

**State Board of Health
Minutes
September 15, 2011 – 9:00 a.m.
Wyndham Hotel Richmond Airport, 4700 S Laburnum Avenue
Richmond, Virginia 23231**

Members present: Bruce Edwards, Chair; Paul Clements; Kay Curling; Eric Deaton; Dr. John deTriquet; Jim Edmondson; Dr. Steven Escobar; Dr. Charles Johnson; Dr. Mary McCluskey; Dr. Bhushan Pandya; Dr. Cathy Slusher; Gail Taylor; and Amy Vest

Members absent: Dr. Anna Jeng and Dr. Bennie Marshall

VDH staff present: Dr. Maureen Dempsey, Chief Deputy for Public Health; Jeff Lake, Deputy Commissioner for Community Health Services; Dr. Marissa Levine, Deputy Commissioner for Public Health and Preparedness; Joan Martin, Deputy Commissioner for Administration; Joe Hilbert, Director of Governmental and Regulatory Affairs; Catherine West, Administrative Assistant; Carol Nixon, Policy Analyst; Maribeth Brewster, Risk Communications Manager; Josh Czarda, Performance Improvement Manager; Bob Hicks, Director, Office of Environmental Health Services; Dr. Keri Hall, Director, Office of Epidemiology; Patrick Bridge, Public Health Training Coordinator, Office of Risk Communication and Education; and James Moss, Emergency Planner, Chesterfield Health District

Others Present: David Johnson, Allyson Tysinger, Robin Kurz, Beth McDonald, Attorney General's Office

Call to Order

Mr. Edwards convened the meeting at 9:00 a.m.

Moment of Silence in Honor of Ed Spearbeck

Mr. Edwards spoke to the Board about Ed Spearbeck who passed away recently. Mr. Spearbeck served as the representative of the Virginia Pharmacists Association on the Board of Health since July 2004. Mr. Edwards reminded the Board that Mr. Spearbeck served with distinction and commented that the Board's thoughts and prayers are with his family. The Board paused for a moment of silence to honor Mr. Spearbeck.

Welcome and Introduction

Mr. Edwards welcomed the public to the meeting. Mr. Edwards indicated that the Board encourages public comment as it is a critical part to the Board meeting. Mr. Edwards informed the public that anyone wishing to speak before the Board during the public comment period is required to sign the sign-up sheet with their name and the topic they wish to discuss.

Dr. Dempsey introduced the VDH agency stars in attendance at this meeting. These are individuals who consistently demonstrate qualities and characteristics important to VDH and to public health. Patrick Bridge is the Public Health Training Coordinator in the Office of Risk Communication and Education. Since the time that Mr. Bridge has taken that position, the program has grown and strengthened to be recognized as a national leader in public health training and community outreach efforts. James Moss is the Emergency Planner for the Chesterfield Health District. Mr. Moss distinguished himself by going beyond the call of duty by serving 24 continuous hours during Hurricane Irene. During that time period, Mr. Moss assumed additional responsibility in addition to his designated role.

Mr. Edwards had those sitting at the meeting table introduce themselves, in particular, recognizing the three Board members in attendance for their first meeting.

Mr. Hilbert reviewed the agenda. There was a motion and second to approve the agenda. The agenda was approved unanimously.

Matrix of Pending Regulatory Actions

Mr. Hilbert reviewed the listing of all of the pending VDH regulatory actions. There were no questions.

Approval of Minutes

A motion was made and seconded to approve the draft minutes of the June 9, 2011 Board meeting. No corrections were noted. The minutes were approved unanimously.

Commissioner's Report

Dr. Dempsey briefed the Board on a variety of topics including VDH's response to the recent earthquake and to Hurricane Irene. VDH was well prepared in advance to respond to both events, as agency staff knew their roles and responsibilities in order to successfully implement agency response plans. Both events required a great deal of work, including monitoring of hospital and nursing homes and ensuring the safety of drinking water. In the aftermath of the earthquake, the status of the North Anna nuclear plant created the most concern. VDH decided to treat this event as an exercise to test its radiological health and safety plans and procedures. There was not any leakage of radiation as a result of the earthquake. VDH did a good job implementing its response plans and monitoring activities. There was no threat to the public.

In response to the hurricane, local shelters opened on Sunday and were closed by Wednesday. All but one shellfish closure was lifted by September 8. Four deaths were caused by falling trees, one death occurred when a resident fell down the steps in his home.

Dr. Dempsey also provided the Board with an updated on maternal and child health issues:

- Teenage pregnancy rate has decreased;
- Infant mortality rate has decreased; and

- Induced terminations of pregnancy have decreased.

Dr. Dempsey briefed the Board concerning WIC and the summer feeding programs. There has been a concerted effort to expand WIC participation. VDH has expanded summer feeding programs.

Dr. Dempsey briefed the Board concerning program development of contracts with charitable organizations receiving state funding through VDH's section of the Appropriation Act; and the status of efforts to issue a RFP for the governance of a state health information exchange.

