townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-412
Regulation title(s)	Regulations for Licensure of Abortion Facilities
Action title	Amend Regulations Following Periodic Review
Date this document prepared	November 4, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. This regulatory action will amend these regulations to: remove unnecessary definitions, insert additional best practices regarding medical testing and laboratory services, insert additional best practices regarding anesthesia service, align the requirements regarding emergency services more specifically with medical best practices, amend the requirements for facility design and construction, and make minor technical amendments. In the time since the Board of Health approved proposed amendments at its September 2015 meeting, the U.S. Supreme Court issued its decision in *Whole Woman's Health v. Hellerstedt,* 579 U.S. ___ (2016). As a result of that June 2016 decision, additional amendments to the regulations were deemed necessary by the Department based on advice from the Office of the Attorney General. The following additional amendments have been proposed: Onsite Inspections–striking certain requirements; Patient's Rights–Striking specific reference to Joint Commission Standards; Infection Control–Striking specific reference to CDC Guidelines;

Maintenance–Striking certain requirements already addressed by existing legal requirements; Firefighting Equipment and Systems–Striking requirements already addressed by existing legal requirements; Design and Construction–Amended to specify that all construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall conform to state and local codes and ordinances.

At a special meeting of the Board of Health on Monday October 24th, several additional amendments to the proposed language were submitted as motions by individual Board members and approved by the Board. The following additional amendments were approved at that meeting:

Definitions- strikes the definition of "first trimester;"

Allowable variances -amends the section to conform with the hospital licensure regulations;

Violation of this chapter or applicable law; denial, revocation, or suspension of license -technical amendment;

Personnel – amends so that copies of personnel records cannot be removed from the premises unless redacted;

Clinical Staff- amends the section to remove the requirement that a physician remain on the premises until the last patient is discharged and an amendment removing the requirement that the physician give a discharge order; language is retained requiring that a physician remain on the premises until all patients are medically stable;

Patient services; patient counseling- amends the definition of first trimester of pregnancy and removes repetitive Code language; Medical testing and laboratory services- amends the section to require facilities to offer STD screening or at a minimum refer patients to clinics that provide such testing as well as requiring that facilities have policies and procedures for patient reevaluation in the event that tissue examination does not confirm termination of the pregnancy;

Anesthesia service – incorporates an office based anesthesia requirement into the regulatory language for further clarity;

Emergency Equipment and Supplies- Removes specific conditions for which emergency drugs must be available; language is retained which requires the supplies be consistent with the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care;

Health Information Records – amends the section to state that specific information detailed in the regulation only be included in a patient's record if medically indicated; language is retained requiring a complete and accurate medical record for each patient;

Required Reporting- removes the requirement to report incidents reported to malpractice insurance carriers or in compliance with the federal Safe Medical Devices Act; and

Abortion Facility Security and Safety- removes the requirement that the facility have policies and procedures related to facility security and related to the dissemination of safety information to employees; language is retained requiring policies and procedures to ensure safety within the facility and on its grounds.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

There are no technical terms or acronyms utilized in this document.

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

The State Board of Health approved final amendments to the Regulations for Licensure of Abortion Facilities (12VAC5-412) on October 24, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulation is promulgated under the authority of § 32.1-127 of the Code of Virginia. Section 32.1-127 of the Code of Virginia requires the Board to promulgate regulations including minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees and the public, (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities, (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions, (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence, and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes and certified nursing facilities. Facilities in which five or more first trimester abortions per month are performed are classified as a category of hospital for the purposes of this requirement (§ 32.1-127(B)(1)).

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. This regulatory action will amend these regulations to: insert additional best practices regarding medical testing and laboratory services, insert additional best practices regarding anesthesia service, align the requirements regarding emergency services more specifically with medical best practices, amend the requirements for facility design and construction, and make minor technical amendments. The regulations are mandated by § 32.1-127 of the Code of Virginia. The regulations ensure health and safety standards are maintained throughout licensed facilities within the Commonwealth. Additional amendments have been deemed necessary by the Department based on

advice from the Virginia Office of the Attorney General in light of the U.S. Supreme Court Decision in *Whole Woman's Health v. Hellerstedt, 579 U.S. ___ (2016)*. Several additional amendments to the proposed language were offered in the form of motions by individual Board members and approved by the Board at a special meeting held by the Board of Health on October 24th, 2016.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

No new regulatory sections are being proposed. The following amendments are proposed:

12VAC5-412-10 Definitions
The terms "medication induced abortion" and "surgical abortion" have been stricken, as they are no longer used in the Regulations based on proposed amendments to 12VAC5-412-370 which have been deemed necessary by the Department based on advice from the Virginia Office of the Attorney General. At a special meeting held by the Board on October 24th the Board voted to remove the definition of "first trimester."

The term "Trimester" has been stricken.

12VAC5-412-30 Classification
This section has been repealed, as it is unnecessary given language already contained in the Code of Virginia.

12VAC5-412-80
At a special meeting held by the Board on October 24th the Board voted to amend this section so it would be in line with the Virginia Department of Health hospital regulations. The section previously stated: "A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time. B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients. C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients. D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed."

It now states: "A. Upon the finding that the enforcement of one or more of these regulations would be clearly impractical, the commissioner shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations, provided safety and patient care and services are

not adversely affected. B. Modification of any individual standard herein for any purpose shall require advance written approval from the OLC."

12VAC5-412-100(C) Onsite Inspection
Subsection C has been stricken. It previously stated: "If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within two hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-130."

12VAC5-412-130 Violation of this chapter or applicable law; denial, revocation, or suspension of license
Subsection A has been amended. It previously stated: "When the department determines that an abortion facility is (i) in violation of any provision of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia."

It now states: "When the department determines that an abortion facility is (i) in violation of §§ 32.1-125.01, 32.1-125.4 or 32.1-135.2 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia."

Subsection B has been amended. It now states: "If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained."

12VAC5-412-180 Personnel
At a special meeting held by the Board on October 24th the Board voted to amend subsection H to state that unless redacted copies of personnel files shall not be removed from the premises.

12VAC5-412-190 Clinical Staff
At a special meeting held by the Board on October 24th the Board voted to amend subsection C to remove the requirement that a physician remain on the premises until the last patient is discharged and further amended the section to remove the requirement that the physician give a discharge order. The subsection retains the requirement that the facility develop, implement and maintain policies and procedures to ensure that there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequately trained health care practitioners remain with the patient until she is discharged from the abortion facility.

12VAC5-412-200 Patient Rights
Specific reference to Joint Commission standards in subsection A has been stricken. It now states: "Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission."

12VAC5-412-220 Infection Prevention
Specific reference to CDC Guidelines in subsection A has been stricken. It now states: "The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all

services provided. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards…"

12VAC5-412-230 Patient services; patient counseling

Subsection A has been amended. It previously stated: "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 a licensed physician. It now states: "Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy Meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider."

Subsection E has been amended to add a requirement to maintain policies and procedures for the provision of or referral for family planning services, and to strike a requirement for post abortion counseling policies. It now states: "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 to its patients."

Subsection F has been amended to remove a requirement for an evaluation of the patient's capacity for self-care and add a requirement for an assessment of a patient's safety for discharge. It now states: "There shall be an organized discharge planning process that includes an assessment of a patient's safety for discharge and discharge instructions for patients to include instructions to call or return if signs of infection develop."

12VAC5-412-240 Medical testing and laboratory services

Subsection A has been amended. It previously stated: "…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. A written report of each laboratory test and examination shall be a part of the patient's record."

Subsection A now states: "…1. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 2. Use of any additional medical testing shall be based on an assessment of patient risk. 3. The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring to patients to clinics that provide such testing. 4. A written report of each laboratory test and examination shall be a part of the patient's record."

Subsection C has been amended. It previously stated: "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 tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately."

Subsection C now states: "The abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion, and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy. The facility shall track and log any specimens sent for further pathologic examination."

12VAC5-412-250 Anesthesia Service

Subsection B has been amended to add an office based anesthesia requirement, that the physician directing and supervising the anesthesia service shall be certified in advanced resuscitative techniques and meet the continuing education requirements.

Documentation language has been added to subsection C. It now states: "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 and shall be documented in the patient's medical record."

Documentation language has also been added to subsection H. It now states: "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 those criteria have been documented within the patient's medical record."

12VAC5-412-280 Emergency Equipment and Supplies

At a special meeting held by the Board on October 24th the Board voted to amend this section to remove a list of specific conditions for which the facility shall maintain emergency drugs. The regulatory language retains the requirement that the emergency drugs at the facility shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

12VAC5-412-290 Emergency Services

Subsection B has been amended to change the reference to the "American Heart Association's Guidelines for Advanced Cardiovascular Life Support" to the "American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care."

Subsection C has been amended. It previously stated: "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."

Subsection C now states: "When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the 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."

12VAC5-412-300 Health Information Records

At a special meeting held by the Board on October 24th the Board voted to amend this section to state that specific information contained in the regulation only need be included in a patient's record if medically indicated. The regulatory language retains the requirement that an accurate and complete medical record or chart be maintained on each patient, and that the record or chart contain sufficient information to satisfy the diagnosis or the need for the medical or surgical services.

12VAC5-412-320 Required Reporting

At a special meeting held by the Board on October 24th the Board voted to amend this section to remove the requirement that facilities report incidents reported to malpractice insurance carriers or in compliance with the federal Safe Medical Devices Act.

12VAC5-412-330 Abortion Facility Security and Safety
At a special meeting held by the Board on October 24th the Board voted to amend this section to remove the requirement that the facility security and safety policies and procedures include provisions related to facility security and regarding the dissemination of safety information to employees and users of the facility.

12VAC5-412-350 Maintenance
Subsection A has been stricken. It previously read: "A. The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that will allow sanitization. B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance."

Section 350 now states: "When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance."

12VAC5-412-360 Firefighting Equipment and Systems
This section has been repealed.

This section previously read: "A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. C. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).

12VAC5-412-370 Facility Design and Construction
This section has been amended.

The section previously stated: "Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia. Entities operating as of the effective date of this chapter as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. In order to determine whether

the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility."

Section 370 now states: "All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall comply with all applicable state and local codes and ordinances."

