jeng), 9 in opposition (Mr. Clements, Mr. Deaton, Dr. deTriquet, Mr. Edwards, Dr. Escobar, Dr. McCluskey, Dr. Slusher, Ms. Taylor, and Ms. Vest). The motion failed.

After a short break, Mr. Edmondson made a motion to amend 12VAC5-412-100.B regarding onsite inspections. The amendment would change the section so that it reads as follows: “The abortion facility shall make available to the OLC’s representative any requested records on site at the facility, except that if OLC representatives request patient medical records, the facility shall first redact any potentially identifying information before OLC representatives may review them. The facility shall allow access to interview the agents, employees, and contractors under the facility’s control, direction or supervision. OLC representatives may not disclose any information obtained in compliance with this Section except as necessary for his or her job duties. Such disclosure may subject the representative to disciplinary action, including job termination. In addition, these documents shall not be available through any open records or freedom of information requests.” Mr. Edmondson said that this amendment is intended to address concerns of the abortion facilities regarding disclosure of certain types of information contained in patient medical records. Dr. Jeng seconded the motion.

Dr. Slusher said that the Board spent extensive time addressing this issue at its September 2011 meeting when it approved the emergency Regulations for Licensure of Abortion Facilities. Dr. Slusher said that amendments to the emergency regulations approved by the Board in September 2011 concerning this issue were sufficient. Dr. Slusher said that OLC inspectors must comply with HIPAA. She also said that as long as the records remain on site at the facility, it is meaningless to redact the records. Certain information should be redacted from a record only if the record leaves the facility.

Dr. Remley told the Board that protecting the confidentiality of patient information is of critical importance to VDH. Dr. Remley assured the Board that the language of the proposed amendment is duplicative of what VDH is already required to do by law. Dr. Remley also told the Board that individual patient records are exempt from disclosure under the Virginia Freedom of Information Act (FOIA). Dr. Remley also told the Board that Virginia is a “closed state” for purposes of providing certified copies of vital records.

Ms. Tysinger advised the Board that it could not include an exemption to FOIA as part of the regulation. Ms. Tysinger further advised the Board that it does not have authority concerning termination of VDH employees. Employee termination is at the discretion of VDH. Mr. Edmondson withdrew his motion, with the unanimous consent of the Board.

Mr. Edmondson moved that 12VAC5-412-100.C be deleted in its entirety. He said that the time lines contained in this section are way too short, and that he is troubled by the 12 month requirement. Dr. Jeng seconded the motion.

Mr. Clements said that the OLC surveyor should have access to all patient records since the last survey to identify any trends, identify current and discharged patients, and to get overall picture of how the facility has operated on a routine basis. Dr. Jeng questioned the basis for requiring a list of all patients for the prior 12 months.

Mr. Bodin told the Board that the main reason OLC requires the list of patients for the prior 12 months is to enable it to select a random sample of patients from the list for purposes of conducting medical chart reviews. Rather than asking the facility to select a sample of patients for chart reviews, OLC asks for a list of all patients and then it selects a random sample. Mr. Edmondson said that the regulations provide for a big penalty if the facility is not able to find the responsible party in a short period of time. Dr. Remley responded by saying that prior to denying, suspending, or revoking any facility's license, VDH would follow a very careful, deliberative process.

Mr. Edmondson withdrew his motion with the unanimous consent of the Board. Following the withdrawal of the motion, there was further discussion by Dr. Jeng and Mr. Bodin concerning selection by OLC inspectors of a random sample of facility patients for purposes of chart reviews. Mr. Edwards stated that the discussion was out of order since the motion had been withdrawn.

In an effort to correct confusing language, Mr. Edmondson made a motion to replace the first sentence of 12VAC5-412-110.B so that it reads: "The administrator shall submit within 15 days of receipt of the inspection report a plan of correction. The plan of correction shall contain for each violation cited: . . ." There being no second, this motion failed.

There was a discussion initiated by Mr. Edmondson concerning whether 12VAC5-412-120.A, which states that OLC shall investigate any complaints regarding alleged violations of the regulations, could promote harassment of abortion facilities. There was further discussion whether only complaints related to health and safety could be investigated. Ms. Tysinger advised the Board that, from a legal perspective, if a complaint is received and VDH does not investigate, the agency could be open to liability. Ms. Tysinger also told the Board that VDH has discretion to handle various complaints differently depending on the nature of the complaint. Dr. Remley told the Board that VDH has a methodology for prioritizing and scheduling complaints for investigation, which is based on the nature and immediacy of the complaint. Dr. Remley also told the Board that it is VDH's responsibility to determine whether a particular complaint is of a harassing nature. There was no motion made to amend this section of the regulations.