Performance Improvement Update

Dr. Dempsey introduced Josh Czarda to finish the Commissioner's report with an update concerning VDH's performance improvement program, which is funded by a grant from the Centers for Disease Prevention and Control (CDC). Josh began work at VDH in January 2011. Since that time, Josh has led and coordinated:

- Commissioner's Performance Improvement Council;
- Development of an agency performance dashboard; and
- Implementation of three agency performance improvement projects:
 - Streamline agency procurement processes;
 - Identify strategies for creating information technology savings; and
 - Increase enrollment in the Plan First Family Planning program.

Looking forward, the VDH performance improvement program will be working to:

- Align the agency's dashboard with metrics posted on the Virginia Performs website;
- Identify best practices; and
- Automate paper/manual processes when possible.

There was a discussion concerning whether performance dashboards were available by district. Josh informed the Board that district-level dashboards would be made available.

Public Comment

Mr. Edwards began the public comment period by stating that the Board encourages public participation. Mr. Edwards indicated that the chair would entertain a motion to extend the time for the public comment period in order for the Board to hear from all that have signed up to speak. A motion was made and seconded. The motion was approved unanimously. There was a discussion concerning whether the Board would hear from members of the public who had not recorded their name on the sign up sheet. Mr. Edwards indicated that the Board would adhere to its public participation policy and hear from only those individuals recorded on the sign up sheet.

All of the public comments made at this meeting related to the Emergency Regulations for Licensure of Abortion Facilities. A total of 32 citizens spoke during the public comment period.

Frances Bouton – She spoke in opposition of the proposed regulations.

Louantha Kerr – She spoke in strong support of proposed regulations.

Tosha Yingling – She is opposed to the regulations and fears that they will result in the closing of clinics that also provide breast cancer screening.

Patrick Hurd – He is a member of the Planned Parenthood organization and spoke in opposition of the proposed regulations, with particular emphasis on building construction.

Corrina Beal – She requested that recent college graduates stand, and spoke in opposition to the proposed regulations.

Patricia Crain – She supports part of the regulations and is opposed to part of the regulations, particularly with regard to building construction.

Gail Frances – She spoke in opposition to the proposed regulations, particularly with regard to building construction.

Rita Dunaway – She spoke in support of the proposed regulations; and stated that it is public duty to ensure that abortion is safe.

Chris Freund – He spoke in support of the proposed regulations.

Rose Codding – She spoke in opposition of the proposed regulations. She indicated that the regulations do not add to safety.

Tom Shields – He spoke in opposition to the proposed regulations; particularly that they are too extensive and are not related to safety.

Melissa Reed – She spoke in opposition to the proposed regulations; particularly that they are unnecessarily burdensome for facilities that provide medical procedures. She indicated that there needs to be a differentiation between medical and surgical abortion procedures.

Wendy Klein – She spoke in opposition to the proposed regulations. She indicated that the regulations are for first trimester abortions which is a safe procedure; other procedures are higher in risk and there is no safety issue.

Delegate Charniele Herring – She thanked the Board for allowing all to speak that want to speak. She spoke in addition to the signed letter submitted to VDH that outlines her concerns. She is opposed to the proposed regulations and has concerns about building construction.

Jill Abbey – She is opposed to part of the proposed regulations and stated the regulations need to be revised. She has concerns about the protection of patient confidentiality by VDH staff. She also sees conflicts with medical ethics. She also stated that safety of patients is compromised by the proposed regulations.

Ruby Nidas – She spoke in support of the proposed regulations and does not believe that regulations go far enough.

Bill Goode – He spoke in general that regulations exist in many areas, mostly for safety concerns. He also spoke against abortion itself. He supports the proposed regulations.

Sheila Cherizard – She spoke in opposition to the proposed regulations as they impact minority, access to contraceptive services and access to health care. She indicated that the regulations will make it more difficult for health centers to provide quality care.

Tarina Keene – She spoke in opposition of the proposed regulations and gave insight on how the regulations came about. She spoke against targeted regulation and asked that the regulations be revised.

Kathy Greenier – She spoke in opposition of certain sections of the proposed regulations; particularly sections dealing with confidentiality and building requirements. She indicated that the regulations are burdensome and endanger women’s health.

Shelley Abrams – She spoke in opposition to the proposed regulations because they are stricter than similar regulations in other states.

Margaret Disney – She spoke in support of the proposed regulations. She indicated that they are a step in the right direction; that this procedure is unregulated and unreported.

Margaret –Beth Meyer – She spoke in support of the proposed regulations. She indicated that there is not a problem with the regulations if facilities are doing what they need to do.

Lisa Brown – She spoke in opposition of the proposed regulations. She indicated areas of concern are access to care, safety of providers, and patients’ confidentiality.

Mark Strandquist – He spoke in opposition to the proposed regulations, stating that the regulations will not make women’s health care safer.

Maureen Whalen – She strongly supports the proposed regulations.

Kathy Marshall – She spoke on behalf of her husband, Delegate Bob Marshall, in support of the proposed regulations. She indicated the regulations are necessary and further stated that she can support the regulations without supporting abortion.

Jeff Caruso – He spoke in support of the proposed regulations.

Eric Scott – He spoke in opposition of the proposed regulations. He said that regulations are needed but the proposed regulations are too strict.

