Regulatory Advisory Panel for the Regulations for Licensure of Abortion Facilities (12VAC5-412)
Building Panel Minutes

April 6th 2:00-3:30 p.m.
Perimeter Center
Second Floor Conference Center Board Room 4
9960 Mayland Drive,
Henrico Virginia 23233

In attendance: VDH Staff: Dr. Marissa Levine, State Health Commissioner, Dr. David Trump, Deputy Commissioner, Erik Bodin, Director of the Office of Licensure and Certification, Fred Kyle Director of the Office of Licensure and Certification's Acute Care Unit, and Susan Horn, Policy Analyst. Panel Members: Ron Clements, Ron Reynolds, Cheri Hainer, Robert Dawson, Emory Rodgers, Julie Walton, and Richard Peterson. Members of the public also attended.

Dr. Levine began the meeting by asking everyone to introduce themselves. She then explained the charge and direction of the panel: specifically for the panel members to utilize their expertise to advise the Commissioner on the current regulatory action pending for the Regulations for Licensure of Abortion Facilities (12VAC5-412). She explained that the Building Panel will focus on the provision of the regulatory chapter related to building and construction standards. Dr. Levine explained that the meeting is a public meeting, meaning that it is open to members of the public; however, as the meeting is not a public hearing the panel will not be accepting public comment.

Dr. Levine again noted that there is a pending regulatory action in place. She then read Section 32.1-127 of the Code of Virginia which lays out the requirements that the Board of Health must follow when promulgating regulations related to the regulation of medical care facilities and services within the Commonwealth. That Section states, "The regulations promulgated by the Board to carry out the provisions of this article shall be in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety….."

Dr. Levine reiterated that the purpose of the panel is for the members to provide their expertise in drafting proposed regulatory language. She noted that the panel will have three meetings and the final meeting will be a joint meeting with the physician's panel in which both panels can confer together. At that point she asked whether any members of the panel had any questions. As there were none she stated she was going to take her leave so that members of the panel can discuss freely without any question of the Commissioner's influence.

At that point Erik Bodin, Director of the Office of Licensure and Certification took over the meeting giving a brief legislative history behind the Regulations for Licensure of Abortion Facilities (12VAC5-412). Mr. Bodin explained that in 2011 the General Assembly passed SB924 which classified all facilities in which 5 or more first trimester abortions per month are performed as a category of hospital. SB924 contained a second enactment clause which stated that the Board of Health must promulgate regulations within 280 days of the enactment of the

bill. Therefore the Board of Health adopted emergency regulations to implement regulations within that time frame. Following the enactment of the emergency regulations, the Department and the Board of Health utilized a standard regulatory process to implement permanent regulations. The final regulations went into effect on June 20th, 2013.

Mr. Bodin then noted that regulations are usually reviewed once every 4 years. However, Governor McAuliffe issued Executive Directive 1 which directed the Board of Health to conduct a periodic review of the Regulations Governing Licensure of Abortion Facilities (12VAC5-412) by October 1, 2014. That review was conducted and the Board of Health received nearly 15,000 comments during the public comment period. Based on comments from the public and Office of Licensure and Certification (OLC) staff, the Commissioner determined it was necessary to amend the regulations. Therefore the Board initiated a standard regulatory action, starting with a Notice of Intended Regulatory Action (NOIRA). During the public comment period of the NOIRA the OLC received close to 5,000 public comments. At this point Dr. Trump stressed that currently the Department is in the Proposed Stage of the regulatory action and is drafting proposed language.

Mr. Bodin then explained the general principles of Executive Order 17 which is related to the development and review of state agency regulations. Mr. Bodin read from Executive Order 17 which states, "All regulatory activity should be undertaken with the least possible intrusion into the lives of the citizens of the Commonwealth and be necessary to protect the public health, safety, and welfare. Accordingly, agencies shall consider: 1. The use of economic incentives to encourage the desired outcomes (such as user fees or marketable permits); 2. The use of information disclosure requirements, rather than regulatory mandates, so that the public can make more informed choices; 3. The use of performance standards in place of mandating specific techniques or behavior; and 4. The consideration of reasonably available alternatives in lieu of regulation. Where applicable, and to the extent permitted by law, it shall be the policy of the Commonwealth that only regulations necessary to interpret the law or to protect the public health, safety, or welfare shall be promulgated. Regulations shall be clearly written and easily understandable. Regulations shall be designed to achieve their intended objective in the most efficient, cost effective manner."

At this point Mr. Bodin asked the panel if they had any questions for him. Hearing none he turned the floor over to Fred Kyle, Director of the Acute Care Unit at the OLC. Mr. Kyle explained the structure of the Acute Care Unit. Mr. Kyle has three supervisors within his unit, who oversee surveyors. Surveyors conduct facility inspections. There are a number of inspections surveyors conduct: the initial inspection at the time of application, biennial inspections which are done on a biennial basis after licensure, revisits, which occur if deficiencies are discovered on a biennial inspection and complaint inspections, which occur if a member of the public makes a complaint against a facility. Mr. Kyle was happy to say that the OLC Acute Care Unit has not received a complaint regarding any of these facilities within eight months to a year.

Mr. Kyle then explained that when a facility is inspected and cited for a deficiency they must submit a valid plan of correction. A surveyor will look for compliance with the facility's plan of correction when conducting a revisit.

Mr. Kyle explained that the OLC is currently issuing renewals of licenses and variances where appropriate as facilities apply for both. Mr. Kyle noted that the variances are related to the Facility Guidelines Institute (FGI) guidelines. Dr. Trump clarified that the variances are related to certain provisions of the FGI guidelines.

