

**State Board of Health
Minutes
December 4, 2014 – 9:00 a.m.
Perimeter Center, 9960 Mayland Drive
Richmond, Virginia 23233**

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

VDH staff present: Marissa Levine, MD, State Health Commissioner; Richard Corrigan, Deputy Commissioner for Administration; Bob Hicks; Deputy Commissioner for Community Health Services; David Trump, MD, Chief Deputy Commissioner; Joe Hilbert, Director of Governmental and Regulatory Affairs; Catherine West, Administrative Assistant; Maribeth Brewster, Risk Communications Manager; Matt LiPani, Public Information Officer; Erik Bodin, Director, Office of Licensure and Certification; Susan Horn, Policy Analyst, Office of Licensure and Certification; Debbie Condrey, Director and Chief Information Officer, Office of Information Management; Adrienne McFadden, MD, JD, Director, Office of Minority Health and Health Equity; Lilian Peake, MD, Director, Office of Family Health Services; Dev Nair, PhD, Director, Division of Policy and Evaluation; Juanita Leon, Billing and Eligibility Supervisor, Chesterfield Health District; and Tobin Joseph, Project Manager, Office of Information Management

Others Present: Cindy Bailey and Robin Kurz, Attorney General's Office

Call to Order

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

Welcome and Introductions

Following introductions, Mr. Edwards welcomed Mary Margaret Whipple to the Board of Health. Ms. Whipple has been appointed as the hospital industry representative on the Board. Mr. Hilbert then reviewed the agenda and the items contained in the Board's notebooks. The agenda was approved by unanimous consent.

Mr. Edwards recognized the large turnout for members of the public at the meeting, located in both Boardroom 2 and Boardroom 1. He reminded the public to maintain appropriate decorum during the meeting. In particular, Mr. Edwards asked the audience to be polite during the meeting, and to please refrain from waving of hands and signs. Mr. Edwards said that members of the audience would be given an opportunity to display their signs during the public comment period. Finally, Mr. Edwards stated that those members of the public that are disruptive during the meeting would be escorted out by security.

Approval of Minutes

The draft minutes of the September 18, 2014 Board meeting were approved by unanimous consent.

Commissioner's Report

Dr. Levine began the Commissioner's report to the Board with the introduction of the "agency stars" for the meeting: Juanita Leon with the Chesterfield Health Department and Tobin Joseph with the Office of Information Management.

Dr. Levine provided the Board with an update on Ebola. There has been an unprecedented outbreak in four West African countries, with a 70 percent fatality rate. While this is a very serious disease, there is no Ebola in Virginia. The disease is not easily transmitted. Early diagnosis and treatment is crucial. The incubation period is from two to 21 days. Individuals are not contagious during that time. Healthcare workers and household members who come into contact with infected individuals are at highest risk of contracting the disease. There is currently no vaccine, but vaccine development trials are ongoing. In the U.S., the federal government has initiated an incoming international traveler screening process through five airports, one of which is Dulles. VDH is working with Dulles on the screening process, to make sure that everyone coming into Virginia is known to VDH. This is a significant effort, primarily involving local health districts in Northern Virginia. VDH and other state agencies have established a Unified Command to coordinate Virginia's ongoing Ebola preparedness planning efforts.

Dr. Levine then provided an update on Virginia's Health Information Exchange (ConnectVirginia) and the All Payer Claims Database (APCD). Implementation of both of these is in progress. The APCD will come into use in early 2015. Dr. Levine also provided an update concerning the electronic death registration system, which will enable health care providers to complete death certificates online. Dr. Levine also reported that VDH is still on track to digitize and create an online index of vital records during 2015.

Dr. Levine briefed the Board on VDH's ongoing efforts to promote thriving infants. More infants are thriving in Virginia. However, a key issue is to reduce disparities that exist in this area. VDH has created a thriving infants strategic plan with stakeholders, focused on helping infants survive and thrive during their first year of life.

Dr. Levine also described the Million Hearts initiative, which is focused on reduction of heart attack and stroke morbidity and mortality. Dr. Levine told the Board that methods and strategies for controlling high blood pressure are known but not sufficiently implemented. Greater success in controlling high blood pressure will help to both improve health and decrease health care costs.