Dr. William Nelson – He spoke in opposition of the proposed regulations. He stated that there is no data that supports that the abortion procedure is unsafe; and that the regulations are a threat to privacy as well as to the safety of providers and patients.

Kate Fowler – She spoke in opposition to the proposed regulations.

Elizabeth Kimbriel – She spoke in opposition to the proposed regulations. She stated that this is an undisguised attempt to close facilities.

Mr. Edwards declared the public comment period to be ended.

Regulatory Action Items

After a brief break, Mr. Edwards reviewed the procedure for the Board to take action on regulatory items. After presentation of the item by VDH staff, the chair will ask for a motion to adopt and for a second. After the motion has been seconded, any discussion can then occur.

Mr. Edwards reviewed Robert’s Rules of Order with the Board and reminded Board members that according to Robert’s Rules, a member cannot amend an amendment to an amendment. Mr. Edwards also 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.

In order to ensure that any amendment language is clear before a motion is made and seconded, VDH staff will display the proposed regulatory language on the screen. The updated language will be read to the Board and any corrections will be made before proceeding to a motion, second, and subsequent discussion.

For today’s meeting, all regulatory action items will be voted on using a roll call vote in accordance with the Board’s bylaws.

Regulations for Disease Reporting and Control (12VAC5-90) – Re-proposed Amendments

Dr. Hall presented the re-proposed amendments. She provided background information about the regulations. These regulations were previously amended to require the reporting of central line infections. Hospitals report via a CDC software system which is used by all states. Prior to the end of the previous Administration, VDH was requested to initiate a regulatory action to require the reporting of additional types of infections. Proposed amendments were approved by the Board and put out for public comment. VDH received extensive negative public comments on the proposed amendments. VDH then decided to issue this re-proposed amendment.

The re-proposed amendment is based on the fact that the federal government now has its own healthcare-associated infections reporting requirements for hospitals which are more extensive than what VDH had originally proposed. The re-proposed amendment requires hospitals to provide VDH with a copy of the report that they provide to CMS.

There was a brief discussion concerning the fact that this regulatory action applies to hospitals, including long term care hospitals, not to nursing facilities.

Mr. Edmondson moved that the re-proposed amendments be approved. Mr. Deaton seconded the motion, which was approved unanimously.

Regulations for Repacking of Crabmeat for Human Consumption (12VAC5-165) – Proposed Amendments

Mr. Hicks presented the proposed amendments. The proposed amendments are a result of periodic review. There have been concerns about product labeling, which are addressed by the proposed amendments. Mr. Hicks explained that VDH has worked with the industry on the proposed amendments.

Dr. deTriquet moved that the proposed amendments be approved. Dr. Pandya seconded the motion, which was approved unanimously.

Lunch

Mr. Edwards announced that the Board would break for a non-working lunch. The meeting will reconvene at 12:45 p.m.

Reconvene

The meeting reconvened at 12:50 p.m. Mr. Edwards asked that Board members request to be recognized to speak by raising their hands. Mr. Edwards also reminded the Board members to keep their comments germane to the topic under discussion.

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

Mr. Hilbert presented the abortion licensure regulations. He reminded the Board about Senate Bill 924 which mandates that the Board of Health promulgate regulations, further specifies that

abortion facilities be a type of hospital, and that the regulations have to be enacted within 280 days. Mr. Hilbert talked about the process that VDH staff used; that VDH followed a thoughtful and deliberate process in drafting the proposed regulations. VDH staff reviewed and analyzed regulations from 22 other states. Those items reviewed included licensure and inspection program, credentialing of facilities, infection control, data reporting, family planning, and facility design and construction. VDH sent a survey to 22 states and received 15 responses. VDH used regulations in effect in South Carolina as a frame of reference as those regulations have been upheld in the 4th Circuit, which Virginia is part of. VDH staff reviewed standards, guidelines, and recommendations developed by several organizations (CDC, American Heart Association, American College of Obstetrics and Gynecology, World Health Organization, National Abortion Federation, Planned Parenthood Federation of America, Joint Commission on Health Care). VDH also reviewed regulations for other healthcare facilities and organizations that VDH regulates. VDH also solicited advice and guidance from the Chairs of the OB/Gyn Departments of Virginia's academic medical centers.

The proposed regulations are for the licensure of facilities; the individual health care practitioners practicing in those facilities will continue to be licensed by the Virginia Department of Health Professions. Regulations have been reviewed by VDH's legal counsel in the Office of the Attorney General. Certain changes were made according to recommendations made by staff of the Office of the Attorney General.

Mr. Hilbert gave a brief overview of regulations, including definitions, procedures for licensure and licensure renewal, provisions for organization and management of facility, provisions for infection prevention, provisions about patient care, handling of medical waste, use of anesthesia, handling of controlled substances, and the requirement for written agreement with a hospital for any patient needing emergency treatment. The regulations also contain a requirement for quality assurance, medical records reporting of deaths, functional safety and maintenance, and design and construction. Mr. Hilbert explained that entities operating as of the date of the effective date may be licensed in current buildings if they submit a plan that will bring them into full compliance within 2 years. He explained further that the regulatory action before the Board also includes two amendments to 12VAC5-410. The rationale is that abortion facilities will be regulated under 12VAC5-412 instead of 12VAC5-410.