Documents Incorporated by Reference
This section has been amended to update those documents incorporated by reference to reflect the most current publications, and to remove documents no longer incorporated by reference in the Regulations.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages of the regulatory action to the public are increased health and safety protections at abortion facilities. The primary disadvantage to the public associated with the regulatory action is some abortion facilities may need to change some of their current operating policies and procedures. This may cause a financial impact on these facilities. That financial impact might be passed on to the facilities' patients. Additional amendments have been deemed necessary by the Department based on advice from the Virginia Office of the Attorney General in light of the U.S. Supreme Court Decision in *Whole Woman's Health v. Hellerstedt, 579 U.S. ___ (2016)*. VDH does not foresee any additional disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of public health and safety. There are no disadvantages associated with the proposed regulatory action in relation to the agency or the Commonwealth.

It is the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements associated with these regulations.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

The proposed amendments are unlikely to adversely affect localities.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulatory action shall not have an impact on the institution of the family and family stability. .

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-412-10*	"First trimester" means the first 12 weeks from conception based on an appropriate clinical estimate by a licensed physician as determined in compliance with § 18.2-76 of the Code of Virginia.	These definitions have been stricken.	At a special meeting held by the Board on October 24th the Board voted to remove the definition of "first trimester." This amendment was suggested by a Board member, with the rationale that defining the term is unnecessary within the Definitions section as it is defined by the Board in the only section in which it is utilized.
	"Medication induced abortion" means any abortion caused solely by the administration of any medication or medications given to a woman in the first trimester of pregnancy with the intent to produce		At the proposed stage, these two additional defined terms were used only in Section 370. Given the amendments to Section 370, which were proposed based on advice from the Virginia

	abortion. "Surgical abortion" means any abortion caused by any means other than solely by the administration of any medication or medications given to a woman in the first trimester of pregnancy with the intent to produce abortion.		Office of the Attorney General, these two terms are no longer used anywhere in the Regulations. Therefore, the two defined terms are no longer necessary.
12VAC5-412-80*	A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time. B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information	A. Upon the finding that the enforcement of one or more of these regulations would be clearly impractical, the commissioner shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations, provided safety and patient care and services are not adversely affected. B. B. Modification of any individual standard herein for any purpose shall require advance written approval from the OLC.	At a special meeting held by the Board on October 24th the Board voted to amend the Allowable Variances section. This amendment was suggested by a Board member with the rationale that it would make the provision consistent with provisions for allowable variances in the hospital licensure regulations.

	becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients. C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients. D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.		
12VAC5-412-100 C*	If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12	Subsection C has been stricken.	This amendment was proposed after Department review based on advice from the Virginia Office of the Attorney General.

	months shall be provided to the surveyor within two hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-130.		
12VAC5-412-130	A. When the department determines that an abortion facility is (i) in violation of ~~any provision of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with ~~all provisions of Article 1 of Chapter 5 of Title 32.1 of the~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license	A. When the department determines that an abortion facility is (i) in violation of ~~any provision of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1~~ §§ 32.1-125.01, 32.1-125.4, ~~32.1-132, 32.1-135.2 or 32.1-137.01~~ or 32.1-135.2 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with ~~all provisions of Article 1 of Chapter 5 of Title 32.1 of the~~ §§ 32.1-125.01, 32.1-125.4, ~~32.1-132, 32.1-135.2 or 32.1-137.01~~ and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the	At a special meeting held by the Board on October 24th the Board voted to add a technical amendment to subsection B. This amendment was suggested by a Board member, with the rationale that it would remove reference to Code sections that pertain to the licensure of hospitals and nursing homes.

	shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).	interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).	
12VAC5-412-180*	A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided. B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable. C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of	Subsection H has been amended: H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file. Unless redacted, copies of personnel files shall not be removed from the premises.	At a special meeting held by the Board on October 24th the Board voted to add a provision which states “Unless redacted, copies of personnel files shall not be removed from the premises.” This amendment was suggested by a Board member, for the protection of the privacy of employees of abortion facilities.

	Pharmacy, whose job duties provide access to controlled substances within the abortion facility. D. The abortion facility shall develop, implement, and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties and appropriate to the level, intensity, and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. E. Job descriptions. 1. Written job descriptions that adequately describe the duties of every position shall be maintained. 2. Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. 3. Job descriptions shall be reviewed at least annually, kept current, and given to each employee and volunteer when assigned to the position and when revised. F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable. G. Personnel policies and procedures shall include,		

	but not be limited to:1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;2. Process for verifying current professional licensing or certification and training of employees or independent contractors;3. Process for annually evaluating employee performance and competency;4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file.		
12VAC5-412-190*	A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined. B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to	A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined. B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur	At a special meeting held by the Board on October 24th the Board voted to remove the requirement that physicians are required to remain on premises until the last patient is discharged. The Board further voted for an amendment to remove the requirement that the physician give a discharge order. These amendments were suggested by a Board member, with the rationale that the stricken

	ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience. C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order, and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility. D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.	in the abortion facility are only performed by physicians who are qualified by training and experience. C. A physician shall remain on the premises until all patients are medically stable.~~, sign the discharge order, and be readily available and accessible until the last patient is discharged.~~ Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. ~~The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge.~~ The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that ~~adequate~~ adequately trained health care practitioners remain with the patient until she is discharged from the abortion facility. D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.	provisions provided no medical benefit. Language is retained requiring that a physician remain on the premises until all patients are medically stable.
12VAC5-412-200 A*	Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of	Specific reference to Joint Commission standards has been stricken. Subsection A now states: Each abortion facility shall establish a protocol relating to the rights and	This amendment was proposed after Department review based on advice from the Virginia Office of the Attorney General.

	Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.	responsibilities of patients. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.	
12VAC5-412-220 A*	The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.	Specific reference to CDC Guidelines has been stricken. Subsection A now states: The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.	This amendment was proposed after Department review based on advice from the Virginia Office of the Attorney General.
12VAC5-412-230 A & B*	A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy as determined in compliance with § 18.2-76 of the Code of Virginia. ~~based on an appropriate clinical estimate by 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. The informed written consent shall be notarized as	A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy ~~as determined in compliance with § 18.2-76 of the Code of Virginia. based on an appropriate clinical estimate by licensed physician.~~meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider. 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. ~~The informed written consent shall be~~	At a special meeting held by the Board on October 24th the Board voted to amend the definition of first trimester abortion based on 13 weeks, 6 days from the last menstrual period, and to remove reference to §18.2-76 of the Code of Virginia. This amendment was suggested by a Board member, with the rationale that the definition would be based on a more clinically accurate time frame and that the reference to the Code section was

	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.	~~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.	unnecessary and repetitive.
12VAC5-412-240*	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.~~ Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 2. ~~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. ~~3. The abortion facility shall develop, implement, and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by~~	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.~~ Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 2. ~~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. [3. The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to clinics that provide such testing. ~~The policies and procedures shall address appropriate responses to a positive screening test.~~] [~~3.~~ 4.] A written report of each laboratory test and examination	At a special meeting held by the Board on October 24th, at the suggestion of individual Board members, the Board voted to amend subsection A3 to restore the requirement that facilities offer STD screening or at a minimum refer patients to clinics that provide such testing. The Board also voted to amend subsection C to remove a requirement for additional testing, and instead require the facility have policies and procedures for patient reevaluation in the event that tissue examination does not confirm termination of the pregnancy. It is the Agency's expectation that a physician, nurse or other health care practitioner will adhere to established standards of practice,

	~~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;~~. If villi or fetal parts cannot be identified with certainty, the patient shall be notified that pregnancy tissue was not identified and the possibility of ectopic pregnancy shall be explained to the patient. In such cases, 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	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;. If villi or fetal parts cannot be identified with certainty, the patient shall be notified that pregnancy tissue was not identified and the possibility of ectopic pregnancy shall be explained to the patient. In such cases, 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 abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion, and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy.~~] The facility shall track and log any specimens sent for further pathologic examination.	

	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).		
12VAC5-412-250B*	B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.	B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia who is certified in advanced resuscitative techniques and has met the continuing education requirements.	At a special meeting held by the Board on October 24th the Board voted to amend the section to incorporate an office based anesthesia requirement into the regulatory language. This amendment was suggested by a Board member for the purpose of providing further clarity.
12VAC5-412-280*	An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions: 1. Cardiopulmonary arrest; 2. Seizure; 3. Respiratory distress;	An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. ~~Drugs shall include, at a minimum, those to treat the following conditions:~~ ~~1. Cardiopulmonary arrest;~~ ~~2. Seizure;~~ ~~3. Respiratory distress;~~ ~~4. Allergic reaction;~~ ~~5. Narcotic toxicity;~~ ~~6. Hypovolemic shock; and~~ ~~7. Vasovagal shock.~~	At a special meeting held by the Board on October 24th the Board voted to amend the section to remove specific conditions for which emergency drugs must be available to treat. The amendment was suggested by a Board member with the rationale that treating the conditions listed would be unnecessary in most cases and that each facility should have the ability to determine what types of emergency drugs to have on hand. Language is retained which requires the supplies be consistent with the American Heart

	4. Allergic reaction; 5. Narcotic toxicity; 6. Hypovolemic shock; and 7. Vasovagal shock.		Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care
12VAC5-412-300*	An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physicians' and nurses' progress notes; h. Condition at time of discharge; i. Patient instructions (preoperative and postoperative); and j. Names of referral physicians or agencies; and 6. Any other information required by law to be maintained in the health information record.	An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. <u>If medically indicated,</u> <u>it</u> shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physicians' and nurses' progress notes; h. Condition at time of discharge; i. Patient instructions (preoperative and postoperative); and j. Names of referral physicians or agencies; and 6. Any other information required by law to be maintained in the health information record.	At a special meeting held by the Board on October 24th the Board voted to amend the section to state that specific information detailed in the regulation only be included in a patient's record if medically indicated. A Board member suggested the amendment with the rationale that the listed information is not always medically indicated or relevant.
12VAC5-412-320*	A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records	A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). B. The abortion facility shall report	At a special meeting held by the Board on October 24th the Board voted to amend the subsection B5 to remove the requirement to report incidents required to be

	(12VAC5-550-120). B. The abortion facility shall report the following events to OLC: 1. Any patient, staff, or visitor death; 2. Any serious injury to a patient; 3. Medication errors that necessitate a clinical intervention other than monitoring; 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and 5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629). C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies. E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the	the following events to OLC: 1. Any patient, staff, or visitor death; 2. Any serious injury to a patient; 3. Medication errors that necessitate a clinical intervention other than monitoring; and 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; ~~and~~ ~~5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629).~~ C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies. E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.	reported to malpractice insurance carriers or in compliance with the federal Safe Medical Devices Act. The amendment was suggested by a Board member with the rationale that the reporting required by subsection B5 can be an act to intimidate an abortion provider.