Dr. Levine updated the Board on the VDH radiological health program. Virginia is considered an "Agreement State" by the U.S. Nuclear Regulatory Commission (NRC). As a result, VDH is authorized to regulate certain uses of radioactive materials. VDH is evaluated every four to five

years by NRC for compliance with Agreement State requirements. VDH received the highest achievable rating from the NRC during its most recent review.

Dr. Levine then provided an update on recent VDH key personnel changes:

- Jennifer Mayton, new Operations Director for Community Health Services.

Abortion Facility Licensure Status Report

Mr. Bodin provided the Board with this update. There are 18 licensed abortion facilities in Virginia. VDH is ensuring that the approach to inspecting abortion facilities is consistent with the approach used to inspect other types of health care facilities regulated by VDH. The complaint unit within VDH's Office of Licensure and Certification (OLC) receives complaints about all types of facilities that OLC regulates. A severity index for deficiencies found during an inspection has been developed; some have higher degree of severity than others. There are several ways for an individual to file a complaint. If deficiencies are found, a plan of correction is requested from the facility. The plan is reviewed to ensure that it is acceptable. If plan is not accepted, the facility is given up to two opportunities to make updates and resubmit. If at the end of the process, the plan is not acceptable, VDH may deny, revoke or suspend the license. A follow-up inspection to determine whether the plan of correction has been implemented can take place at OLC's discretion or at the Commissioner's request.

Mr. Bodin reviewed the complaints received to date. The kinds of complaints received and the findings of the complaints are not substantially different for abortion facilities than for other types of facilities that OLC regulates. Mr. Bodin described one complaint that was received; investigation determined that the complaint was substantiated but the practice complained of was not a practice that was in violation of the regulations. Mr. Bodin also explained that three complaints that were received involved practices that were not under VDH jurisdiction, but rather were under the jurisdiction of the Board of Medicine (BOM) or the Board of Nursing (BON). Until such time as the BOM or BON completes their investigation, the BOM or BON does not acknowledge or discuss a complaint. OLC will be notified when the investigations are completed.

Mr. Bodin briefly discussed the variance provision of the regulations. The last facility grace period for compliance with the design and construction requirements of the regulations ended in October of 2014. Temporary variances can be issued to specific regulations. Thirteen have requested a variance to the regulations; 12 of the variance requests have been granted and one is still under consideration.

There was discussion concerning substantiated vs. unsubstantiated complaints. Mr. Bodin told the Board that it was possible that the issue/facts underlying a complaint may in fact have occurred, but when OLC subsequently inspects the facility concerning the complaint; it cannot find any evidence that substantiates the complaint. There was further discussion concerning whether OLC inspectors are able to find evidence of correction of the issues underlying the complaint. There was discussion concerning the use of randomized chart reviews during the complaint inspection process. Mr. Bodin said that if and when OLC knows the specific patient who was the subject of the complaint, as well as the specific day in question, the inspectors will

pull that patient’s chart for review, as well other patient charts for that same day. There was discussion concerning the fact that OLC facility surveyors have access to the charts of all facility patients. There was further discussion concerning the degree of severity of complaints.

Mr. Beall then stated that the Board has heard significant public comment on both sides of the issue. He told the Board that it is difficult to reconcile competing comments without being able to look at specific facility inspection documents. Mr. Beall stated that he had requested, at the June 2014 Board meeting, to see those facility inspection reports and plans of correction, and that he had reiterated that request at the September 2014 Board meeting. He expressed some frustration and disappointment that those reports were not yet available to Board members. Mr. Beall told the Board that he is hesitant to vote on potential amendments to the regulations without first being able to review the direct source documents. Mr. Beall requested that all facility inspection reports be posted to a website, at the point they become public records, so that they are available to those Board members who wish to review them.

Mr. Edwards asked Mr. Bodin if it is possible for VDH to fulfill Mr. Beall’s request. Mr. Bodin responded that Mr. Beall’s request would be fulfilled.