Mr. Hilbert told the Board that since the draft emergency regulations were posted on VDH's website on August 26 at approximately 5:00 p.m., 646 comments were received in support and 543 comments were received in opposition.

Mr. Hilbert stated that if the Board adopts emergency regulations, they will be submitted for executive branch review (by the Office of the Attorney General, the Department for Planning and Budget, the Office of the Secretary of Health and Human Resources, and the Governor). A Notice of Intended Regulation Action (NOIRA) will be published simultaneously at the time of the effective date of the emergency regulations. This will begin the process of promulgating permanent regulations to replace the emergency regulations when they expire. There will be a 30-day public comment period on the NOIRA on the Virginia Regulatory Town Hall website. VDH will also hold public hearings concerning the NOIRA.

Finally, Mr. Hilbert explained that upon approval of the emergency regulations by the Governor, VDH's Office of Licensure and Certification will begin to implement this new facility licensure and inspection program. This will include development and distribution of a guidance document pertaining to the regulations. The guidance document will be posted on the Virginia Regulatory Town Hall. OLC will also begin reaching out to providers that VDH is aware of from their reporting to the Division of Vital Records. He also told the Board that it is never VDH's intent in any licensure or permitting programs to shut down facilities or to revoke licenses as the default option. Rather, VDH always works hard to help licensees to come into compliance with regulatory provisions.

Mr. Edwards called a motion to amend 12VAC5-410 and adopt 12VAC5-412. Mr. Deaton moved that 12VAC5-410 be amended and 12VAC5-412 be adopted. Dr. Johnson seconded the motion.

The Chair asked the Board if there was any discussion concerning the motion. Mr. Edmondson stated that in his role as a consumer representative to the Board, he is particularly concerned about patient safety and access, provider safety, and privacy. To that end, he told the Board that he would propose a series of amendments reflecting those concerns. He stated that he knows that there will be regulations. His intention is to try to make the proposed regulations better, not to not to avoid regulation altogether.

Mr. Edmondson's first amendment – He stated that the regulations should address patient safety without limiting access to women's health services. His first suggested amendment was to distinguish between physical plants between facilities that perform medical vs surgical procedures. He stated that the facility requirements for surgical procedures are different than those for medical procedures. In Section 10, definition section, he proposed to change the definition of "abortion facility" by adding the word "surgical" so that the section reads: "Abortion facility" means a facility in which five or more first trimester surgical abortions per month are performed." Mr. Edmondson made a motion to amend this section of the regulation. There being no second, this motion failed.

Mr. Edmondson's second amendment – He said that he wanted to make the process of renewal after licensure more rational. As stated in the draft regulations, licenses will be renewed by April 30 of each year. However, it is likely that some licenses will be issued in early 2012, and then would have to be renewed in April 2012. Mr. Edmondson proposed adding a new subsection D in 12VAC5-412-60 to read: "Any license issued before April 30, 2012 shall not expire until April 30, 2013. No additional fee will be required for the period from May 1, 2012 until April 30, 2013." Mr. Edmondson made a motion to amend this section. Dr. McCluskey seconded the motion. There was a discussion that facilities approved prior to April 2012 will still fall under the regulations. This motion passed 10-3, with Ms. Taylor, Ms. Vest, and Mr. Clements voting no.

Mr. Edmondson's third amendment – He told the Board that this suggested amendment concerns the requirement that all existing facilities are treated as new facilities. Mr. Edmondson stated that he deals with building codes as part of his profession. While it is not his intent to "grandfather" all facilities, he wants to moderate the proposed requirements. A number of

facilities have been built to standards, and he wants to differentiate between older facilities and facilities built under fairly recent guidelines. To that end, he proposed adding at the end of the first paragraph of 12VAC5-412-380, a sentence that reads: “Notwithstanding the previous sentence, any facility that has complied with the relevant and corresponding sections of the Guidelines issued after January 1, 2000 shall be deemed to be in compliance, and no further alterations to its facilities may be required of the facility until the Commissioner determines that a major rehabilitation of that facility is required due to patient safety issues or facility obsolescence.” Mr. Edmondson moved adoption of the change as presented. Dr. deTriquet seconded. Ms. Tysinger then offered legal advice that the General Assembly has mandated in the Code of Virginia that the Board must comply with the current edition of The Guidelines for Design and Construction of Hospital and Health Care Facilities. She said that this amendment exceeds the Board’s statutory authority. The regulations have to comply by law with the current guidelines. Ms. Tysinger’s advice to the Board was that it could not adopt this motion. Dr. deTriquet suggested that if a motion exceeds the authority of the Board, the maker can withdraw the motion. Mr. Edwards asked if there was any objection to this motion being withdrawn. Mr. Edmondson objected. Since there was no unanimous consent, Mr. Edwards called for a vote. This motion failed 1-12, with Mr. Edmondson voting yes.

