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

April 20th 3:30-5:00 p.m.
Perimeter Center
Second Floor Conference Center Board Room 3
9960 Mayland Drive,
Henrico Virginia 23233

In attendance: VDH Staff: 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, Joe Hilbert, Director of Governmental and Regulatory Affairs, and Susan Horn, Policy Analyst. Panel Members: Dr. David Chelmow, and Dr. Serina Floyd. Members of the public also attended.

Members of the Building Panel (in attendance until 4:00): Ron Clements, Ron Reynolds, Cheri Hainer, Robert Dawson, Emory Rodgers, Julie Walton, and Richard Peterson.

Dr. Trump welcomed the physicians. He then requested all panel members to introduce themselves. At that point Mr. Rodgers explained the recommendation of the Building Panel, giving the details of their suggested amendments to Section 370 of the Regulations for Licensure of Abortion Facilities (Regulations). A member of the Physician's Panel asked if the building requirements were to apply to all facilities even those facilities that only provide medical abortion. Mr. Rodgers noted that would be functional program question or a question for the Board of Health which could be addressed within the definition section of the Regulations. Dr. Chelmow noted that the construction guidelines are in his opinion overboard for those facilities which are only writing prescriptions. He stated there is precedent for such a separation of requirements within the Regulations, as there are different requirements for facilities offering varying levels of anesthesia.

A panel member asked if there can be an amendment to separate out those facilities which only perform medical procedures. Ms. Horn noted that the Code of Virginia classifies the facilities by the number of abortion performed per month and the Code does not differentiate between medical and surgical abortion. Mr. Clements stated that means in order to create such a distinction legislation would need to be enacted. Dr. Chelmow noted that he didn't know how to undertake the legal piece of the consideration; he was simply trying to take on the task of the panel.

Dr. Chelmow asked if all the provisions delineated within the FGI Guidelines were really necessary for safety purposes. Mr. Rodgers noted the building panel was not tasked with determining the relevancy of each provision. Dr. Chelmow noted concern that the FGI Guidelines include things such as awnings and parking. Mr. Rodgers stated the Uniform Statewide Building Code (USBC) would not be controlling in terms of awnings but would address parking. Mr. Dawson stated that the USBC bases usage and occupancy categorization on how many patients are able to self preserve. Dr. Chelmow noted that the medical procedure that

is utilized for first trimester abortions is substantially the same as that which is utilized when a woman miscarries; but now there are vastly different regulations for essentially the same procedure. He stated he doesn't believe anyone would argue that doctors throughout the Commonwealth are performing the procedure for miscarriages unsafely.

Dr. Floyd asked if this language will allow for grandfathering of existing facilities. Mr. Rodgers explained that usually retrofitting is not necessary or required by the USBC unless required by legislation. Dr. Floyd asked if facilities can be grandfathered. Mr. Bodin explained that VDH OLC previously received guidance from the Office of Attorney General that due to the fact that these facilities were not previously licensed they are required to be considered new facilities.

Dr. Trump asked if there was anything else the Building Panel wished to discuss. Hearing nothing further Dr. Trump thanked the Building Panel and dismissed them.

Dr. Trump then reintroduced Joe Hilbert and noted that at the last meeting there were some questions regarding the history of the regulations. Dr. Trump stated that Mr. Hilbert was in attendance to answer any questions related to historical issues. Dr. Floyd asked if there was a reason why the regulatory action was restricted to those sections reviewed by the panel. Ms. Horn noted that the Virginia Department of Health (VDH) OLC conducted a periodic review of the Regulations. Any sections of the Regulations the public highlighted as needing amendment during the public comment period of that review were opened for amendment in the following Notice of Intended Regulatory Action (NOIRA). Hearing no further questions the panel moved on to a recap of the last meeting.

Mr. Bodin stated that the minutes accurately reflect the work done by the panel during the last meeting; however he would like to review some of the questions which came up. Mr. Bodin noted that the Physician's Panel asked whether the Regulations should differentiate between electronic and written medical records. Mr. Bodin noted that OLC researched this issue and created a memo provided to the Physician's Panel. The memo states that in order for OLC to incentivize the use of electronic records and be in line with industry standards both the term "electronic record" and "written record" should be utilized within OLC regulations. In a future update of the Regulations the OLC shall ensure the insertion of the term "electronic record" where appropriate throughout the regulatory chapter.