Mr. Beall then commented concerning a recent official advisory opinion received from the Attorney General, concerning 1) whether a VDH hospital licensing inspector who is a nurse is required to make a report of suspected child abuse or neglect under Virginia Code § 63.2-1509 upon reviewing the medical record of a fourteen-year-old girl who was pregnant and received services, such as prenatal or abortion services, at the hospital; and 2) whether a hospital licensing inspector is required to make a report to law enforcement given that it is a crime to have carnal knowledge of a child between the ages of thirteen and fifteen under Virginia Code § 18.2-63. Mr. Beall told the Board that he had read the opinion carefully, and observed that the legal answer is not always the right answer. He told the Board that a government official should be held to a higher standard, and recommended that when VDH facility inspectors know that a crime has been committed, they should report the matter to law enforcement authorities. Dr. Levine told the Board that she agreed with Mr. Beall, and commented on the difference between legal requirements and moral/ethical standards. Dr. Levine also said that VDH is in the process of re-evaluating agency policy related to this issue, in order to ensure that an appropriate policy is in place and that all agency staff are properly trained to implement that policy.

Dr. Levine also told the Board that, when VDH knows the “who, what or when,” a more explicit investigation of a complaint can be made. However, a number of complaints that have been submitted do not contain that type of specific information.

Dr. Seeds inquired whether local EMS agencies were used by VDH to evaluate requests for variances to the design and construction requirements of the regulations. Mr. Bodin responded that EMS agencies were not contacted as part of VDH’s evaluation of the variance requests.

Ms. Getter commented concerning the terminology used by VDH (i.e. substantiated and unsubstantiated) to categorize facility complaints. She requested that VDH consider the use of different terminology, such as “investigated and corrected,” or “investigated but not found.” Mr.

Bodin said that OLC would give consideration to that request, as it continues to examine its overall process for administering the abortion facility licensure and inspection program.

There was further discussion concerning the types of information considered by VDH when granting a variance, the time frame for acting on variance requests, the most typical source of facility complaints, whether facilities are eligible to reapply for a variance when the variance expires, and whether or not facility complaint records contain patient identifying information.

There was additional discussion concerning the process for requesting variances to the design and construction requirements of the regulations. Mr. Bodin explained that all facilities requesting a variance have to provide VDH with an explanation of 1) what they are requesting; 2) how and why the requested variance does not adversely affect patient safety; and 3) the facility's proposed long-term solution to the issue. Mr. Bodin explained that VDH would evaluate any subsequent variance request based on what was contained in a facility's first request and actions that the facility had taken since the initial request. Finally, Mr. Bodin advised the Board that five of the 18 licensed abortion facilities have informed VDH that they are in compliance with the design and construction requirements of the regulation.

Matrix of Pending Regulatory Actions

Mr. Hilbert reviewed the summary of all pending VDH regulatory actions. Since the September 2014 meeting, there has been one regulatory action that the Commissioner has taken on behalf of the Board while the Board was not in session. That action was to approve the final exempt action to amend the Regulations for the Licensure of Home Care Organizations (12VAC5-381). This action will bring the regulations into conformance with recent changes made to various sections of the Code of Virginia.

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

- Rules and Regulations Governing Campgrounds (12VAC5-450);
- Rules and Regulations Governing the Construction of Migrant Labor Camps (12VAC5-501); and
- Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals (12VAC5-200).

Public Comment

Mr. Edwards discussed the rules and procedures by which the public comment period would be conducted. Pursuant to the Board's public participation policy, each individual has a maximum of two minutes in which to address the Board.

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

Mr. Edwards outlined the procedure for the public comment period. He stated that this is one meeting in a series of meetings regarding the Regulations for Licensure of Abortion Facilities. There will be additional opportunities for the public to speak about these regulations at future meetings. In order to maximize the number of people that can speak, Mr. Edwards said that Mr. Hilbert would call the name of the speaker and an on-deck name for the next speaker. Mr. Edwards further stated that there are two sets of sign-in sheets for the public comment period; one for Boardroom 2 and one for Boardroom 1. Mr. Edwards explained that names would be called from the sheets for Boardroom 2 first and then if time allows, from the sheets for Boardroom 1. Mr. Edwards asked that speakers comply with the two-minute time limit. He also stated that any person signed up to speak could cede their time slot to another individual. Finally, he asked that speakers not be unduly repetitive of what other speakers have already said.