Dr. Pandya asked whether it is within the Board’s authority to seek the advice of the Attorney General’s Office through Ms. Tysinger before a motion is made. Mr. Edwards put this question to the Board. The Board concurred that advice of the Attorney General’s Office will be sought before a formal motion was put on the table before the Board for the remainder of this meeting.

Mr. Edmondson’s fourth amendment – In order to differentiate between existing and new facilities, Mr. Edmondson proposed a change to the first sentence of the first paragraph of 12VAC5-412-380 so that it begins “Abortion facilities built after January 1, 2012” Further, Mr. Edmondson proposed that the last line of the second paragraph of that section be amended to read: “. . . them into full compliance with this provision within the later of i) two years from the date of licensure or ii) the date that the Commissioner determines that the facility is obsolete or in need of rehabilitation or replacement to protect patient safety.” Ms. Tysinger advised the Board that, as with the previous proposed amendment, this proposed amendment exceeds the Board’s authority. Mr. Edmondson moved that the regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson’s fifth amendment – He told the Board that this proposed amendment would permit the State Health Commissioner to have the same flexibility in making variances as he or she has with respect to other medical facilities. Mr. Edmondson proposed adding the words “or permanently” in the second clause of 12VAC5-412-90 so that the sentence reads: “. . . the Commissioner may grant a variance temporarily or permanently waiving the enforcement” Ms. Tysinger advised that there is an overarching issue that the Board should consider; which is that the Board should be prudent in allowing any commissioner to undermine the intent of the Board or the law. Ms. Tysinger advised that once the word “permanently” is inserted, the commissioner’s hands are tied. There was a discussion concerning the commissioner’s ability to revoke variances. Mr. Edmondson moved that the regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's sixth amendment – He stated that, as drafted the regulation goes beyond what the enabling legislation requires by referring to the entire Article 1 of Chapter 5 of Title 32.1. Mr. Edmondson said that some of the provisions of Article 1 are not relevant to abortion clinics. For example, there are requirements relating to organ donation which are clearly beyond the relevant scope of first trimester abortions. Mr. Edmondson proposed replacing the entire subsection A of 12VAC5-412-130 with the following: “When the department determines that an abortion facility is (i) in substantial violation of any applicable regulation related to the health and safety of patients, or (ii) is permitting, aiding or abetting the commission of an illegal act in the abortion facility, the department may deny, suspend or revoke the license to operate an abortion facility.” Ms. Tysinger advised the Board that §§ 32.1-126 and 32.1-135 of the Code of Virginia govern when VDH can revoke licenses and that the existing language in the proposed regulation tracks exactly the existing language in the Code. There was a discussion of whether the proposed amendment language broadens or narrows the authority of the commissioner, particularly with the use of the word “substantial”. Mr. Edmondson agreed to removing the word “substantial” in his proposed amendment to 12VAC5-412-130 and moved that the regulation be amended as proposed. There being no second, this motion failed.

Mr. Edmondson's seventh amendment – Mr. Edmondson stated that the reference to Article 1 of Chapter 5 of Title 32.1 in subsection B of 12VAC5-412-130 goes beyond what the enabling legislation intended. He proposed deleting the reference to the entire Article 1 of Chapter 5 of Title 32.1 in subsection B of 12VAC5-412-130 by striking those words in the sentence that begins “If a license or certification” Ms. Tysinger advised that the regulation as drafted is consistent with language within the Code of Virginia and that, when possible, the language should remain consistent. Mr. Edmondson moved that the proposed regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's eighth amendment – He told the Board that this proposed amendment dealt with concerns with respect to confidentiality and privacy, as well as allocation of resources for OLC staff and clinics. This proposed amendment also reflects comments submitted by Dr. Jeng. Mr. Edmondson proposed adding a second sentence to 12VAC5-412-100 to read: “Any such employee must properly identify himself or herself as an inspector designated by OLC; the facility may verify the identity of the inspector prior to his or her admission.” Ms. Tysinger suggested changing the word “may” to “shall.” Ms. Tysinger also advised the Board that this proposed language already exists in the Code. There was a discussion about the procedures for identification for staff that inspect existing facilities regulated by VDH. Mr. Edmondson moved that the proposed regulation be amended as stated. Dr. Slusher seconded. Mr. Edmondson reminded the Board members that, as others have noted, the operation of abortion clinics is subject to much emotion and disagreement; and that has been a history of objection and harassment for clients seeking services. He said that the Board needs to be explicit, in order that “so called” inspectors do not gain access to these facilities. Dr. Escobar stated that he agreed with that perspective. As a veterinarian, he is familiar with state inspection process and with attempts to unlawfully enter a facility. Dr. Escobar further stated that it does no harm to be redundant in regulatory language. Mr. Edwards called for a vote. This motion passed as amended 11-2, with Ms. Curling and Dr. McCluskey voting no.

