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

April 6th 3:30-5:00 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: Dr. Eduardo Lara-Torre, Dr. Serina Floyd, and Dr. David Chelmow. 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 Physicians Panel will focus on the provisions of the regulatory chapter apart from the building and construction standards.

Dr. Levine noted that the panel will meet three times and the third meeting will be a joint meeting with the Building Panel and will be an opportunity for the physicians to provide their medical expertise to the building panel. 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 noted that the Regulations for the Licensure of Abortion Facilities recently underwent a Periodic Review. Following the periodic review, it was determined that the Regulations needed to be amended and a regulatory action was undertaken. 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 stated that the Virginia Department of Health would like to present the Board of Health with draft proposed language at the Board's June meeting. 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. Prior to Dr. Levine leaving, she and Dr.

Trump noted that the third meeting of the panel will be rescheduled so as to avoid scheduling conflicts which had arisen with a majority of panel members.

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. Mr. Bodin noted that the OLC and the Department is currently in the proposed stage of the regulatory action and is drafting proposed language. He then noted that the later in the meeting staff will circulate draft language to the panel; he stated that this language is a starting point and intended to spark discussion amongst panel members. He stressed that this language is not finalized and is only intended to provide a "jumping off point" for panel members to begin deliberations.

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 concluded that he hopes he's provided the panel with a good idea as to where they are today and the Commissioner's charge. He then 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 noted that he was going to provide the panel with a brief background of the Acute Care Division. 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 then 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 then 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 temporary. Dr. Trump noted that variances are valid for one year and must be renewed; it is the discretion of the Commissioner to renew a variance.

At this point Mr. Bodin requested that Susan Horn pass out the draft language that has been worked on by the Department to all panel members. Copies were also presented for members of the public to view.

The panel began by analyzing Section 240 of the Regulations: Medical testing and laboratory services. Ms. Horn explained the public comments which prompted the suggested language in front of the panel which is as follows:

C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the patient shall be notified that pregnancy tissue was not identified, possibility of ectopic pregnancy shall be explained to the patient, the patient shall be offered a pathologic examination of the tissue including a disclosure of the cost and should the patient desire the tissue specimen shall be sent for further pathologic examination. ~~and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.~~ The facility shall track and log any specimens sent for further pathologic examination.

Ms. Horn noted that this proposed amendment was created from comments from the American Congress of Obstetricians and Gynecologists (ACOG) and from an OLC staff member. ACOG suggested that rather than requiring mandatory additional testing that the regulation should allow the testing to be permissive and allow the decision to be one between physician and patient. The OLC staff member noted in her comment that facilities have not been tracking this testing and therefore there is no way for the facility to determine whether it is necessary to follow up. The physician's panel did not have any suggested edits to subsection C but asked if it was possible to suggest edits to other subsections of 240. Dr. Trump stated it was. They suggested edits to subsection A as follows:

A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed for each patient.

1. Use of any additional medical testing shall be based on an assessment of patient risk. ~~The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.~~

2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

~~3. The abortion facility shall develop, implement, and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.~~

The physician's panel also asked for the OLC to research how other entities that regulate medical records in terms of written records and electronic records. Ms. Horn noted that she will look into the issue.

Next the panel analyzed section 250 of the Regulations: Anesthesia service. Ms. Horn explained the public comments which prompted the suggested language in front of the panel which is as follows:

H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria <u>and that criteria has been documented within the patient's medical record.</u>

Ms. Horn noted that this proposed amendment was suggested by OLC staff. She stated that the regulations require documentation of patient's status upon discharge within another section of the regulations. However, OLC staff noted that several facilities have not been noting this important aspect of patient care within the patient's medical records. The staff member commented that reiterating the requirement here will reinforce the importance of documenting patient status upon discharge.

The physician's panel did not have any additional suggestions for this particular section but did note several questions, specifically if any facility is utilizing the type of sedation noted within subsection G as this is typically the type of sedation utilized in a hospital setting.

Then the panel reviewed section 230 of the Regulations: Patient services; patient counseling. Ms. Horn explained the public comments which prompted the suggested language in front of the panel which is as follows:

B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person~~.~~<u>, which shall be notarized as required by § 16.1-241 of the Code of Virginia.</u> If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

An OLC staff member noted that some facilities are failing to notarize parental consent which is a requirement by law. She noted that there is no mention of this statutory requirement within the regulations. A panel member asked for clarification of the statutory requirement. Mr. Bodin explained that Section 16.1-241 of the Code of Virginia requires that "A physician shall not knowingly perform an abortion upon an unemancipated minor unless consent has been obtained or the minor delivers to the physician a court order entered pursuant to this section and the physician or his agent provides such notice as such order may require." He then provided the definition of consent "(i) the physician has given notice of intent to perform the abortion and has received authorization from an authorized person, or (ii) at least one authorized person is present with the minor seeking the abortion and provides written authorization to the physician, which shall be witnessed by the physician or an agent thereof. In either case, the written authorization shall be incorporated into the minor's medical record and maintained as a part thereof." The definition of "authorization" is "the minor has delivered to the physician a notarized, written statement signed by an authorized person that the authorized person knows of the minor's intent to have an abortion and consents to such abortion being performed on the minor."

Upon Mr. Bodin's explanation the panel suggested additional edits that are as follows:

A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by an appropriately trained licensed provider working within the scope of their license ~~licensed physician~~.

B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person~~.~~, which shall be notarized as required by § 16.1-241 of the Code of Virginia. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

C. A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant to the provisions of § 18.2-76 of the Code of Virginia.

D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.

E. The abortion facility shall offer each patient seeking an abortion, in a language or manner she understands, appropriate counseling and instruction in the abortion procedure and shall develop, implement, and maintain policies and procedures for the provision of or referral for family planning services ~~and post-abortion counseling~~ to its patients.

F. There shall be an organized discharge planning process that includes an assessment of a patient's safety for discharge and ~~an evaluation of the patient's capacity for self-care and~~ discharge instructions for patients to include instructions to call or return if signs of infection develop.

Finally the panel reviewed Section 290: Emergency Services. Ms. Horn explained the public comments which prompted the suggested language in front of the panel which is as follows:

C. ~~A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.~~ When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.

ACOG noted within their public comment that this type of written agreement is not necessary as the provisions of The Emergency Medical Treatment And Labor Act (EMTALA) render it unnecessary. ACOG also noted concerns that some facilities may not be able to obtain such written agreements as the closest hospital may refuse to enter into such an agreement for a variety of reasons. The physician's panel agreed with the suggested edit and that such an agreement was unnecessary due to EMTALA. They had one suggested additional edit which is as follows:

C. ~~A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.~~ When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the ~~emergency department staff~~ appropriate receiving facility staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.

The panel requested copies of their suggested edits, and also stated they would like to utilize their time at the second physician's panel meeting to analyze other sections of the regulatory chapter.

Mr. Bodin thanked the panel for their time and noted again that the third panel meeting will be moved in order to accommodate panel member's schedules.