All of the individuals that spoke during the public comment period commented about the Regulations Governing Licensure of Abortion Facilities (12 VAC5-412) and the Notice of Intended Regulatory Action (NOIRA) for those regulations. The following individuals addressed the Board:

- Delegate Robert Marshall – He spoke in support of retaining the regulations as is and stated that the architectural standards protect women.
- Bishop E. W. Jackson – He spoke in support of the regulations and commented that the standards should be stricter.
- Janet Robey – She spoke in support of maintaining the regulations as is.
- Louantha Kerr – She spoke in support of protective abortion facility regulations.
- Jeff Caruso – He spoke in support of maintaining the regulations as is.
- Chris Freund – He spoke in support of maintaining the regulations as is.
- Frances Bouton – She spoke in support of the regulations.
- Victoria Cobb – She spoke in support of maintaining the regulations as is.
- Cheri Britt – She spoke in support of strict parental consent laws with regard to abortion procedures.
- Dr. Ike Koziol – He spoke in support of the NOIRA.
- Dr. Kris Kennedy – She spoke in support of amending the regulations.
- Amanda Allen – She spoke in support of the NOIRA and amending the regulations.
- Dar Sarina Floyd – She spoke in opposition of the regulations.
- Heather Shumaker – She spoke in support of the NOIRA and amending the regulations.
- Louisa Thanhowser – She spoke in support of the NOIRA and amending the regulations.
- Amanda Spence – She spoke in opposition of the regulations.
- Casey Mattox – She spoke in favor of maintaining the regulations as is.
- Jessica Cochrane ceded her time to Carla Herrmann – Ms. Herrmann read her niece's story about her experience with an abortion facility.
- Billy Mullins – He spoke in support of the regulations.
- Sharon Utz – She spoke in opposition of the regulations.
- Rosemary Coddling – She spoke in support of the NOIRA and amending the regulations.
- Margie Del Castillo – She spoke in support of amending the current regulations.
- Freeda Cathcart – She spoke in support of the NOIRA.
- Lian Bily – She spoke in support of the NOIRA and amending the current regulations.

- Josephena Winfield – She spoke in support of the NOIRA.
- Melanie Ziff – She spoke in opposition of the regulations.
- Bill O’Brien – He spoke about the psychological and spiritual trauma of abortion procedures.
- Frederick Michael Decker – He spoke in support of the current regulations and of enforcing the regulations.
- Johanna Garcia – She spoke in support of Planned Parenthood clinics.
- Adrian Jones – He encouraged the Board to educate themselves about Planned Parenthood.
- Brent Hockema – He spoke in support of the current regulations.
- Will Langford – He spoke in support of reasonable regulations.
- Henry Guevara ceded his time to Joshua Dart – He spoke in opposition of the NOIRA and abortion.

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

Regulatory Action Items

Regulations for Licensure of Abortion Facilities (12VAC5-412) – Notice of Intended Regulatory Action (NOIRA)

Mr. Bodin presented the NOIRA. He began by reviewing the provisions of Virginia’s regulatory process under the Administrative Process Act, and then discussed the history of the regulations. Mr. Bodin then described the periodic review of the regulations that was conducted as required by Executive Directive No. 1. The outcome of the periodic review was the Commissioner’s decision to initiate a regulatory action to amend the regulations, utilizing the Commonwealth’s standard, three-stage regulatory process. The first stage of Virginia’s regulatory process is the NOIRA stage, required to initiate process to amend regulations. During the NOIRA stage, the agency provides a broad idea of what types of issues it intends to address through regulatory amendments. Should the Board approve the NOIRA, it will be submitted for executive branch review and, upon approval by the Governor, will be published in the Virginia Register of Regulations for a 30-day public comment period. During the proposed stage, draft proposed regulatory amendments are developed and presented to the Board for its consideration. Following approval by the Board, a proposed regulatory action is submitted for executive branch review and, upon approval of the Governor, is published in the Virginia Register of Regulations for a 60-day public comment period. During the final stage, draft final regulatory amendments are developed and presented to the Board for its consideration. Following approval by the Board, a final regulatory action is submitted for executive branch review and, upon approval of the Governor, is published in the Virginia Register of Regulations for a 30-day final adoption period. Mr. Bodin explained to the Board that the standard, three-stage regulatory process typically takes about 18 to 24 months to complete.