Next, Mr. Bodin noted that in the previous meeting the Physician's Panel asked if any facility is utilizing the method of anesthesia enumerated in 12VAC5-412-250 (G). He stated that upon a review of the files of the licensed facilities and polling surveyors, it does not appear that any facility is currently utilizing this form of sedation. However, he noted these Regulations will govern should any facility determine to utilize this form of anesthesia in the future.

Mr. Bodin and Dr. Trump then requested that the panel review their recommendations from the last meeting. The recommended language of the panel was displayed on a projection for all present to see. The panel began with Section 230, Patient services; patient counseling. The recommended language is 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.

Dr. Floyd noted that the suggested change to this section would require a technical change to the definition of "first trimester" within the definition section. Ms. Horn stated OLC will note the technical change and integrate it into the regulatory action should such a technical change be permitted upon consultation with the Office of the Attorney General.

The panel then reviewed Section 240 Medical testing and laboratory services. The recommended language is 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.~~
~~4.~~ 3. A written report of each laboratory test and examination shall be a part of the patient's record.

B. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) (42 CFR Part 493).

1. Facilities for collecting specimens shall be available on site.
2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.
3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.

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.

D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).

The panel suggested a reformatting of the section based on the recommended amendments specifically that subsections A(1) and A(2) be switched, so that the section makes more sense. The finalized recommendation is as follows:

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1. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. ~~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. Use of any additional medical testing shall be based on an assessment of patient risk. ~~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.~~

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D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).

The panel then reviewed Section 250 Anesthesia service. The recommended language is as follows:

A. The anesthesia service shall comply with the office-based anesthesia provisions of the Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).

B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.

C. When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration.

D. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 B:

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;
5. Continuous electrocardiograph;
6. Devices for measuring blood pressure, heart rate, and respiratory rate;
7. Defibrillator; and
8. Accepted method of identifying and preventing the interchangeability of gases.

E. Elective general anesthesia shall not be used.

F. If deep sedation or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until the patient meets the discharge criteria.

G. In addition to the requirements of subsection D of this section, an abortion facility administering deep sedation or a major conductive block, or administering general anesthesia in an emergent situation, shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 C:

1. Drugs to treat malignant hyperthermia, when triggering agents are used;
2. Peripheral nerve stimulator, if a muscle relaxant is used; and
3. If using an anesthesia machine, the following shall be included:
   a. End-tidal carbon dioxide monitor (capnograph);
   b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;
   c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
   d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;
   e. Pressure-compensated anesthesia vaporizers, designed to administer a constant nonpulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;
   f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered;
   g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and
   h. A gas evacuation system.

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 and that criteria has been documented within the patient's medical record.

The Physician's Panel had no further comments or edits to Section 250.

The panel then reviewed Section 290 Anesthesia service. The recommended language is as follows:

A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, and related items for resuscitation and control of hemorrhage and other complications.

B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support.

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 Physician's Panel had no further comments or suggested edits to Section 290.

The Physician's Panel then approved the meeting minutes from the last meeting.

At this point the panel requested to review and make suggested edits to other sections of the Regulations. The panel decided to start at section 10 the Definitions section and move through systematically noting any of their recommendations. Dr. Lara-Torre sent his suggestions via email prior to the meeting. His suggestions were considered during this discussion.

Under Section 10, Dr. Lara-Torre noted that a distinction between surgical and nonsurgical abortion should be made. He stated that the Regulations should only be applied to surgical abortion as medication abortion does not cause the same risk and does not require the same patient needs. Drs. Chelmow and Floyd agreed. Dr. Floyd again noted the necessary technical change to the term "first trimester." Dr. Lara-Torre suggested a change to both "first trimester" and "trimester" to redefine trimester as a 13-week period rather than 12. Dr. Chelmow stated there isn't consensus within medical literature on the length of a trimester.