	OLC, except as required or permitted by law. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.		
12VAC5-412-330	The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: 1. Abortion facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and 3. Provisions for disseminating safety-related information to employees and users of the abortion facility.	The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: ~~1. Abortion facility security;~~ ~~2.~~ Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and ~~3. Provisions for disseminating safety-related information to employees and users of the abortion facility.~~	At a special meeting held by the Board on October 24th the Board voted to amend the section to remove of the requirement that the facility have policies and procedures related to facility security and written policies regarding the dissemination of safety information to employees and users of the facility. The amendment was suggested by a Board member with the rationale of preventing this material from being obtained by someone trying to compromise the security of an abortion facility.
12VAC5-412-350*	A. The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization. B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and	Subsection A has been stricken. The section now states: When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of	This amendment was proposed after Department review based on advice from the Virginia Office of the Attorney General.

	implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.	testing and maintenance.	
12VAC5-412-360*	A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. C. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).	This section has been repealed.	This amendment was proposed after consultation with the Virginia Office of the Attorney General because compliance with applicable fire and safety laws and regulations is required by 12VAC5-412-370 as amended.
12VAC5-412-370*	A. All construction of new buildings and additions or major renovations to existing buildings for occupancy as an abortion facility shall conform to state and local codes, and zoning	This section has been amended. The section now states: All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall comply	This amendment was proposed based on advice from the Virginia Office of the Attorney General.

	ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). All construction of new buildings and additions or major renovations to existing buildings for occupancy as an abortion facility that perform only surgical abortions or a combination of surgical and medication induced abortions shall be designed and constructed consistent with Part 1 and section 3.8 of Part 3 of the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 edition, The Facilities Guidelines Institute (2014 guidelines), pursuant to § 32.1-127.001 of the Code of Virginia. Abortion facilities that perform only medication induced abortions shall be designed and constructed consistent with sections 1.1, 1.3 and 1.4 of Part 1 of the 2014 guidelines. Abortion procedures may take place in a procedure room, as detailed in Section 3.8-3.1 of Part 3 of the 2014 guidelines, except that minimum square footage requirements for procedure rooms used for the provision of surgical abortion do not need to be greater than 120 square feet, with a minimum room dimension of 10 feet and a minimum clear dimension of 3 feet at each side and at the foot of the bed. Rooms designed in accordance with Section 3.8-3.2 of Part 3 of the 2014 guidelines are not required for abortion facilities. Section 3.7-3.6.13.1(2) of Part 3 of the 2014 guidelines shall not apply to facilities that do not have a	with all applicable state and local codes and ordinances.	

	room designed in accordance with section 3.8-3.2. Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with the applicable sections of the 2014 guidelines. The certification shall be forwarded to the Office of Licensure and Certification of the Virginia Department of Health. B. In order to determine whether the abortion facility's design and construction is consistent with the applicable sections of the 2014 guidelines, the commissioner may obtain additional information from the facility or its architect.		

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

There were 9,114 total comments received. Of those total comments 3,319 individuals made more than one comment leaving 5,795 non duplicate individual comments. Of the total non-duplicate comments received 5,210 were in support of the regulatory action and 585 were in opposition.

Virginia Regulatory Town Hall
693 comments were made on the Virginia Regulatory Town Hall. Of those 693 comments 62 were duplicates leaving 631 non duplicate comments. 569 comments were in opposition to the regulatory action and 62 comments were in support of the regulatory action.

Hand Delivered Letters

2,380 letters were hand delivered with 263 duplicates for a total of 2,117 non duplicates. 2,115 letters submitted were in support of the regulatory action and 2 letters were in opposition of the regulatory action.

Letters Received Via Email
6,008 letters were received via email. There were 2,990 duplicates for a total of 3,018 non-duplicates. 3,017 were in support of the regulatory action and 1 was in opposition.

Public Hearing
33 people spoke during a public hearing held by the Virginia Board of Health. Four people that spoke also commented via letter/email. 16 spoke in support of the regulatory action and 13 were in opposition.

Commenter	Comment	Agency response
The Honorable Kaye Kory, Virginia House of Delegates via letter.	Asking Board of Health to amend the regulations of abortion providers in the Commonwealth to reflect medical evidence and remove any undue burden on a woman's ability and right to abortion.	The Agency notes the support for the proposed amendments.
Sara Shannon via letter.	Asking Board of Health to follow the Supreme Court's ruling in Whole Woman's Health v. Hellerstedt.	Additional amendments have been proposed to comply with the Supreme Court's ruling.
John Comerford via letter.	Asking the Board to maintain the current Virginia regulations.	The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Masiel G Vergara via letter.	Asking the Governor to insert new policies that will prevent abortion.	The Agency notes the comments, but abolishing abortion is beyond the scope and authority of these regulations.
Angel A Ruiz via letter.	Asking the Governor to insert new policies that will prevent abortion.	The Agency notes the comments, but abolishing abortion is beyond the scope and authority of these regulations.
Rodrigo Velasquez via letter.	Deep support for the amendments proposed.	The Agency notes the support for the proposed amendments.
Maggie Disney, Margarette Botham, Josh Hetzler, Chris Freund, Victoria Cobb, Jeff Caruso, LaDean Barnes, Daniel Howell, Jill Zackrisson, Richard Wiley, Don Blake, and Barry Hodges via Public Hearing.	Asking the Board to reject the proposed amendments.	The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Janice Craft and Janet Dix via Public Hearing	Supports the proposed amendments and the Governor's recommendations.	The Agency notes the support for the proposed amendments as well as support for the Governor's recommendations.
Martha Cassell via Public	Wants all safety regulations in place and there is another life to consider.	12VAC5-412 is written to comply with Virginia Code § 32.1-127.

Hearing		
Pam Messina via Public Hearing	Wants strong regulations.	12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Heather Shumaker, Miguel Davies, Anna Sholl, Jill Abbey, Sarena Floyd, Rebecca Gutwalt, Margaret Beth Meyer, Elisa Pharo, Laura Foronda, Ida Dawnhildie, Charissa Davis, Gail Deady, Cianti Reed, Rachel Robinstein, Nichole Grim, Michelle Wooten via Public Hearing	Asking Board of Health to adopt the proposed amendments.	The Agency notes the support for the proposed amendments.
Kenneth Oshhanski via Public Hearing	Make policies based on science not politics.	The Agency believes that no response is necessary for these comments as they do not speak to the proposed amendments.
530 persons commented via the Virginia Regulatory Town Hall in opposition to the proposed amendments.	Asking the Board to reject the amendments and keep the regulations as is, or to strengthen them in a non-specific way, to protect women's health.	The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with the Virginia Code § 32.1-127.
29 persons commented via the Virginia Regulatory Town Hall in support of the proposed amendments.	Asking the Board to adopt the amendments.	The Agency notes the support for the proposed amendments.
28 persons commented via the Virginia Regulatory Town Hall in opposition to abortion or with comments not specific to the proposed amendments.	Commenters asked that abortion be abolished or offered quotes from scripture.	The Agency notes the comments, but abolishing abortion is beyond the scope and authority of these regulations.

26 persons commented via the Virginia Regulatory Town Hall in support of abolishing TRAP regulations.	Commenters asked the Board to abolish the "TRAP" regulations and classified them as unnecessary and a barrier to a woman's right to an abortion.	The Agency notes the comments, but abolishing abortion facility regulations is beyond the scope and authority of the Board as the Code of Virginia requires the regulations.
Barbra Jill McCabe, MD, FAAP, Commonwealth Emergency Physicians via the Virginia Regulatory Town Hall	I generally support the Board of Health's proposed amendments to the regulations for the licensure of abortion facilities in the Commonwealth. I strongly support the governor's recommendations for the regulations for the licensure of abortion facilities in the Commonwealth. As an emergency physician, I frequently care for pregnant patients, manage emergency complications of pregnancy, perform procedures with sedation. As a hospital administrator I oversee quality and safety for my department and the hospital in which I work, I am very familiar with the federal guidelines for that govern preparedness of emergency departments across the commonwealth of Virginia.	The Agency notes the support for the proposed amendments as well as the Governor's recommendations.
	I SUPPORT the Board's recommended amendments to Section 12VAC5-412-250, regarding documentation of anesthesia services in the patient record. I routinely perform procedural sedation and the recommendation is consistent with current standards. "Emergency Cardiovascular Care" has replaced "Advanced Cardiovascular Life Support" as defined by the American Heart Association. Capacity to perform "Emergency Cardiovascular Care" is adequate to provide sedation in the outpatient clinic setting.	The Agency notes the support for the recommended amendments to 12VAC5-412-250-Anesthesia Service.
	I OPPOSE the Board's recommended amendment to Section 12VAC5-412-10 that "first trimester" of pregnancy be defined as "the first 12 weeks from conception as determined in compliance with § 18.2-76 of the Code of Virginia." Similarly, I OPPOSE the Board's recommended amendment to Section 12VAC5-412-230(A) that "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 a licensed physician as determined in	The Agency notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.

	compliance with § 18.2-76 of the Code of Virginia."	
	In addition, I SUPPORT Governor Terry McAuliffe's recommendation for Section 12VAC5-412-230 that "first trimester" of pregnancy be defined as "13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider."	The Agency notes the support for the Governor's recommendations.
	In the healthcare environment, it is universally accepted that the pregnancy length be determined by the first date of the last menstrual period, and that along with physical exam are sufficient to determine gestational age. Likewise, the first trimester of pregnancy is defined as a gestational age through 13 weeks and 6 days. The second trimester begins at 14 weeks.	
	I SUPPORT the Board's recommended amendment to Section 12VAC5-412-10 to separately define "medication induced abortion" and "surgical abortion" and SUPPORT the substance of those definitions. Although both methods are reasonable and safe alternatives for women seeking termination of pregnancy, they should be defined separately as they are different procedures.	The Agency notes the support for a past recommended amendment to 12VAC5-412-10-Definitions. The Agency is no longer recommending this amendment as the terms are no longer used in the Regulations based on advice from the Virginia Office of the Attorney General.
	I SUPPORT the Board's recommended amendments to Section 12VAC5-412-370, regarding design and construction standards for abortion facilities, and SUPPORT Governor McAuliffe's additional recommended amendments to this section. There is abundant evidence that pregnancy terminations can be performed safely in freestanding clinics and in the office setting with proper equipment for performing in office surgical procedures. In fact, when compared with hospitals, the complication rate for the procedure is greater for those performed in hospitals, and at best equal when adjusted for pre-existing medical conditions. Surgical procedures are routinely performed in the office setting, and there is no medical evidence supporting the need to replicate the physical environment of the hospital to improve safety.	The Agency notes the support for the proposed amendments to 12VAC5-412-370-Facility Design and Construction as well as the Governor's recommendations.