Mr. Bodin told the Board that the NOIRA for 12 VAC5-412 identifies six areas of proposed amendments:

Parental Consent

Clarify the requirements of parental consent. Ensure all requirements of parental consent are within the regulations.

Medical testing and laboratory services

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

Anesthesia Service

Incorporate additional best practice standards. Add a documentation requirement.

Administration, storage and dispensing of drugs

Align these provisions more precisely with the Code of Virginia. Remove an unnecessary restriction that is not required by the Code of Virginia.

Emergency Services

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

Facility Design and Construction

Update the design and construction requirements.

Mr. Bodin told the Board that regulations for the licensure of abortion facilities are required by the Code of Virginia, and that VDH will ensure that the regulations comply with the provisions of Executive Order 17, which pertains to the review and development of state regulations. Mr. Bodin told the Board that public hearings will be scheduled and held during the regulatory process. Dr. Escobar moved that the NOIRA be approved with Mr. Edmondson seconding the motion. Mr. Edwards then asked if there was any discussion concerning the motion.

Dr. Seeds told the Board that he felt obligated to correct misconceptions that may be held by the public concerning the OB/GYN advisory committee that helped VDH, in the summer of 2011, to develop the emergency regulations governing licensure of abortion facilities. Dr. Seeds, who was a member of the advisory committee, told the Board the advice offered by the advisory committee was not ignored by VDH. Dr. Seeds explained that the advisory committee was not asked to advise concerning development of the facility design and construction requirements of the regulations. Dr. Seeds stated that the advisory committee reviewed and considered information prepared by a wide range of organizations including the National Abortion Rights Action League, Planned Parenthood, and the National Abortion Federation. Dr. Seeds said that the advisory committee's recommendations were consistent with information prepared by those organizations. The advisory committee also considered abortion facility regulations promulgated by South Carolina, which had been the subject of legal challenge but ultimately upheld by the

U.S. Fourth Circuit Court of Appeals. Dr. Seeds also told the Board that he personally challenges statements that have been made concerning the safety of abortion procedures. He said that information from the Centers for Disease Control and Prevention concerning abortion procedures is voluntarily reported and incomplete. Dr. Seeds then stated that the two years that the permanent abortion facility regulations have been in effect does not provide sufficient experience upon which to determine that the regulations should be amended. Rather, Dr. Seeds said that a periodic review every four years, as contemplated by Executive Order 17, is appropriate. Finally, Dr. Seeds stated that, given that variances have been granted to facilities, the notion that Virginia will lose abortion facilities as a result of the regulations is not reasonable.

Mr. Beall told the Board that he appreciated Dr. Seeds' comments. He stated that before the Board considers any amendments to the regulations, it should have access to the abortion facility inspection documents.

Ms. Getter asked if it was within the Board's authority and discretion to limit the scope of the NOIRA, so that it would be narrower than as proposed by VDH staff. Mr. Hilbert responded that the Board had the authority to limit the scope of the NOIRA prior to approving it. Ms. Getter then expressed the desire that the NOIRA contain more detailed information concerning type of amendments being considered by VDH.

Dr. Slusher told the Board that the statutory mandate for the regulations has not changed, and variances have been issued where appropriate. She stated that a periodic review every four years, as contemplated by Executive Order 17, makes sense. Consequently, she said that she is not sure that the regulations need to be examined at this time. She said that more data is needed before deciding to amend the regulations.

Ms. Hines stated that VDH staff had outlined a lengthy regulatory process, and that the Board is not being asked to decide on amending language at this time. Ms. Brosche stated that she is not opposed to looking at the regulations, but she agreed with the comment that a little more detail is needed in the NOIRA concerning the type of regulatory amendments that are being considered.

Mr. Beall asked if an advisory committee, similar to the type of advisory committee that Dr. Seeds participated on in 2011, will be appointed as the regulatory process moves forward. Dr. Levine said that she will consider doing so, based on the Board's comments. Dr. Levine also told the Board that VDH has had a lot of experience with the regulations, and believed that sufficient information existed to be examined as part of a review of the regulations.