Dr. Floyd suggested an amendment to Section 20 which would state that no information gathered by this regulatory chapter will be released in violation of Section 2.2-3705.2 of the Code of Virginia. She suggested that a provision specifically related to patient confidentiality is important due to the sensitive nature of the procedure being performed. Dr. Chelmow agreed that a provision regarding confidentiality needed to be provided. He noted that abortion facilities and their patients had special risks not shared by other facility and patient types, and needed special privacy protections.

Dr. Floyd asked a question about Section 80. She noted that it is her understanding that the variances under this section expire. Mr. Bodin and Dr. Trump commented a variance expires with the facility license and must be reapplied for each year. Dr. Trump noted that the definition of variance suggests that it is temporary in nature; otherwise it is considered a waiver. She suggested an amendment to section 80 which would allow for a permanent variance or waiver.

In section 100 Dr. Lara-Torre had the comment that that the section is worded very strongly and may infringe on a patient's right to privacy. He noted that he believes the information currently allowed to be provided to surveyors is more than what is necessary for a surveyor to make an assessment of a patient's quality of care and compliance with the Regulations. Dr. Chelmow suggested the addition of a minimum necessary standard, again stressing the necessity of confidentiality for these patients.

For Section 110, Dr. Floyd asked if under current practice a facility objects or disagrees with something written in a report if there is a method for the facility to challenge what's in the report. Mr. Kyle noted that the facility would call the supervisor and provide evidence regarding the inaccuracy. At that time the report would be amended and resubmitted to the facility. Dr. Chelmow asked if the time frame of the plan of correction process is commensurate with other regulatory chapters. Mr. Bodin answered that it is.

All the physicians suggested an edit to Section 120, which would state that the OLC shall only investigate substantiated or credible complaints rather than all complaints. Several staff members asked how OLC would be able to determine whether a complaint was credible without investigation. Dr. Chelmow noted this issue but stated he is concerned that these facilities are susceptible to harassment.

Dr. Floyd made a comment about Section 130. She asked if this section was also commensurate with other regulatory chapters. She noted concern with subsection C which allows suspension of a license to be for an indefinite time. She stated it is important to ensure these facilities have the opportunity to have their license reestablished in a timely manner.

For Section 160, Dr. Floyd noted that using the terminology of "admission" and "discharge" is inappropriate as patients aren't admitted and discharged at these types of facilities. Dr. Chelmow stated this may be acceptable as these facilities are now being classified as a type of hospital.

At Section 200, Dr. Floyd noted that she has been informed that this section conflicts with the Joint Commission Standards of Ambulatory Care, which is problematic as it's incorporated by reference. She stated this section should be made compliant with these standards. She also noted that it is possible that as these standards have been incorporated by reference the other subsections may not be necessary.

At Section 220, Dr. Floyd asked if C (3) and (11) were really necessary. Mr. Bodin noted these sections are consistent with other regulatory chapters of a similar nature. Dr. Chelmow stated that he would suggest removing subsection D (1) as it seems to imply that the facility would have to stock and administer vaccines which would be inappropriate for these types of facilities to do.

At Section 260 (B), Drs. Lara-Torre and Floyd asked why the administration of drugs to induce a termination of pregnancy is limited to physicians. Dr. Lara-Torre stated that this area truly needs revision as medication abortion can and should be able to be prescribed by a trained nurse practitioner under a supervision agreement with a physician. He stated their license and

prescribing authority should not be limited by these regulations. Ms. Horn noted that prescribing or administering drugs to cause an abortion by anyone other than a physician is a class 4 felony under Section 18.71 et. seq. of the Code of Virginia. Therefore the criminal code does not permit the amendment the physicians are suggesting.

Finally, Dr. Chelmow stated that Section 300 subpart 5 (b) should be amended to eliminate the radiologist's report of x-rays. Instead Subpart 5(b) should be amended to state diagnostic test.

At this point the Physician's Panel asked if they would have an opportunity to review the minutes from this meeting. Dr. Trump answered yes. He asked if they felt a third meeting was necessary, they stated they did not feel a third meeting was necessary.

Dr. Trump thanked the Physician's Panel for their time and expertise and dismissed the panel.