Mr. Edmondson's ninth amendment – He told the Board that, with regard to issues of patient confidentiality and allocation of resources for inspection, he does not know if there are enough resources to conduct an annual inspection. Mr. Edmondson suggested leaving the frequency of inspection to the discretion of the commissioner in 12VAC5-412-110. Mr. Edmondson proposed amending the first sentence of 12VAC5-412-110.A to read: “An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary in the discretion of the Commissioner.” Ms. Tysinger stated that, at the very least, this section of the regulation should track the Code of Virginia such that inspections should be not less often than biennially. Mr. Edmondson stated that Ms. Tysinger's suggestion was acceptable to him. Dr. Levine indicated that the suggested amendment would be in line with current statutes for other facilities that are regulated by VDH. Mr. Edmondson moved that subsection A be amended by changing the first sentence to read: “An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary but not less often than biennially.” Dr. Pandya seconded. Mr. Edwards called for a vote. This motion was adopted as amended 12-1 with Ms. Vest voting no.

Mr. Edmondson's tenth amendment – He told the Board that he had concerns with the provisions in 12VAC5-412-110.B as it related to privacy issues. Mr. Edmondson proposed amending subsection B by completely replacing it with the following language: “The abortion facility shall make available to the OLC's representative on its site (not to be taken off site) any records that he or she requests, provided that the abortion facility shall redact the names and other identifying information on any patient records that the OLC representative requests unless the patient authorizes the use of the records without redacting. The facility shall allow access to interview the agents, employees, contractors, and any person under the facility's control, direction or supervision, provided any such interview subject is given reasonable notice to appear. The OLC representative may not interview any patient without the patient's express permission.” Ms. Tysinger advised that the Code gives VDH broad access to determine compliance. She further advised that this amendment could limit VDH's ability to determine compliance. She suggested that VDH staff speak to the proposed amendment. Dr. Levine said that the issue of confidentiality is critical. She told the Board that all inspections are unannounced; inspectors do access records but do not take the records with them when they leave a facility; and inspectors interview patients only with the patient's permission. She also told the Board that any confidential information remains confidential; patient information is always held confidential.

There was a discussion concerning the applicability of the federal HIPAA statute as well as VDH policies and procedures for protecting patient confidentiality during the inspection of other types of health care facilities. Mr. Edmondson stated that patients are often harassed on their way into a facility. Therefore, he said it is important to clarify the patient's right to privacy, despite the presence of agency practices and statutory requirements.

Mr. Clements stated that, having gone through VDH surveys as a nursing home administrator, it is common practice for VDH staff to review patient records. He said it is more of a hardship for facility staff to have to redact patient information. He said that VDH staff do request copies of information once they leave a facility. Mr. Clements has never felt that a patient's confidentiality has been breached in surveys by VDH staff.

Ms. Tysinger reminded the Board that VDH is bound by HIPAA and FOIA requirements. She also stated that if information is redacted, it may be harder to pursue if a violation exists.

There was further discussion concerning whether or not patient numbers should be redacted in order to protect confidentiality.

Mr. Edmondson moved that the regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's eleventh amendment – He told the Board that this proposed amendment also deals with patient records and privacy issues. Mr. Edmondson proposed amending 12VAC5-412-110.C. by completely replacing it with the following language: “The OLC’s representative will conduct an inspection/survey during normal business hours. If the administrator or nursing director or another person authorized to give access to patient records is not already on the premises, then one of these persons will make he or herself available as soon as possible on the same day. Records will be provided promptly subject to the requirements of Subsection B above. Failure to comply with this subsection shall be grounds for penalties as determined by the Commissioner.” Ms. Tysinger advised that the Code provides the right to enter at any reasonable time, and that this proposed amendment could infringe on the right of the commissioner as authorized by the General Assembly. There was a discussion concerning the fact that VDH licenses many facilities that operate on a 24/7 basis and that there is no expectation that surveyors would go into the facility any time other than normal business hours. Mr. Edmondson moved that the regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's twelfth amendment – He told the Board that this proposed amendment is also related to patient privacy. Mr. Edmondson proposed adding a new subsection C to 12VAC5-412-330. The new subsection would read: “The VDH Report of Induced Termination of Pregnancy for any individual abortion whether surgical or medical shall not be disclosed to the public by any means.” Ms. Tysinger advised that Virginia law does not distinguish between medical or surgical with regard to abortion procedures so that this reference should be deleted from the proposed amendment. She further advised that the reports referred to in this section of the proposed regulation are considered to be vital records, so that information is not disclosed. Mr. Edmondson stated that there are many instances in the emergency regulations where existing Code language has been incorporated. He said further that, because of the sensitive nature of the regulations, inclusion of this language is warranted. Mr. Edmondson agreed to strike the words “whether surgical or medical” and moved that the suggested amendment reads: “The VDH Report of Induced Termination of Pregnancy for any individual abortion shall not be disclosed to the public by any means.” There being no second, this motion failed.

Mr. Edmondson's thirteenth amendment – He told the Board that he was concerned that the time frames established by the regulations for preparing and submitting plans of correction were very short. In order to provide a reasonable time to correct deficiencies, he proposed amending 12VAC5-412-120.B from “15 working days” to “30 calendar days” and amending 12VAC5-412-120.C from “30 working days” to “90 calendar days”. Ms. Tysinger advised that there is no legal issue with this suggested amendment but that VDH staff may like to be heard concerning it.