Ms. Getter then made a motion to amend the NOIRA by removing medical testing from the scope of the NOIRA. The motion was seconded by Dr. Seeds. Mr. Edwards asked if there was any discussion concerning the motion. There was a brief discussion concerning the merits of the motion. Mr. Edmondson urged Ms. Getter and Dr. Seeds to reconsider the need for the motion,

pointing out that the NOIRA is simply the beginning of the regulatory process, and that the Board does not have to deal with actual proposed amending language at this time. Ms. Hines told the Board that she concurred with Mr. Edmondson’s statement.

Mr. Edwards then called for a roll-call vote on the motion to amend the NOIRA by deleting the language pertaining to medical testing. The vote was five in favor of the motion (Ms. Getter, Mr. Kuhlman, Dr. Seeds, Dr. Slusher, and Ms. Vest), and 10 opposed (Mr. Beall, Ms. Brosche, Mr. East, Mr. Edmondson, Mr. Edwards, Dr. Escobar, Ms. Hines, Dr. Miller, Ms. Prichard, and Ms. Whipple). The motion failed.

There being no further discussion, Mr. Edwards then called for a roll-call vote on the motion to approve the NOIRA for 12VAC5-412. The vote was 13 in favor (Mr. Beall, Ms. Brosche, Mr. East, Mr. Edmondson, Mr. Edwards, Dr. Escobar, Ms. Getter, Ms. Hines, Mr. Kuhlman, Dr. Miller, Ms. Prichard, Dr. Slusher, and Ms. Whipple), and two opposed (Dr. Seeds and Ms. Vest). The NOIRA was approved.

Lunch Presentation

Dr. Levine introduced Dr. Adrienne McFadden, Director of VDH’s Office of Minority Health and Health Equity as the lunch speaker. Dr. McFadden gave an overview of the VDH rural health program.

There was a discussion of efforts to address health workforce issues in rural areas through initiatives such as the State Loan Repayment Program and the Conrad-30 visa waiver program. There was additional discussion concerning the role that telemedicine can play in addressing health care issues in rural Virginia. The Board also discussed the implications on rural areas of the Commonwealth’s failure to expand eligibility for the Medicaid program. Dr. McFadden described collaboration between VDH and the Department of Housing and Community Development, as well as collaboration between VDH and the Virginia Dental Association. Dr. Seeds told the Board that while medical school graduations in Virginia have increased, post-graduate medical residency slots have not increased. This increases the likelihood that Virginia’s medical school graduates will not practice in the Commonwealth. Dr. Levine thanked Dr. McFadden for her presentation, and stated that rural Virginia is confronted by many significant issues, including economic development issues, that have implications for the health status of its residents. Addressing those issues will require coordinated focus and effort.

Regulatory Action Items

Procedures for the Submission of Health Maintenance Organizations Quality of Care Performance Information (12VAC5-407) – Fast track Amendments

Ms. Condrey presented the fast track amendments, which are the result of a periodic review of the regulations. The proposed amendments enhance clarity and update or eliminate outdated information. Ms. Hines moved that the fast track amendments be approved with Dr. Seeds seconding the motion. The Board unanimously approved the fast track amendments.

Regulations for the Conduct of Human Research (12VAC5-20) – Final Amendments

Dr. Peake presented the final amendments, which are the result of a periodic review of the regulations. The final amendments enhance clarity and update outdated information. The final amendments were initially presented to the Board at its September 2014 meeting. At that time, action on the final amendments was postponed in order for VDH to provide answers to questions that members raised at that meeting. The final amendments now reflect changes made as a result of the questions raised in September 2014. A definition was added for “minor increase or minimal risk.” Clarifying language was added for consistency with language in the federal regulations. Language was modified to include individuals with vulnerable populations to be consistent with federal regulations. Finally, redundant language was addressed. Dr. Escobar moved that the final amendments be approved with Mr. Beall seconding the motion.

Mr. Beall stated that he had raised most of the questions at the September 2014 meeting and commended Dr. Nair for taking the time to discuss his concerns. There was a brief discussion of vulnerable populations and the federal regulations. There being no further discussion, the final amendments were approved unanimously by voice vote.