	I SUPPORT the Board's recommended amendments to Section 12VAC5-412-290, regarding emergency services. In order to be compliant with EMTALA, Emergency Departments and Hospitals throughout the Commonwealth must be prepared to manage patients needing emergency care after office surgical procedures. There are no other circumstances in which an outpatient facility must have a pre-determined contract for emergency services. Furthermore, upcoming national Emergency Department Quality Standards include preparedness for managing pregnancy and complications, including those related to termination.	The Agency notes the support for the proposed amendments to 12VAC5-412-290-Emergency Services.
Bruce Kemp via the Virginia Regulatory Town Hall	The May 2, 2016 issue of Virginia Register of Regulations purports to make a "technical change" with the proposed addition of the terms "medication induced abortion" and "surgical abortion" in order to "tailor the facility design and construction guidelines more precisely to the requirements of each facility." The limited public record of the actions taking place within many of these clinics is enough to show that this distinction between types of abortions, and therefore a need for different design standards, is unwarranted. For example, according to an inspection report at the Virginia Women's Wellness Center in Virginia Beach, it was discovered that for 36.6 percent of patients that had medication abortions in January 2014, a repeat medication dose or a surgical procedure was required to complete the abortion. And these are just the ones we know about from that facility. Other inspection reports indicate similar issues. The women in these scenarios can often require additional surgical procedures to complete the abortion process. It only makes common and medical sense that the women would return to the same clinic in order to address the failed medication abortion. Furthermore, according to the FDA, RU-486 is only to be used until 49 days gestation and if used according to FDA guidelines has an 8 percent failure rate.	The Agency notes the opposition to a past proposed amendment. The Agency is no longer recommending this amendment as the terms are no longer used in the Regulations based on proposed amendments to 12VAC5-412-370 which have been offered based on advice from the Virginia Office of the Attorney General.

	The farther along in gestation a woman is, the more likely it is that RU-486 will fail. According to the New England Journal of Medicine, statistics indicate that there is a 17 percent failure rate at 50-55 days, and a 23 percent failure rate at 57-63 days. Virginia Women's Wellness' rate of 36.6 percent failure is over four times the average. Knowing these facts and realizing that this scenario is the case for many women undergoing abortions, it is disingenuous at best, and volatile to women's health at worst, to change the regulations to create such a distinction in health and safety standards among clinics. I recommend keeping the current regulations.	
David R. Barrett, Immediate Past Chairman of The Family Foundation of VA via the Virginia Regulatory Town Hall	The rationale given by Commissioner Levine and VDH for eliminating the written agreement was, "The written agreement is not necessary due to the Emergency Medical Treatment and Labor Act (EMTALA). 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. Likely impact: Less burdensome regulations." EMTALA is not a replacement for a written agreement. EMTALA is an "anti-dumping" law, designed to prevent hospitals from transferring uninsured or Medicaid patients without at least providing a basic medical screening examination. As the Commissioner noted during discussion from the September 2015 BOH meeting, this requirement is already in the Board of Medicine Office-based Anesthesia regulations, so how can it be too burdensome? If it is too burdensome, does the Department of Health still expect abortion facilities to come into compliance with the Office-based Anesthesia transfer agreement requirement? Does the federal government think that a written transfer agreement is too burdensome for all providers of Medicaid/Medicare patients? Federal regulations for CMS services require a written agreement between hospitals and	The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127. The Emergency Medical Treatment and Labor Act (EMTALA) is established in Section 1867 of the Social Security Act. It imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination when a request is made for examination or treatment for an emergency medical condition, including active labor, regardless of an individual's ability to pay. Therefore, EMTALA does ensure that patients presenting with emergency medical conditions receive appropriate treatment. Reference: https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html The referenced amendment does not change the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards.

	outpatient facilities. If a written agreement is not currently in place, every physician performing surgery must have admitting privileges at a nearby hospital. Fifteen states require facilities to have hospital transfer agreements in place, including our neighbor to the South, North Carolina. Another 15 require either a transfer agreement or hospital admitting privileges, including our neighbor to the North, Maryland. Written transfer agreements are appropriate and serve a purpose in the rest of the medical community. All of VA's abortion facilities currently have a written agreement. As far as we know, there has never been a deficiency cited at any abortion facility regarding a written agreement. To remove written agreements from the regulations would not serve the purpose of amending the abortion facility regulations as stated in the regulatory action documents…"Upon review, the Department of Health found areas of the regulations which could be improved, therefore protecting the health and safety of patients of these facilities to a higher degree." Removal of this requirement will lead to less patient care and safety. The health of patients would not be protected nor improved. I recommend keeping the written transfer agreements in the abortion facility regulations. At the very least, the Commissioner and VDH should not remove the requirement that facilities should be adequately prepared if and when emergencies arise. Even if one believes abortion facilities are unable to secure transfer agreements, the provisions for the transfer agreement should still be made a part of Emergency Services. An effective emergency transfer depends upon the existence of an established procedure, which is why this is just good medical practice, whether mandated by accrediting agencies or government regulations, or not. In the absence of a written agreement, more information regarding emergency situations needs to be included in this section. I suggest using language from	The Board of Medicine's regulations for the use of office-based anesthesia currently require physicians to have a transfer agreement if they use moderate or greater sedation, and that is the Agency's expectation.

	Maryland's abortion regulations, as follows: "The abortion facility shall have an effective procedure for the transfer of patients to a nearby hospital when care beyond the capabilities of the facility is required. Procedures for emergency transfer to a hospital shall include, at a minimum: (1) Written protocols and procedures related to emergency transfer procedures; (2) A mechanism for authorization and notification of the hospital of a pending emergency case; (3) A mechanism for arranging appropriate transportation to the hospital; (4) Protocols for transmitting a copy of the patient's medical record to the hospital; and (5) Appropriate training for staff in the facility's written protocols and procedures When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to 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."	
Jeff Caruso, Virginia Catholic Conference via the Virginia Regulatory Town Hall	In section 230(B), after "authorized person", the Governor proposes striking "which shall be notarized as required by sec. 16.1-241 of the Code of Virginia." There are two problems with this: The proposal is technically flawed. There is no word "which" following the words "authorized person" in the document containing the Board's proposed amendments. After "authorized person", another sentence begins. It says, "The informed written consent shall be notarized as required by sec. 16.1-241 of	The Agency notes the opposition to the Governor's recommendations. The Agency has not proposed the amendment that the commenter references.

	the Code of Virginia." The requirement in the Code of Virginia that the written consent of the minor's parent, guardian or other authorized person be notarized should be reflected in this regulation as well. Code sections are referenced throughout these regulations. The Code section for the notarization requirement should certainly be referenced too. That requirement is no less important than others. In addition, differentiating between safety requirements for facilities that perform surgical abortions and safety requirements for facilities that perform chemical abortions, as the proposed amendments do, is overly simplistic and misguided. RU-486 is not just "writing a prescription." Sometimes it does not result in a complete abortion, and the patient comes back for a surgical procedure. Abortion ends lives and is not health care. But as long as abortion centers are permitted to operate, they must not be allowed to self-regulate. The recent suspension of abortions at a Fairfax facility due to 26 health and safety violations shows this all too well. Strong abortion center regulations are essential for the health and safety of Virginia women and must be maintained not weakened.	
Victoria Cobb, Family Foundation of Virginia via the Virginia Regulatory Town Hall	The Department of Health (VDH) recently suspended the license of an abortion center in Fairfax, owned by Dr. Steven Brigham. This action came after an inspection discovered dozens of health and safety violations. The inspection report itself is 52 pages long. We have for years brought Dr. Brigham's record of disregard for health and safety to the Board's attention. Quite frankly, he should not be allowed to operate any type of facility in Virginia. According to newspaper reports, Pennsylvania "banished" him from that state because of a similar record of safety violations, and New Jersey has ordered him to sell his abortion centers in that state. It has become abundantly clear he should not be allowed to own a facility in Virginia. Regardless of "plans of correction,"	The Agency notes the opposition to the regulatory action. The comments did not provide any suggested amendments to specific sections of the proposed regulations. 12 VAC 5-412 is written to comply with Virginia Code § 32.1-127.

	regardless of promises, he has made it clear that he does not care about women's health and safety. In addition, some of the amendments adopted by the Board to make to the existing health and safety standards would make it easier for the likes of Steven Brigham to operate in Virginia. The suggested amendments would make it easier for the abortion industry to deceive women into believing they've had an abortion when they haven't. The Planned Parenthood in Richmond did just that, whether intentionally or simply through neglect, as was revealed in the August 2015 inspection report of that abortion center. Under current regulations, the "conception material" obtained from the abortion must be sent to a lab to verify that is indeed a human being. The proposed changes would leave it up to the abortion center to make that determination, mislead patients, either intentionally or accidentally because of improperly or poorly trained staff. 2015 inspection report of that abortion center. Under current regulations, the "conception material" obtained from the abortion must be sent to a lab to verify that is indeed a human being. The proposed changes would leave it up to the abortion center to make that determination, mislead patients, either intentionally or accidentally because of improperly or poorly trained staff. Incredibly, at the abortion center in Fairfax that had its license suspended recently, violations include a lack of training for staff who were assigned to determine if the "material" was indeed a baby. The staff member given the task said, "Well (another staff member) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." Clearly, some abortion centers do not care or are not well-staffed enough to properly analyze the "conception material" (that would be the human baby) that is disposed of during an abortion. Another change adopted by the Board is	The Agency notes the opposition to a past

	a top goal of the abortion industry: differentiate between surgical abortions and so-called “medication” abortions (i.e. chemical abortions). The industry claims that with “medication” abortions, all they do is “write a prescription,” but that is far from the truth. They want to differentiate because they claim that some abortion centers do “only medication” abortions and therefore shouldn’t be held to the same health and safety standards as those that do surgical abortions. Yet, according to inspection reports at the Virginia Women’s Wellness Center in Virginia Beach, again owned by Dr. Steven Brigham, it was discovered that for 36.6 percent of patients that had medication abortions in January 2014, a repeat medication dose or a surgical procedure was required to complete the abortion. According to the FDA, RU-486 is only to be used until 49 days gestation and if used according to FDA guidelines has an 8 percent failure rate. The farther along in gestation a woman is, the more likely it is that RU-486 will fail. According to the New England Journal of Medicine, statistics indicate that there is a 17 percent failure rate at 50-55 days, and a 23 percent failure rate at 57-63 days. Virginia Women's Wellness' rate of 36.6 percent failure is over four times the average. Its plan to correct the problem: “These cases will no longer be documented in the complication log.” While some members of the Board may believe the changes being made to the health and safety standards that theoretically make them more in line with “standard medical practice,” the fact is that people like Brigham don’t operate according to any standard medical practice or with the best interest of their patients in mind. You may also believe that Dr. Brigham is a “rogue” operator who is an outlier from the norm in Virginia. Let’s take a look at just a couple of other abortion center owners and operators in Virginia: Diane Derzis has operated abortion centers across the nation, including A	proposed amendment. The Agency is no longer recommending this amendment as the terms are no longer used in the Regulations based on proposed amendments to 12VAC5-412-370 which have been offered based on advice from the Virginia Office of the Attorney General.