Dr. Levine indicated that the language in the proposed regulation is consistent with current regulations for facilities VDH regulates. Mr. Edmondson moved that the proposed regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's fourteenth amendment – He told the Board that this proposed amendment is intended to protect the confidentiality of information concerning health care providers. In order to protect health care provider confidentiality, Mr. Edmondson proposed amending 12VAC5-412-150 by adding this sentence at the end of the section: “OLC representatives may not disclose any policies, procedures or plans obtained in compliance with this Section except as necessary for his or her job duties, and may never reveal such information to the public. Such disclosure may subject the representative to disciplinary action, including job termination.” Ms Tysinger advised that the overall suggested amendment does not present a problem but suggested changing the word “may” to “shall” and changing the word “compliance” to “accordance”. She further advised that the language about termination of an employee (“except as necessary for his or her job duties, and may never reveal such information to the public. Such disclosure may subject the representative to disciplinary action, including job termination”) may not fall within the scope of the Board's authority to enforce; rather, termination would fall under the purview of the Department of Human Resource Management. Ms. Tysinger said she would need to research this particular language should the amendment pass. Mr. Edmondson moved that the proposed regulation be amended as suggested. There being no second, this motion failed.

Mr. Edmondson's fifteenth amendment – In order to protect health care provider confidentiality, Mr. Edmondson proposed a new subsection, J, to 12VAC5-412-170, to read: “Nothing in these regulations shall authorize any employee or agent of the OLC or the department to copy or disclose to any party by any means information regarding facility personnel unless such employee or agent is in violation of the law or regulations governing abortion clinics. Violation of this provision shall be grounds for disciplinary action including termination of employment.” Ms. Tysinger made a recommendation for rewording the suggested amendment as follows: “OLC representatives shall not copy or disclose any personal identifying information regarding any staff member of an abortion facility unless such information is necessary to document or report a violation of law or these regulations.” There was a discussion concerning current legal requirements for reporting information concerning physicians to state regulatory agencies (such as the Board of Medicine), how the provisions contained in the proposed regulations compare to current requirements, and how the proposed provisions would work in practice. Mr. Edmondson made a motion to adopt the proposed amendment as suggested by Ms. Tysinger. There being no second, this motion failed.

Mr. Edmondson's sixteenth amendment – He again told the Board that there was a need to protect the confidentiality of health care providers, and to align the process of disclosure to what the Board of Medicine would require. Mr. Edmondson proposed amending 12VAC5-412-180 by adding a new subsection E. That subsection would read: “Nothing in these regulations shall be interpreted to overlap or conflict with the rules of the Medical Society of Virginia or any supervisory agency with respect to the practice of medicine by physicians. Further, notwithstanding anything to the contrary in these regulations, no employee or agent of the OLC or the department may disclose the names or other identifying information of any medical practitioners employed by or providing services at an abortion clinic. Violation of this provision

shall be grounds for disciplinary action including termination of employment.” Ms. Tysinger proposed changing the second sentence to read: “OLC representatives shall not disclose any personally identifying information regarding any physician or other health care practitioner licensed by a health regulatory board, employed by or providing contract services to an abortion facility unless such information is necessary to document or to report a violation of these regulations or make a report as required by law.” There was a discussion that VDH staff did work closely with Board of Medicine staff in developing the draft language in this section of the regulations.

There was further discussion concerning current legal requirements for reporting information concerning health care practitioners to the Department of Health Professions; how VDH complies with those requirements; and how VDH protects confidentiality in the process.

Mr. Edmondson moved that 12VAC5-412-180 be amended by adding subsection E to read: “Nothing in these regulations shall be interpreted to overlap or conflict with the rules of the Medical Society of Virginia or any supervisory agency with respect to the practice of medicine by physicians. OLC representatives shall not disclose any personally identifying information regarding any physician or other health care practitioner licensed by a regulatory health board, employed by or providing contract services to an abortion facility unless such information is necessary to document or to report a violation of these regulations or make a report as required by law. Violation of this provision shall be grounds for disciplinary action including termination of employment.” There being no second, this motion failed.

Mr. Edmondson’s seventeenth amendment – He told the Board that the emergency regulations contain a specific prohibition to the use of general anesthesia in abortion facilities. In order to clear up redundancy and inconsistency, Mr. Edmondson proposed amending the regulations by taking out all references to general anesthesia in 12VAC5-412-250. There was a discussion that this section was drafted by VDH in consultation with the Virginia Department of Health Professions, based on The Board of Medicine regulations governing the use of office-based anesthesia. Mr. Hilbert told the Board that the intent was to incorporate by reference the existing Board of Medicine regulations for office-based anesthesia which physicians are already subject to, and to prohibit the use of elective general anesthesia. Dr Pandya asked that if the statute considers these facilities as hospitals, is restricting the use of general anesthesia permissible. Ms. Tysinger responded that she thought that it was permissible. She stated that the Board is allowed to distinguish different categories of hospitals in promulgating regulations. Mr. Edmondson indicated that given the discussion, he would withdraw the proposed amendment, but wished the discussion to remain part of the public record.

There was a discussion concerning whether or not there are any facilities that perform only medical abortions. Ms Tysinger advised the Board that from a legal perspective, there is no distinction between medical and surgical abortions. There was further discussion that a medical abortion can still result in a surgical procedure.