At this point Mr. Bodin explained that the Regulations for the Licensure of Abortion Facilities require that facilities comply with both the Virginia Uniform Statewide Building Code (USBC) and certain provisions of the latest edition of the FGI Guidelines for Design and Construction of Health Care Facilities. Mr. Bodin then fielded a question from a member of the panel asking what the FGI was. Mr. Bodin explained that the Facility Guidelines Institute is an organization previously known as the American Institute of Architects which publishes a document once every four years of guidelines for the design and construction of health care facilities.

Another panel member asked if there was a theme in terms of what provisions of the Guidelines facilities are not complying with. Mr. Bodin explained that the FGI Guidelines are extremely comprehensive and detailed, and that a number of these facilities are older buildings, some of which were previously residential structures. Due to the passage of SB924 in 2011 these facilities now have to come into compliance with the Guidelines. Mr. Bodin made it clear that the Regulations for the Licensure of Abortion Facilities (12VAC5-412) incorporate certain sections of the FGI Guidelines by reference.

A member of the panel asked if there a statute that requires the use of the FGI Guidelines. Mr. Bodin answered yes, Section 32.1-127.001 of the Code of Virginia requires that the regulations promulgated by the Board of Health for the licensure of hospitals include minimum standards for design and construction 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 which is now the Facility Guidelines Institute.

Emory Rodgers, a panel member stated that the USBC follows the Governor's Executive Order 17, which requires simplification of regulations and tasks agencies with making their regulations less burdensome. Mr. Rodgers affirmed that the USBC states that it supersedes state and local codes. He asked how that provision of the USBC would coincide with Section 32.1-127.001 of the Code of Virginia, he asked for the Virginia Department of Health to obtain a legal analysis. He provided several examples as to how the supremacy of the USBC takes place.

Mr. Rodgers noted that outpatient surgical facilities are not classified as hospitals within the building code; rather they are classified as "Business Group B", which is an "office professional or service-type transactions." He further noted that a majority of patients at these types of facilities would be deemed ambulatory, which means the individual is capable of self-preservation and able to evacuate the facility on their own without assistance. This is important and classifications within the USBC can hinge on how many individuals in a facility are ambulatory or non-ambulatory.

Mr. Rodgers noted that it is important to ensure that there are not multiple agencies overseeing the same aspects of regulation. He also believes there is a problem with the retroactive

application of the FGI Guidelines. He noted that at no point has the USBC required retroactive application. He then reiterated that he believes that it is tricky issue that the Regulations state that the FGI guidelines trump the USBC and reaffirmed his suggestion that the Office of the Attorney General work on analyzing the issue. He stated that the USBC has a proven track record.

Mr. Rodgers noted that the USBC allows for more stringent provisions in the case of a functional design issue but he is unsure how that issue would come into play here. Another member suggested that the OLC consider utilizing the FGI Guidelines only in cases where the USBC does not regulate the issue at hand. Another member suggested going through both the FGI Guidelines and the USBC and doing a side by side comparison.

Mr. Bodin took this time to explain that the FGI Guidelines do not have section for abortion facilities; the sections selected for inclusion in the regulations and incorporated by reference are those most closely aligned to abortion facilities, specifically those related to outpatient surgical facilities. Others mentioned there is a definition of abortion facility within the USBC: ambulatory care centers. Ron Clements suggested that rather than supplanting the Building Code that the USBC should be amended if there are elements that are not sufficient.

Cheri Hainer asked if any of these facilities are licensed as hospitals. Mr. Bodin stated no, these facilities are licensed as abortion facilities which the Code classifies as a type of hospital. Ms. Hainer noted that this issue could determine the type of classification of the facility. Others observed that there is a definition of ambulatory surgical center within the USBC. A panel member asked what is the intent of the regulatory requirement which states the FGI Guidelines take precedence over the USBC. Mr. Bodin noted that Section 32.1-127.001 of the Code of Virginia was amended to incorporate the FGI Guidelines in 2007, well before the licensure of abortion facilities. Mr. Bodin supposed that this legislative change was due to the fact that the FGI Guidelines are more applicable to health care facilities; he also noted that several other states utilize the FGI Guidelines. Rich Peterson stated that the FGI Guidelines create national consistent guidelines of industry standards.

Dr. Trump asked for some clarification from the panel regarding building classifications in terms of the distinction of an ambulatory/non-ambulatory facility. Panel members stated that the USBC requires a determination of sedation to ascertain whether or not a patient is able to self ambulate. Members articulated that they believe the USBC requires less than 4 patients to be non-ambulatory in order for the facility to be considered an ambulatory facility.

Mr. Bodin noted the time and suggested that the panel wrap up. He asked what panel members need from the OLC for the next meeting. Panel members suggested a side by side comparison of the USBC and the FGI Guidelines. Further the panel requested a legal analysis of the seeming contradiction that arises due to the fact that the USBC states that it trumps state and local codes and the abortion facility regulations state that the FGI Guidelines supersede the Building Code.

Again the panel asked why the building requirements were retroactive. Mr. Bodin explained that the Virginia Department of Health OLC was advised that as these facilities were not previously licensed, that they were all legally to be considered new facilities. He noted that is why the two-year grace period was written into the regulations.

Dr. Trump thanked the panel for their time and asked the members to keep April 20th on their calendars, noting that at that time the panel may be ready to consider specific language to recommend to the Commissioner.