	Capital Women's Health Center in Richmond. The Administrator of A Capital Women's Health Center, Shelley Abrams (formerly Shelley Statum), was the former director of Derzis' New Woman All Women Health Center (Birmingham, AL) as well as the director of Derzis' Mississippi center – Jackson Women's Health Organization. A significant number of Derzis' abortion centers have been closed due to egregious health and safety violations. In 2012, Derzis was ordered to shut down her New Woman All Women abortion clinic in Birmingham, Alabama, after inspectors found 76 pages of violations following the hospitalization of three patients in one day for abortion complications. Officials have been fighting to close her Mississippi abortion center for years. William Fitzhugh owns/operates abortion centers in Richmond, Charlottesville, Roanoke and Newport News. Fitzhugh's abortion centers have been found to have a litany of health and safety violations, including unlicensed staff members illegally mixing drugs for patients and transporting narcotics from one facility to another with no record or documentation. In fact, the Charlottesville facility had no records in accordance with federal and state laws regarding the drugs used at the facility, including Schedule II narcotics like Fentanyl, a drug now becoming a major problem in the drug trade. Fitzhugh administered medications and wrote prescriptions at his Charlottesville facility without a current DEA number for that abortion center. For multiple violations of state and federal drug laws Fitzhugh received nothing more than a reprimand. In 1989, Fitzhugh was involved in a botched abortion on Margaret Codfelter, in which he perforated her uterus and left parts of the dead baby inside. He sent her home without informing her of her life-threatening condition. Margaret died two days later. Between them, Brigham, Derzis and Fitzhugh own and operate seven of the sixteen (fifteen operating with the Fairfax suspension) abortion centers in Virginia. And that's really just the tip of the iceberg when it comes to these "rogue" operators. They each have a long history of	

	mistreatment of patients and disregard for health and safety standards. Reviews of the inspection reports of other independently operated abortion centers (i.e. not owned by Planned Parenthood) are similarly disgusting. I recognize that "evidence based medicine" is a catchy phrase to hide behind when changing these health and safety standards, but the amendments you've adopted fly in the face of all the evidence found through inspection reports. If nothing else, the Brigham incident is yet another reminder that all the promises by representatives of the abortion industry that abortion centers in Virginia are safe and well maintained were blatant lies.	
Dorothea Henry via the Virginia Regulatory Town Hall	The most recent suspension of the abortion facility license of Steve Brigham's Virginia Health Group in Fairfax, VA with 52 pages of inspection violations, and the inspection wasn't even completed, is cause for concern. It is long past time for Steve Brigham to stop operating facilities in Virginia, or anywhere in the US. According to the Washington Post, "Brigham has had his medical license temporarily suspended, relinquished or revoked or has faced criminal charges in several states, including New York, Pennsylvania, New Jersey, Florida and California." Vicki Saporta, president of the National Abortion Federation, said in a statement, "Evidence of wrongdoing at Brigham's American Women's Services facility in Fairfax is part of a clear pattern of repeated and serious misconduct that poses a significant threat to patient safety, and which cannot be allowed to go unchecked in Virginia." Vicki Saporta also stated back in 2012, responding to a botched abortion in which a woman was driven to an ER and dropped off by Mr. Brigham, and subsequently found nearly three dozen viable fetuses in his clinic's freezer, "Steve Brigham is a substandard provider and should not be practicing medicine or	

	running an abortion clinic anywhere in the United States." It's time that the Health Commissioner, VDH and the Board of Health to prohibit Steve Brigham from operating abortion facilities in Virginia. He has clearly shown a track record of abhorrent healthcare practices in no less than five states. We must not wait until someone dies. To that end, we must add a clause into the abortion regulations that allows for the denial of a license to applicants like Mr. Brigham, whose conduct has caused the revocation of a prior license. Mr. Brigham owns four facilities in Maryland, one in which a patient died from a heart attack, the physician wasn't certified in cardiopulmonary resuscitation and a defibrillator at the facility didn't work. His other clinics have been suspended multiple times. In response, Maryland re-evaluated its abortion regulations, and as a result, added the following language: Denial of License for Prior Revocation or Consent to Surrender License. (1) The department may deny a license to: (a) A corporate applicant if the corporate entity has an owner, director, or officer: (i) Whose conduct caused the revocation of a prior license; or (ii) Who held the same or similar position in another corporate entity which had its license revoked; (b) An individual applicant: (i) Whose conduct caused the revocation of a prior license; or (ii) Who held a position as owner, director, or officer in a corporate entity which had its license revoked; or (c) An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.	

	According to 12VAC5-412-130, "the department may deny, suspend, or revoke the license to operate an abortion facility." Therefore I recommend adding this language to Virginia's Abortion Regulations 12VAC5-412-130. Denial, Revocation, or Suspension of License. Thank you for considering my concern and all that you do for Virginia.	The Agency notes the recommendation and shall consider it for inclusion as a part of a future regulatory action.
Amanda Allen, Center for Reproductive Rights via the Virginia Regulatory Town Hall	Majority of proposed amendments are a step in the right direction I. The Center for Reproductive Rights supports the majority of the proposed amendments to the current abortion regulations proposed by the Board of Health, and all of the proposed amendments to the current abortion regulations proposed by Governor McAuliffe. We write to express support for the majority of the proposed Board of Health amendments to the regulations governing first trimester abortion provision, and to oppose two of these proposed amendments. We further write to express strong support for Governor Terry McAuliffe's recommendations regarding these regulations. The Center for Reproductive Rights (CRR) is a non-profit legal advocacy organization. In the United States, we have litigated cases in federal and state courts to ensure that governments at all levels do not infringe upon the constitutionally protected right of women to decide whether and when to bear children. We have successfully litigated several cases to prevent governments from imposing medically inappropriate regulations on abortion providers to the detriment of women seeking abortion care. Indeed, on June 27, 2016, in a challenge CRR brought on behalf of independent abortion providers in Texas, the U.S. Supreme Court struck down Texas restrictions similar to some of the existing regulations at issue in this comment that imposed medically unjustifiable requirements on abortion facilities.	The Agency notes the support for the proposed amendments as well as the Governor's recommendations.

	Governor's proposed amendments will likely cure the presumptively unconstitutional requirement that abortion facilities conform to hospital-like building standards, as applied to existing first trimester facilities. See Whole Woman's Health v. Hellerstedt, --- S.Ct. ----, 2016 WL 3461560, at *2 (2016) (holding that a law that regulates abortion is unconstitutional unless the medical benefits outweigh the burden on access to abortion, and specifically holding that Texas's regulations requiring abortion clinics to conform to hospital-like standards are unconstitutional because they fail this balancing test.). We applaud the Board and Governor for taking steps to ensure these regulations reflect medical evidence and do not infringe upon women's constitutional rights or threaten their health. Below we describe our support for proposed amendments to the regulations on abortion clinics regarding 1) medication abortion and construction requirements, 2) transfer agreements, 3) trimester dating, 4) referral and discharge, 5) hospital and nursing home licensure and inspection, and 6) medical testing, laboratory services, ectopic pregnancy, and documentation. We also describe our opposition to the Board of Health's proposed amendments to trimester dating. II. The Center for Reproductive Rights supports all proposed amendments concerning medication abortion and construction requirements, which better reflect the fact that there is no medical reason to regulate the provision of abortion differently than other office-based surgical or medical procedures. The first trimester abortion procedure is a simple and extremely safe outpatient procedure that can be performed in a physician's office. See Facts on Induced Abortion in the United States, Guttmacher Institute, https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#9 (last updated May 2016). In fact, 95% of all abortion care is performed in outpatient facilities. See Rachel K. Jones and Kathryn Kooistra, Guttmacher Institute,	