Dr. Jeng moved that the words "any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.)" in the first sentence of 12VAC5-412-130.A be replaced with "§§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2, and 32.1-137.01 of the Code of Virginia". Dr. Jeng further moved that the words "related to the health and safety of patients" be added after the words "applicable regulation" in the same sentence. Dr. Jeng further moved that the words "in accordance with § 32.1-135 of the Code of Virginia" be deleted from the end of 12VAC5-412-130.A. Mr. Edmondson seconded the motion. Dr. Jeng told the Board that certain sections in Article 1 of Chapter 5 do not apply to abortion facilities. Ms. Tysinger said that wording of the regulatory provision is designed to track the Code of Virginia. Ms. Tysinger also said that VDH has released a guidance document to track specific Code sections, and that according to the VDH guidance facilities will not be held in violation of inapplicable Code sections. She also told the Board that, by law, a facility has to be in compliance with all statutes, and that needs to be clear in the regulations.

At the request of Mr. Clements, Ms. Tysinger provided an overview of the key provisions of the statutory sections referenced in Dr. Jeng's proposed amendment. Mr. Bodin confirmed that the referenced Code sections are addressed in the VDH guidance document.

The Chair called for a roll-call vote, 2 in favor (Mr. Edmondson and Dr. Jeng), 9 in opposition (Mr. Clements, Mr. Deaton, Dr. deTriquet, Mr. Edwards, Dr. Escobar, Dr. McCluskey, Dr. Slusher, Ms. Taylor, and Ms. Vest). The motion failed.

There was a discussion initiated by Mr. Edmondson concerning 12VAC5-412-150.B, which pertains to disclosure of abortion facility ownership. Mr. Edmondson said that he is concerned about harassment. There was a discussion concerning the fact that the VDH hospital licensure regulations contain the same requirement. Ms. Tysinger said that the inclusion of this provision in the regulations is a policy decision for the Board. No motion was made to amend this section of the proposed regulations.

There was a discussion concerning 12VAC5-412-160.A.5, pertaining to obtaining informed written consent of the patient. Dr. Slusher said that the content of the informed consent would be under the purview of the Board of Medicine. The Board of Health's proposed regulations states that the facility must have policies and procedures for obtaining informed written consent of the patient prior to the initiation of any procedures. Dr. Remley told the Board that the inspection of the facility would determine if the policy exists and is in effect. Dr. Remley said that any issues pertaining to the facility's compliance with the informed consent statute would be referred to the Board of Medicine. No motion was made to amend this section.

Mr. Edmondson then discussed 12 VAC5-412-180, which he said consisted of a series of highly prescriptive provisions. He asked if there is consistency between this section and the regulations for the licensure of hospitals. Dr. Remley said that this provision is consistent with the hospital regulations. Dr. Remley also told the Board that when deficiencies have been found in compliance with these provisions on the part of hospitals, VDH has worked with hospitals to correct the deficiencies. No motion was made to amend this section.

Dr. Slusher initiated a discussion concerning 12VAC5-412-290.C, pertaining to written agreements for emergency treatment. Dr. Slusher said that this section needs some additional provisions pertaining to communication between the abortion provider and the receiving provider. Dr. Slusher moved that the following language replace the existing 12VAC5-412-290.C so that the section reads "When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise." Mr. Deaton seconded the motion. Mr. Edmondson said that this type of requirement poses a problem for abortion facilities with no hospital, or only one hospital, located close by. There was a discussion between Dr. Slusher, Mr. Deaton, and Mr. Edmondson concerning how transfer agreements work in practice. There was further discussion involving Mr. Clements concerning the extent to which some hospitals might not be willing to enter into a written agreement with an abortion facility. There was further discussion of whether to delete the existing wording of 12VAC5-412-290.C. Mr. Deaton made a

secondary amendment to keep the existing wording of 12VAC5-412-290.C and to add the language included in the primary motion at the end of the section. The Chair called for a roll-call vote for the secondary amendment, 7 in favor (Mr. Deaton, Mr. Edwards, Dr. Escobar, Dr. McCluskey, Dr. Slusher, Ms. Taylor, and Ms. Vest), 4 in opposition (Mr. Clements, Dr. deTriquet, Mr. Edmondson, and Dr. Jeng). The secondary amendment passed.

There was further discussion with regard to the primary amendment. Mr. Edmondson asked if this is an issue that might be beneficiary of a waiver. Dr. Remley said in response that the language of this section was drafted based on the recommendation of clinicians, with the primary intent of ensuring that severe complications would be referred to the right place. The Chair called for a roll-call vote on the primary amendment as amended by the secondary amendment, 8 in favor (Mr. Deaton, Dr. deTriquet, Mr. Edwards, Dr. Escobar, Dr. McCluskey, Dr. Slusher, Ms. Taylor, and Ms. Vest), 3 in opposition (Mr. Clements, Mr. Edmondson, and Dr. Jeng). The motion passed.