There was discussion concerning 12VAC5-412-110 pertaining to the handling of any records taken off-site as a result of an on-site inspection. There was discussion concerning the extent to

which certain information would first need to be redacted from the record in order to protect patient confidentiality.

After further discussion, Dr. Slusher made a motion to amend 12VAC5-412-110.B by adding this sentence to the end: “If records or copies are removed from the premises, patient name and address contained in such records shall be redacted by the abortion facility before removal.” Mr. Edmondson seconded the motion. Mr. Edmondson further stated that one of the provisions in this section that concerned him, from the perspective of privacy, is the provision of a list of patients. He said that such a list is non-essential and is at risk of being disclosed. Mr. Edmondson wished to discuss the motion further but was ruled out of order.

Dr. Pandya made a motion to amend the amendment to read “If copies of records are removed . . .” Dr. Escobar seconded this amendment to the motion. Mr. Edwards called for a vote on the amendment to the amendment. The motion carried unanimously (13-0) that the proposed amendment to 12VAC5-412-110.B would read: “If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the abortion facility before removal.”

Dr. Pandya made a motion to change the word “shall” to “may” in the approved amendment. There was a discussion concerning the effect of changing “shall” to “may.” The Chair asked if there was any further discussion. Hearing no further discussion, the Chair called for a vote on this motion. There being no second, this motion failed.

Mr. Edwards called for a vote to the primary amendment to 12VAC5-412-110.B to read: “If copies of records are removed from the premises, patient name and address contained in such records shall be redacted by the abortion facility before removal.” This amendment was adopted unanimously, 13-0.

Mr. Edmondson indicated that he saw no purpose to the sentence starting with “A list of current . . .” in 12VAC5-412-110.C since the inspector has access to all of the records. Mr. Edmondson so moved that this sentence be deleted from this section. There being no second, this motion 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. 12 voted in favor, one in opposition (Mr. Edmondson) and the motion was adopted.

Mr. Edwards called for a short recess, to reconvene at 4:00 p.m.

Member Reports

The meeting was reconvened at 4:00 p.m.

Dr. Mary McCluskey – Managed Care Health Insurance Plans. She discussed issues pertaining to healthcare reform, health insurance exchanges, primary care, and medical homes.

Kay Curling – Corporate Purchaser of Health Care. She discussed issues pertaining to health care costs, employee wellness programs, and healthcare reform.

Paul Clements – Nursing Home Industry Representative. He discussed issues pertaining to reimbursement and hurricane response activities.

Gail Taylor – Consumer Representative. No report. She expressed praise for all VDH staff who provided services in response to the recent hurricane and earthquake.

Dr. Charles Johnson – Virginia Dental Association. He discussed the Virginia Dental Association's Mission of Mercy (MOM) program which has had 49 missions in 11 years serving 39,000 patients. The next MOM programs are scheduled for October 1 in Grundy and November 5 in Emporia. The Virginia Dental Association is working with Medicaid to get more dentists to apply to be providers; 78% of dentists are not Medicaid providers.

Amy Vest – Virginia Pharmacists Association. She offered words of gratitude for Ed Spearbeck's service and acknowledged how much he accomplished throughout his years of service to the Board. She talked about the National Drug Take Back Day scheduled for October 29; more information on locations can be found on the Drug Enforcement Administration's website. She also informed the Board that pharmacists in Virginia are geared up to immunize for flu.

Jim Edmondson – Consumer Representative. No report. He has been heavily involved in review of the Emergency Regulations for Licensure of Abortion Facilities.

Dr. Bhushan Pandya – Medical Society of Virginia. No report. He is working with stakeholders on a pilot program for the use of telemedicine in Southwestern Virginia. He is also gearing up for the annual health fair in Danville (November 5); he is looking forward to support from VDH for this event.

Eric Deaton – Hospital Industry. He said that he is excited to work with VDH on the health care reporting requirements. He also discussed issues pertaining to reimbursement.

Dr. John deTriquet – Local Government. He discussed issues pertaining to hurricane response. He told the Board that the City of Chesapeake is proactive in preparing and responding to these types of events. He also discussed issues concerning mosquito control. He said that public health and local government work well together.

Dr. Catherine Slusher – Medical Society of Virginia. No report.

Dr. Steven Escobar – Virginia Veterinary Medical Association. He said the Virginia Veterinary Medical Association is gearing up to monitor potential legislation concerning animal protection, which he said is an emotionally charged issued.

Bruce Edwards – Emergency Medical Services Representative. He discussed issues concerning training and support for rescue squads, and development of a strategic plan to strengthen rescue

squads. He also briefed the Board concerning issues involved with providing emergency medical services for patients with behavioral and developmental disorders.

Other Business

There was a brief discussion about the time for the next Board meeting (December 9, 2011) and that meetings will be held on Fridays in 2012. There was a motion to approve the proposed 2012 meeting schedule (March 23, 2012; June 15, 2012; September 14, 2012; December 14, 2012). The motion was seconded and approved unanimously.

Adjourn

The meeting adjourned at approximately 4:27 p.m.