	Abortion Incidence and Access to Service in the United States, 2008, 43 Perspectives on Sexual and Reproductive Health, no. 1, at 42 (March 2011). The current regulations require compliance with sections of the Facilities Guidelines Institute (FGI) Guidelines for Design and Construction of Health Care Facilities ("the Guidelines") pertaining to hospital design and construction. As the Supreme Court recently held, there is no medical justification for – and patient health and safety is not advanced by – requiring pre-viability abortions to be performed in a hospital-like setting. Whole Woman's Health v. Hellerstedt, --- S.Ct. ----, 2016 WL 3461560, at *36 (2016). The Supreme Court further ruled that in particular there is "no benefit" whatsoever to a surgical center requirement in the context of medication abortion. Id. at *30. The court clarified that determining whether or not a law is an undue burden on the right to abortion requires courts to analyze whether or not the asserted benefits of a law outweigh the burdens that law places on access to abortion. Id. at 21. The case specifically addressed Texas surgical center requirements similar to those in the Virginia regulations that are the subject of this comment, determined that these types of regulations unconstitutionally burden the right to abortion, and struck them down. Id. at *36. Imposing cost-prohibitive and hospital-like design and construction standards where these standards are not medically necessary is not intended to advance patient health and safety, but rather to shut down abortion facilities by making it impossible or extremely difficult for facilities to comply. Because pre-viability abortion can be and is performed safely in an office-based setting, abortion facility regulations should not require adherence to any portion of the hospital design and construction standards outlined in the Guidelines. There is no legitimate medical reason to regulate medication or surgical abortion differently than the provision of any other medication or similar office-based surgical procedure. Accordingly, these	

	amendments may not cure the constitutional defect inherent to applying any portion of the Guidelines to facilities where pre-viability abortions are performed or provided. However, given the current statutory framework, we support the Board's recommended amendment to Section 12VAC5-412-10 to separately define "medication induced abortion" and "surgical abortion" as well as their amendments to Section 12VAC5-412-370, regarding design and construction standards for abortion facilities. Further, we support Governor McAuliffe's additional recommended amendments to Section 12VAC5-412-370. The Board's recommendation and the Governor's recommendation to require new abortion facilities to achieve minimal consistency with the Guidelines moves Virginia one step closer to bringing the regulations for the licensure of abortion facilities in line with the medical reality of first trimester abortion while staying within the Board's statutory mandate. Similarly, the Board's recommendation and the Governor's recommendation that new medication-only abortion facilities achieve consistency with even fewer sections of FGI is an improvement. In short, there is no health or safety reason that first-trimester abortion–whether surgical or medication-based–must occur in a hospital-like setting, as recognized by the recent Supreme Court case of Whole Women's Health v. Hellerstedt, which held that surgical center requirements for abortion clinics are presumptively unconstitutional. Whole Woman's Health v. Hellerstedt, --- S.Ct. ----, 2016 WL 3461560, at *36 (2016). Both the Board and the Governor's recommendations for design and construction are an important first step, given the Board's statutory mandate, to bring the regulations for the licensure of abortion facilities in line with the medical reality and evidence-based practice of first trimester abortion. III. The Center for Reproductive Rights supports the Board of Health's proposed amendments concerning emergency	

	services because they remove a medically unnecessary transfer agreement requirement. We support the Board's recommended amendments to Section 12VAC5-412-290 regarding emergency services. Not only is first trimester abortion extraordinarily safe, with complications in less than 1% of cases, but the vast majority of hospitals are required to take patients in need of emergency care pursuant to the federal EMTALA (Emergency Medical Treatment and Labor Act). There is no medical or safety need for abortion facilities to have transfer agreements with hospitals. Under the Supreme Court's recent decision of Whole Woman's Health v. Hellerstedt, a transfer agreement requirement would be closely scrutinized to ensure the burdens on access to abortion did not outweigh the benefits to women's health. See Whole Woman's Health v. Hellerstedt, --- S.Ct. ----, 2016 WL 3461560, at *21 (2016). Moreover, hospitals do not follow a standardized protocol when entering into transfer agreements – rather, transfer agreement requirements vary. In fact, hospitals may refuse to grant transfer agreement requests for reasons unrelated to patient care, such as political pressure. Finally, the hospital with which a clinic has a transfer agreement may not be the closest emergency hospital to a woman experiencing complications post-procedure, so this requirement would not serve any safety purpose for such women. See WWH v. Hellerstedt, --- S.Ct. ----, 2016 WL 3461560, at *30 ("complications [from medication abortion] would almost always arise only after the patient has left the facility."). Thus, this amendment – unanimously recommended by the physician advisory to the Board of Health – would help ensure that medically unnecessary transfer agreement requirements are not imposed on first trimester abortion clinics. IV. The Center for Reproductive Rights opposes the Board of Health's proposed amendments regarding trimester dating,	

	and supports Governor McAuliffe's proposed amendments to date pregnancy in a more medically accurate manner. Abortion regulations, like any regulation of medical procedures, should be evidence-based and medically appropriate. Therefore, we oppose the Board of Health's recommended amendments defining the first trimester of pregnancy. Specifically, we are opposed to the recommended amendment to Section 12VAC5-412-10 stating that the "first trimester" of pregnancy be defined as "the first 12 weeks from conception as determined in compliance with § 18.2-7.6 of the code of Virginia[,]" as well as the Board of Health's recommended amendment to Section 12VAC5-412-230(A), stating that "[a]bortions 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 a licensed physician as determined in compliance with § 18.2-7.6 of the Code of Virginia." We oppose these amendments because "12 weeks from conception" is a technically inferior measure of the end of the first trimester of pregnancy, both in terms of the way a pregnancy is dated ("12 weeks") and the unit of measurement for that date ("from conception"). In the practice of medicine, pregnancy is measured in days or weeks from the first day of a woman's last menstrual period (LMP) – not from conception – and totaling 40 weeks. Cf. Planned Parenthood of Central Florida. v. Philip, Case No. 4:16cv321-RH/CAS, at *19-21 (N.D. Fla. June 30, 2016) (describing how medical professionals measure gestational age from LMP, and finding "no medical justification" for defining the last day of the first trimester other than as 13 weeks, 6 days LMP.. "Conception" is also not a medical term and is not generally used by medical professionals to date or measure pregnancy. Cf. id. Moreover, Code § 18.2-76 is irrelevant to the definition of "first trimester" as it does not address how to date pregnancy; it should not be referenced for that purpose. Instead, we support Governor Terry	

	McAuliffe's recommendation for Section 12VAC5-412-230 that the "first trimester" of pregnancy be defined as "13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider." It is generally accepted that the first trimester ends at 13 weeks 6 days LMP. The National Abortion Federation's Clinical Policy Guidelines refer to the 2nd trimester as "more than 14 weeks from LMP." See National Abortion Federation, Clinical Policy Guidelines, Standard 10.2, 27 (2016). There are also a number of medical journals which reference 14 weeks LMP as the first trimester. See, e.g., Frances Casey, et al., A Randomized Controlled Trial Evaluating Same-Day Mifepristone and Misoprostol Compared to Misoprostol alone for Cervical Preparation prior to Second-Trimester Surgical Abortion, Contraception 87 (accepted manuscript 2016) (defining second-trimester as after 14 weeks LMP); Matthew Reeves, et al., Doxycycline serum levels at the time of dilation and evacuation with two dosing regimens, Contraception 79, 129-133 (2009) (defining the beginning of second trimester as 15 weeks LMP). Moreover, while the regulations currently provide for a clinical "estimate by a licensed physician," health care providers other than physicians are capable of dating, and often do date, pregnancies. Therefore, the Governor's amendment is more medically accurate than the current amendment proposed by the Board of Health, and should be included in the final regulations. V. The Center for Reproductive Rights supports the Board of Health's proposed amendments concerning referral and discharge. We support the Board's recommended amendment to Section 12VAC5-412-230(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 and post abortion counseling services to its patients." We further support the Board's recommended amendment to Section 12VAC5-412-230(F): "There shall be an organized discharge planning process that includes an evaluation of the patient's capacity for self-care and an assessment of a patient's safety for discharge and discharge instructions for patients to include instructions to call or return if signs of infection develop." These amendments were unanimously recommended by the physician advisory panel to the Board of Health. VI. The Center for Reproductive Rights supports the Board of Health's proposed amendments concerning hospital and nursing home licensure and inspection due to increased clarity for compliance. We support the Board's recommended amendment to Section 12VAC5-412-130 to clearly demarcate which sections of the "Hospital and Nursing Home Licensure and Inspection" portion of the Virginia Code apply to abortion facilities. This clarity will be important to ensure abortion facilities have appropriate notice regarding which provisions of the law they must comply with. VII. The Center for Reproductive Rights supports the Board of Health's proposed amendments concerning medical testing, laboratory services, ectopic pregnancy, and documentation. Finally, we support the Board's recommended amendments to Section 12VAC5-412-240 regarding medical testing, laboratory services, and ectopic pregnancy. We further support the Board's recommended amendments to Section 12VAC5-412-250 regarding documentation of anesthesia services in the patient record. These amendments were unanimously recommended by the physician advisory	

	panel to the Board of Health. VIII. Conclusion The Center for Reproductive Rights thanks you for taking the time to review our comments, and for amending the regulations to better reflect the medical reality of first trimester abortion care. We urge you to adopt all the Governor's recommendations and the Board amendments that we list above as supporting.	
Senator Barbara Favola, VA State Senate via the Virginia Regulatory Town	As co-chair of the Women's Healthcare Caucus in the Virginia General Assembly, I ask the Board of Health to amend the targeted regulation of abortion providers (TRAP) in the Commonwealth. These targeted regulations, which require abortion providers' offices, but not any other type of medical office, to comply with hospital and ambulatory surgical center (ASC) regulations, provide no discernible health benefit to women. Abortion is one of the safest medical procedures performed in the United States today. First-trimester abortion, in particular, is a safe, non-surgical, outpatient procedure that is routinely and safely practiced in doctor's offices–not hospitals—throughout the country and in the Commonwealth. Leading medical experts, including the American Congress of Obstetricians and Gynecologists, have long opposed TRAP. Moreover, no less an authority than the United States Supreme Court has ruled that similar restrictions in Texas constitute an undue burden on a woman's ability to access an abortion, and are unconstitutional. Whole Woman's Health v. Hellerstedt, 579 U.S. __ (2016). The Supreme Court, in striking down the Texas law, held that there was ample evidence in the record to support the federal district court's conclusion that "'[m]any of the building standards mandated by the act and its implementing rules have such a tangential relationship to patient safety in the context of abortion as to be nearly arbitrary.'" Id. at __ (quoting Whole Woman's Health v. Lakey, 46 F. Supp. 3d 673, 684 (2014)). In	The Agency notes the support for the proposed amendments as well as the Governor's recommendation's.