Dr. McCluskey then made a motion to reconsider the vote by which the Board previously approved the amendment to 12VAC5-412-370 concerning facility design and construction requirements. The motion was seconded by Ms. Vest. Mr. Clements expressed concern that the amendment to 12VAC5-412-370 that was approved by the Board may not be upheld. Ms. Tysinger advised the Board that the proposed regulations have to be reviewed and certified by the Office of the Attorney General. Ms. Tysinger also said that she does not believe that the proposed regulation as amended will be certified. Ms. Tysinger said that if the proposed regulation is not certified, it would come back to the Board. Mr. Clements said that each of the Board members need to vote the way they see fit, but they also need to know what the consequences are. Mr. Deaton said that the Board has only very limited information concerning existing buildings. Given that, if there are buildings that do not meet the regulatory standards, can that be addressed through issuance of a variance? Ms. Tysinger said that the Commissioner could grant a variance to any of the sections of the regulation. Dr. Remley told the Board that the regulations authorize a variance when the standard or requirement poses an impractical hardship unique to the abortion facility, and when a temporary variance would not endanger the safety or well-being of patients. There was a discussion initiated by Dr. McCluskey concerning the legality of the Board's actions in voting to approve the amendment to 12VAC5-412-370, and whether or not the Board exceeded its statutory authority in approving that motion.

Ms. Tysinger said that the Board is bound by the provisions of § 32.1-127.001 of the Code of Virginia. The amendment made to 12VAC5-412-370 in the proposed regulations conflicts with state law and exceeds the Board's authority. Ms. Tysinger also said that the Attorney General's Office would not offer suggested language to resolve that conflict. Mr. Clements then said that the Board could amend the proposed regulations to give the facilities more time than two years to come into compliance with the design and construction requirements. Dr. Slusher asked if different wording to the amendment would make any difference. Ms. Tysinger responded that her legal opinion is that VDH does not have much "wobble room."

Mr. Edmondson said that the legal interpretation provided by the Office of the Attorney General is wrong, and that the Board has not exceeded its authority. Mr. Edmondson said that the Code of Virginia does not require that the Board treat existing facilities as new facilities. Dr. Jeng said

that the amendment agreed to by the Board is the same provision that is currently found in the hospital licensure regulations.

Dr. Escobar said that the Board is required to protect the public, and that the Board does not exist to be a “rubber stamp.” Dr. Escobar said part of the Board’s job is oversight and review to provide what is medically appropriate.

The Chair called for a roll-call vote on the motion, 5 in favor (Mr. Deaton, Mr. Edwards, Dr. McCluskey, Ms. Taylor, and Ms. Vest), 6 in opposition (Mr. Clements, Dr. deTriquet, Mr. Edmondson, Dr. Escobar, Dr. Jeng, and Dr. Slusher). The motion to reconsider failed.

Mr. Edwards called for any other discussion on the main motion on the floor to amend 12VAC5-410 and adopt 12VAC5-412 as amended during the foregoing discussions. No further discussion was held. Mr. Edwards called for a roll-call vote on the main motion. 8 voted in favor (Mr. Clements, Dr. deTriquet, Mr. Edmondson, Mr. Edwards, Dr. Escobar, Dr. Jeng, Dr. Slusher, and Ms. Taylor), 3 in opposition (Mr. Deaton, Dr. McCluskey, and Ms. Vest). The motion was approved.

Board Action Items

Mammogram Report Guidelines

Mr. Harrison presented this item to the Board. The Guidelines pertain to review of mammography records indicating dense breast tissue, and pertain to specific language that is required to be included in mammogram report letters. VDH has sent a letter to mammography machine registrants about the new requirement, which is effective 7/1/12. The Attorney General's Office endorsed the guidelines. Dr. Remley reminded the Board about the public comment heard earlier in the day on this topic. Mr. Deaton moved that the guidelines be approved. The motion was seconded by Mr. Clements. The guidelines were approved unanimously by the Board by a show of hands.

National Registry of Emergency Medical Technicians – Allocation Methodology for Payment of Initial Testing Expenses

Mr. Brown presented this item to the Board. The Code of Virginia gives the Commissioner authority for certification of emergency medical services personnel. The State EMS Advisory Board approved adopting the use of a national registry for purposes of testing EMS personnel. VDH is asking the Board to approve a methodology for allocating a portion of existing “4 for Life” funding to cover the costs of using the national registry for testing purposes. The allocation methodology was approved unanimously by a voice vote.

Member Reports

The Chair suggested rather than having formal member reports, that individual members share anything of concern.

Mr. Deaton said that Pittsylvania County established a goal of taking 10,000 blood pressure screenings during the month of May. A total of 9400 screenings were actually performed.

Dr. Slusher said that Rockingham Memorial Hospital is offering free Tdap vaccinations. She also commented concerning the legislation enacted by the General Assembly mandating the inclusion of specific information concerning breast density in mammogram report letters.

Mr. Edmondson asked that the Board be kept informed concerning next steps in the COPN litigation. Dr. Remley assured the Board members that they would be kept fully informed.

Dr. Remley told the Board that the proposed regulations for licensure of abortion facilities would be submitted for executive branch review. The emergency regulations for licensure of abortion facilities are still in effect.

Adjourn

The meeting adjourned at approximately 5:27 p.m.