Regulations Governing Virginia Newborn Screening Services (12VAC571) – Final Amendments

Dr. Peake presented the final amendments, which adds severe combined immunodeficiency to the Virginia newborn screening panel. Currently, the regulations require screening for 29 conditions. If the final amendments are approved, and with the emergency regulations that were approved in September 2014, which added critical congenital heart disease to the screening panel, a total of 31 conditions will be included in the Virginia screening panel. Dr. Miller moved that the final amendments be approved with Ms. Brosche seconding the motion.

There was a brief discussion about the cost of the screening services. There being no further discussion, the final amendments were approved unanimously by voice vote.

Member Reports

Dr. Benita Miller – Virginia Dental Association (VDA). She expressed appreciation for Dr. McFadden’s presentation and talked about the significant issue of access to dental care and how that impacts chronic disease. She told the Board about the Mission of Mercy (MOM) program that provides care in mostly rural areas of Virginia. In the last 15 years, the MOM program has provided services to over 55,000 patients. Dr. Miller also discussed the concept of community dental health care, which could involve a lay community health worker to provide education about preventive care, and to coordinate access to a dentist. She asked that the Board consider having a lunch presentation from the VDA at a future meeting.

Hank Kuhlman – Consumer Representative. No report

Faye Prichard – Local Government. No report.

Jim Edmondson – Corporate Purchaser of Health Care. Mr. Edmondson expressed frustration about the lack of information concerning newly-insured households under the Affordable Care Act.

Brad Beall – Consumer Representative. No report.

Theresa Brosche – Virginia Nurses Association (VNA). She told the Board that the VNA continues work on the implementation of the recommendations from the Institute of Medicine's *Future of Nursing* report. She stated that Virginia is a leader in this initiative. Finally, she thanked Dr. Levine and VDH staff for their ongoing work and timely updates regarding Ebola.

Dr. Steven Escobar – Virginia Veterinary Medical Association (VVMA). No report.

Amy Vest – Virginia Pharmacists Association. She read a report from the Drug Enforcement Agency (DEA) regarding the prescription drug take-back days program that DEA sponsors. The total amount of prescription drugs collected in the four years that the take-back program has been operating is 2,411 tons. There was a brief discussion of secured collection boxes located at pharmacies, and methods for disposing of the collected drugs.

Dr. Catherine Slusher – Medical Society of Virginia (MSV). She told the Board that MSV's annual meeting, which was held in October, was well attended. She indicated that the highlight of the meeting was Dr. Levine's presentation on Ebola and VDH's preparedness and response efforts.

Megan Getter – Public Environmental Health Representative. No report.

Dr. John Seeds – Medical Society of Virginia (MSV). Dr. Seeds told the Board that MSV continues to work on the problem of prescription drug abuse, as well as on telemedicine initiatives.

Linda Hines – Managed Care Health Insurance Plans. She told the Board that Virginia Premier is partnering with the emergency medical services community to streamline funding sources for coordination of care. She indicated that approximately 30,000 Virginians are covered.

Tommy East – Nursing Home Industry Representative. No report.

Mary Margaret Whipple – Hospital Industry. She told the Board that hospitals are under a lot of stress, particularly rural hospitals. There is a big responsibility for hospitals regarding Ebola. She also told the Board that Medicaid expansion is important for hospitals.

Bruce Edwards – Emergency Medical Services (EMS) Representative. – He told the Board that the annual EMS symposium was held in November, providing 25,000 hours of continuing education. He also told the Board that the Governor's awards for members of the EMS community were presented at the symposium.

Other Business

There was further discussion concerning the timeframe within which VDH will have a special website established for Board members in order to access copies of abortion facility complaints, inspection reports and plans of correction. Mr. Beall requested that the site be available within three or four weeks prior to the March 19, 2015 Board meeting. Dr. Levine said that the website would be available by that time frame.

Mr. Edwards praised VDH staff for all of the preparations that had been made in advance of the Board meeting. He also let the Board know that he and Dr. Levine would be talking by phone on a monthly basis, in between Board meetings. Dr. Levine thanked Mr. Edwards for the manner in which he conducted the Board meeting.

Adjourn

The meeting adjourned at approximately 2:49 p.m.

DRAFT