	addition, the Court noted there was ample evidence in the record to support the district court's conclusion that ASC requirements "place[] a substantial obstacle in the path of a woman seeking abortion." Id. at __. In Virginia, as in Texas, requiring abortion providers to comply with hospital and ASC regulations is not a measure designed to advance patient health and safety – it is a sham, targeted restriction designed to cut off Virginia women's access to safe, legal abortion. I ask the Board of Health to heed the decision of the United States Supreme Court in Whole Woman's Health, and to amend the regulations of abortion providers in the Commonwealth to reflect medical evidence, to legitimately advance patient health and safety, and to remove any undue burden on a woman's ability to access her constitutional right to abortion	
Stephanie Harlow via the Virginia Regulatory Town Hall	The CDC, ACOG, NAF, even the state of Virginia recommend STD screenings for sexually active women. We should not remove this evidence-based healthcare from the abortion regulations. The CDC's 2015 Sexually Transmitted Diseases Treatment Guidelines state, "Primary prevention of STDs includes performing an assessment of behavioral risk (i.e., assessing the sexual behaviors that may place persons at risk for infection) as well as biologic risk (i.e., testing for risk markers for HIV acquisition or transmission). As part of the clinical encounter, health-care providers should routinely obtain sexual histories from their patients and address risk reduction as indicated in this report." "In addition to obtaining a behavioral risk assessment, a comprehensive STD/HIV risk assessment should include STD screening." ACOG's 2011 Women's Health Stats & Facts lists recommendations of screening: - "ACOG recommends annual screening for chlamydia of all sexually active women ages 25 and younger, as well as annual screening of other asymptomatic women at high risk for infection." - "ACOG recommends annual screening for gonorrhea of all sexually active women	The Agency notes the opposition to the regulation. The referenced amendment does not change the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards. The physician regulatory advisory panel recommended the elimination of subsection A 3, as this provision is unrelated to abortion procedures. The referenced amendment does not prevent a facility from providing STD testing based on an assessment of patient risk.

	ages 25 and younger, as well as other asymptomatic women at high risk for infection." - "ACOG recommends routine HIV screening for all women ages 19–64, regardless of their individual risk factors." NAF's 2016 Clinical Policy Guidelines states, "Women at high risk for Chlamydia, gonorrhea, or other sexually transmitted infections should be offered testing." The Health Commissioner's 2016-2020 Virginia Plan for Well-Being lists as Foundational Goals for AIM 3: Preventive Actions, "Virginians are free from sexually transmitted infections" and "In Virginia, cancers are prevented or diagnosed at the earliest stage possible." Abortion facilities might be the only place a woman is seen by a licensed healthcare professional. How can Virginia be free from STI's when it has removed the medically-appropriate requirement from abortion facilities to include STI screening? The Commissioner and VDH should not remove 12VAC5-412-240.3, "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."	
Thomas Morr via the Virginia Regulatory Town Hall	The rationale given by Commissioner Levine and VDH for eliminating policies and procedures for the screening of STDs from the abortion facility regulations was stated as follows: “The physician's regulatory advisory panel suggested the elimination of subsection A 3, as this provision is unrelated to abortion procedures.” It is unfortunate that the panel of physicians advising the Health Commissioner, VDH and the Board of Health on abortion facility regulations is unaware of how STDs and abortion care are related. · The CDC understands that its guidelines “**are applicable to any patient-care setting that serves**	The Agency notes the opposition to the regulation. The referenced amendment does not change the Agency’s expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards.

	persons at risk for STDs." First in its list or patient-care settings are "**family-planning clinics.**" The CDC understands that "physicians and other health-care providers play a critical role in preventing and treating STDs." · ACOG understands that "anyone who has had sexual contact with another person may get an STI. STIs may not cause symptoms. Even if there are no symptoms, your health can be affected." · According to ACOG 2011 Women's Health Facts and Stats, there are 19 million new STD cases each year, over 9 million in women ages 15-24. STDs are hard to diagnose, lead to serious health problems, and if not adequately treated, up to 40% of women can develop PID - a leading cause of ectopic pregnancy and infertility. · NAF's Clinical Policy Guidelines recommend women who are at high risk for STIs be offered testing. · The CDC and ACOG recommend screening at annual visits for chlamydia, gonorrhea, HIV. · US Preventative Services Task Force agrees with almost all of the CDC's recommendations for STD screening. · The Health Commissioner has developed "Virginia's Plan for Well-Being." One of the goals of the Plan is, "Cancers are prevented or diagnosed at the earliest stage possible," with multiple strategies related to increasing cancer screenings. STD screening related to cervical cancer clearly helps with that goal. Unmistakably the medical community understands the relationship between STDs and abortion, and sees a medical need for these kinds of services. Developing, implementing and maintaining policies and procedures related to the screening of STDs consistent with CDC Guidelines is good, quality healthcare clearly supported by medical best practices. Furthermore, to be in compliance with existing regulations, all of VA's abortion facilities must currently have policies and procedures for STD screening consistent with the CDC Guidelines. As far as we can tell, there have only ever been just two recorded instances of inspection	The physician regulatory advisory panel recommended the elimination of subsection A 3, as this provision is unrelated to abortion procedures. The referenced amendment does not prevent a facility from providing STD testing based on an assessment of patient risk.

	violations regarding STD screening. We know of no other facilities have expressed any concern that complying with CDC Guidelines regarding STD screening to be too burdensome or medically unnecessary. There has been no confusion by these abortion facilities as to the relationship between STD screening and abortion. To remove implementation of CDC Guidelines regarding STD screening from the regulations would not serve the Purpose of amending the abortion facility regulations as stated in the regulatory action documents…"Upon review, the Department of Health found areas of the regulations which could be improved, therefore protecting the health and safety of patients of these facilities to a higher degree." In fact, the health of patients would not be improved nor protected; the health and safety of patients and the community would suffer if there were no longer policies regarding STD screening. During the September 2015 Board of Health meeting, there was discussion that "VDH does want patients to be assessed for risk and tested when appropriate but to be less prescriptive in the regulations about how that is accomplished." The CDC Guidelines says they **"should be regarded as a source of clinical guidance rather than prescriptive standards."** The CDC does not see their policy guidelines as prescriptive. Asking facilities to create and implement policies and procedures developed by the individual abortion facility is not prescriptive. Even so, Commissioner Levine and VDH offered no alternative, and recommended removing the requirement. If VDH understands STD screening to be appropriate, then an appropriate substitution should be given as an alternative instead of removing the requirement completely. I highly recommend keeping the language as originally written, allowing for each facility to develop and maintain its own policies and procedures to ensure the "treatment of persons who have or are at risk for sexually transmitted diseases," as stated in the CDC Guidelines.	
Rose Codding, Falls Church	Falls Church Healthcare Center ("FCHC") supports the Board of Health's proposed	The Agency notes the support for the proposed amendments as well as the

Healthcare Center via the Virginia Regulatory Town Hall	amendments to the Final Regulations for the Licensure of Abortion Facilities and commends the Governor for his recommendations to return to science-based rulemaking to ensure that medical care is between a patient and her or his doctor. We know firsthand what happens when rule making and regulations run contrary to this important standard. At FCHC we know firsthand what protecting the health and safety of our patients means. FCHC was established in 2002 to offer our patients opportunities to live productive and healthy lives with integrated full spectrum reproductive health services. FCHC is a medical practice dedicated to pro-choice gynecology and wellness. As a faith-based center, FCHC is proud of its high-quality and caring patient service, its ACOG Fellows Board Certified doctors, and its community involvement which includes: serving as a VDH Pandemic facility, a sex education resource for church and school youth groups, and a training site for prestigious medical schools. FCHC has provided quality reproductive healthcare in Virginia for over a decade with a distinguished record of excellent medicine and compassionate support for women and families. We know firsthand that the abortion services provided by FCHC – and indeed provided by the vast majority of independent abortion care providers in Virginia and across the country – are among the safest of all in-office medical procedures. This was recognized by the Supreme Court of the United States in its June 27, 2016, opinion in Whole Woman's Health v. Hellerstedt, whereby the Court invalidated TRAP (Targeted Regulations Against Abortion Providers) regulations in the State of Texas. First hand we know the ability for FCHC to continue to provide our reproductive health services in a safe, cost-effective manner has been threatened in recent years by the many TRAP regulations in Virginia imposing a heavily prescriptive regulatory regime meant to price abortion facilities out of existence and to delay and deny access to patients. We know firsthand the burden to patients and doctors alike created by the waiting	Governor's recommendation's.

	periods, mandatory 24 hour sonograms and bureaucratic administrative requirements only appropriate to hospitals put in place in Virginia. These problems were exacerbated by the General Assembly's efforts to impose its views on the practice of medicine through House of Delegates amendments to S. 924 accepted by the Senate on a tie breaking vote by then Lt. Gov. Bolling. And yes we know firsthand that 12VA5-412 has virtually nothing to do with patient safety or quality of care. Indeed, FCHC has never had a medical issue arise that would have been avoided if the physical and administrative changes necessitated by the 12VA5-412 had been put in place. We know firsthand the items that would have been required of FCHC under the TRAP regulations were not grounded in evidence-based medicine and its onerous burdens were wholly disproportionate to the very low risks involved in reproductive healthcare. As with the Texas TRAP regulations invalidated by the Supreme Court, Virginia's TRAP regulations would serve only to deprive women of safe, legal, high-quality care that they need at a time in their lives that are already full of challenges. Moreover we know firsthand that the expenditures required pursuant to the promulgated regulations would have no relation to quality of care, patient safety or patient satisfaction. FCHC could not cover the enormous costs of such remodeling through increases in fees charged to patients because many of FCHC's patients could not afford such cost increases. Money spent on regulations that have no scientific or medical basis would also reduce the amount of money available to FCHC to make improvements to its facilities that do promote patient safety, care and service. For these reasons, we know that the regulations must be amended. Accordingly, FCHC generally supports the Board of Health's proposed amendments to the regulations for the licensure of abortion facilities in the Commonwealth because they would substantially ease medically unnecessary burdens. Moreover, FCHC strongly supports the Governor's recommendations for the	

	regulations because such recommendations address the concerns expressed by the Governor in his May 11, 2014, Executive Directive – "that the extreme and punitive regulations adopted [in 2013] jeopardize the ability of most women's health centers to keep their doors open and place in jeopardy the health and reproductive rights of Virginia women." FCHC believes that approval of the final regulations and the Governor's recommendations at the Board of Health's next meeting is of vital importance. FCHC believes that the Board of Health should ensure in adopting final regulations that the only regulations left in place are those based on sound medical evidence. FCHC also requests that the Board can adopt at its next meeting additional amendments and improvements such as those advanced by FCHC in comments earlier in this proceeding without requiring further rulemaking procedures. Those amendments and improvements are reflected in Appendix A below. More broadly, it will be important for the Commonwealth to engage in a constitutional review of its entire scheme of abortion regulations to eliminate provisions inconsistent with the United States Supreme Court's Whole Woman's Health v. Hellerstedt decision and the Supreme Court's reaffirmation that women have the right to make their own decisions about abortion and that the right to make those decisions may not be infringed by medically unnecessary burdens imposed by the government. The Court's decision calls into question both regulations adopted previously by the Board of Health, which the Board of Health can propose to amend, and Virginia statutes that must be amended by the General Assembly or struck down by the courts. But first things first. At the very minimum as a positive step forward, FCHC urges the Board to adopt the Board's proposed amendments, as well as the Governor's recommendations, to protect the health, safety, access, ensure confidentiality of women seeking abortion services in the Commonwealth of Virginia, and to ensure the availability of safe, high-quality	

	reproductive healthcare for the women of Virginia. Then we will know firsthand that Virginia's rulemaking ensures and reflects real care for women and their families as has been VDH Public Health practice for decades. Respectfully submitted,,Rose Codding, Director,Falls Church Healthcare Center Appendix A Recommendations Submitted in this Proceeding by Falls Church Healthcare Center RECOMMENDED AMENDMENTS / ADMINISTRATIVE ISSUES • 12VAC5-412-30. Classification Define the class of hospital as such: "Class 4 –Office-based Out-Patient Medical Practices and non ASC, non Hospital-Based Abortion Facilities." • 12VAC5-412-50(F). Request for Issuance 12VAC5-412-70. Return and/or Reissuance of License -Remove the requirement that a change in administrators or ownership triggers an automatic need for re-licensure. (Notification is appropriate but with reasonable timing of 30 days after change.) The current requirement interferes with best business practices and discourages investors who want to improve licensed facilities. -Subsection E of 412-70 is too broad and needs to be clarified. For example, in this section, and in section 412-140, there is no definition of "operator". Also, changes in ownership should be relevant to health and safety only if they change the functional program or operation of the facility. • 12VAC5-90. Right of Entry 12VAC5-100. On-site Inspections -The regulations should further differentiate between complaint driven inspections and routine inspections. -For routine inspections, the regulations should implement an inspection system on a scheduled basis, as done with the CLIA system used by OLC, so that the inspection system is based on a commitment to support and improve a practice rather than be punitive. -Though not specific to a needed amendment I want to voice my support for	The Agency notes the recommendations and shall consider them for inclusion as part of a future regulatory action.

	VDH's proposed "rating" so to categorize major, minor, administrative etc. deficiencies that may be cited during inspection. OLC Director presented this idea to the Board of Health in December. I also support including a "grading" system for medical facilities similar to what is used for restaurant inspections. • 12VAC5-412-170. Administrator Section 170 is far too onerous in dictating how a smaller facility accomplishes Section 170's objectives. Health centers should have greater flexibility in assigning the tasks set out in Section 170 to appropriate staff in a way that assures compliance without requiring the hiring of a single administrator responsible for all such tasks. To hire and retain a single person to do all of the tasks required in Section 170 on an ongoing basis would require paying a hospital administrator's salary. That is simply beyond the reach of small health centers. • 12VAC5-412-210. Quality Management -Quality assurance programs and review systems should be designed relative to the business size and functional program. Right now the regulations don't recognize that there may be a need for different programs between small and large women's health centers as well as where different types of abortion care are provided. -Medication abortions should be facilitated in a gynecology practice and not discouraged. -This regulation should be amended to better reflect the realities of a small health center. It is overbearing and counterproductive to the effective operation of the smaller facility to require governing bodies, quality assurance committees of four or more staff members, and administrators in smaller doctor's offices or medical practices. -This section needs to be amended so that the requirements for smaller abortion facilities are consistent with the regulations affecting other doctors' offices and health care facilities of similar size. • General Applicability -Do not make broad citations to sections of related regulations without specifying what that regulation is supposed to ensure. For example reference to the	

	NFP's or the FGI (which should not even be included as part of the regulation) should specify which provisions and for what purpose(s) reference (s) are made. e.g. Is the regulation cited for the purpose of insuring that fire extinguishers are on site? For training staff how to handle fire emergencies? For other purposes? The references should be specific so that compliance is more realistic and not to apply a shot-gun effect of blasting well-meaning facilities that want to comply. -A licensed facility should be advised directly of changes to the regulations, similar to what advisories are given for CLIA changes. -Provision of Medication Abortion should be regulated as any other general medical service provided in a doctor's office setting. RECOMMENDED AMENDMENTS / CLINICAL ISSUES • General Applicability Delineate appropriate regulations for Medication Abortion and D & C abortions. Provision of Medication Abortion should be regulated as any other general medical service provided in a doctor's office setting. • 12VAC5-412-320. Required Reporting -Though the regulations currently include in Section B mandatory reporting within 24 hours of a catastrophic event, adding to this section a system of self-reporting of adverse events (as we now do for morbidity reporting), and apply this to all health care facilities would facilitate VDH/OLC's monitoring safety of medical services throughout Virginia. Attached for reference see NAF"s current reporting system of quality indicators. -Amend to clarify the events listed in 12VAC5-412-320 2 and 5 • 12VAC5-412 Part VII Design and Construction -Amend so the applicability of local building and fire codes have precedence. Any Medical facility should be guided by and comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code as will be demonstrated by issuance of occupancy permits and fire marshals' inspections. -Reference to and applicability of FGI	

	included in this section is unwarranted for doctors' office providing office-based, non-invasive procedures. ACOG and CMS guidelines even specify the suitability for abortion care in the office-based outpatient setting. These FGI guidelines are not medically appropriate and are not applied to other office-based healthcare facilities. It is detrimental to patients and wastes healthcare resources to require that a medical office providing abortion care be outfitted like an inpatient hospital or ASC.	
Richard Wiley via the Virginia Regulatory Town Hall	The Governor's proposed amendment #2 represents a significant departure from the widely-held medical standard on the length of the first trimester, which the current regulations recognize as being 12 weeks - not 13 weeks and 6 days, as the Governor proposes. For instance, the federal Office on Women's Health (OWH) states that the first trimester is week 1 to week 12 after a woman's last menstrual period. Pregnancy.org states that "The second trimester begins at 12 weeks." Other significant medical authorities reflect the same. Moreover, the National Institutes of Health states in its U.S. National Library of Medicine that "A fetus at 12 weeks can make a fist and suck its thumb." Clearly, by 12 weeks, it is indisputable that the child in the womb is fully formed with all of the corresponding characteristics most associated with personhood. Without a doubt, "the State's profound interest" in protecting "life or potential life" in the womb, as affirmed in Planned Parenthood v. Casey, contemplates the legitimate interest in protecting fetal life at its more advanced stages. When the General Assembly passed laws regulating abortion procedures and restricting clinics to performing only first trimester abortions, its clear purpose was to permit greater latitude of abortions for the portion of the pregnancy when the fetus was less fully formed. But given that by the 12th week of the pregnancy we know for sure that the fetus can do virtually all of the things that typical babies can do (e.g. making a fist and sucking its	The Agency notes the opposition to the Governor's recommendations.

	thumb), any termination of the child after that stage in development cannot warrant the same latitude the General Assembly had in mind. Therefore, the restrictions placed on abortion clinics limiting them to abortions during the first trimester must comport with this correct legal and contextual understanding. As such, the 12 week standard, as is currently recognized by the regulations and by leading medical authorities, should remain in place. Additionally, it is also true that the later in the pregnancy an abortion is conducted, the greater the risks are to health and safety. Especially in light of the proposed changes to the regulations stripping many of the requirements for abortion clinic health and safety standards, the act of simultaneously extending the period in the pregnancy within which the child may be aborted in those clinics can only make for a less safe and riskier environment. Consequently, this change should be discouraged. For all of these reasons, I recommend retaining the current gestational time frame for the first trimester as reflective of the first 12 weeks of pregnancy.	
W. Scott Cox via the Virginia Regulatory Town Hall	The National Abortion Federation's basic standard of care regarding the identification of products of conception following an abortion states, "Termination of pregnancy must be confirmed prior to the woman leaving the facility or further evaluation must be initiated." One Board of Health member who is a doctor stated in the September 2015 BOH meeting, the proposed language of the amended regulations "falls short of the standard of care." Asking a patient if they want further evaluation based on their ability to pay is simply malpractice. The rationale given by Commissioner Levine and VDH for eliminating further evaluation was that it "removes mandatory additional testing and makes the testing permissive, allowing the physician and patient to discuss and determine the need for additional testing," leading to "improved patient care." Removing basic standards of care will not lead to improved patient care, but raise the risk that further complications or	The referenced amendment does not change the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards. The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127. The amendment in 12VAC5-412-240 subsection C removes mandatory additional testing and makes the testing permissive, allowing the physician and patient to discuss and determine the need for additional testing. A further amendment in subsection C requires the provider to track this additional testing should it be

	serious harm will occur, if the regulations are left as proposed by VDH. Based on abortion care "consensus, rigorous review of relevant medical literature, and known patient outcomes," if the termination of the pregnancy cannot be confirmed, further evaluation must be initiated, and must not wait for the result of a doctor patient discussion regarding the cost of further evaluation. These are "evidence-based guidelines" from within the abortion care community. And quite frankly, just good healthcare. The World Health Organization's "Safe Abortion" describes in a section titled, "Tissue examination following surgical abortion," After surgical methods of abortion, immediate examination of the products of conception is important to exclude the possibility of ectopic pregnancy and assess whether the abortion is likely to be complete…If the aspirate does not contain products of conception, ectopic pregnancy should be suspected and the woman should undergo further evaluation. The WHO's "Safe Abortion" continues in a section titled, "Ectopic Pregnancy" If ectopic pregnancy is suspected, it is essential to confirm the diagnosis immediately and to initiate treatment or transfer the woman as soon as possible to a facility that has the capacity to confirm diagnosis and provide treatment. The inspection of aspirated tissue following a surgical abortion procedure can nearly eliminate the risk of an ectopic pregnancy going undetected. In the absence of evidence-based guidelines from the Commissioner or VDH, the non-prescriptive guidelines presented by the National Abortion Federation will suffice. Therefore I recommend amending 12VAC5-412-420.C. in the following way: 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	performed, so the facility can determine if follow up is necessary. This proposed amendment was a recommendation of the physician advisory panel.

	certainty, the patient must be reevaluated and the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy., and referred appropriately. Patient follow-up must continue until one of the following has been documented 1. The diagnosis of ectopic pregnancy has been excluded; 2. Clinical resolution of a possible ectopic pregnancy has been ensured; or 3. Transfer of care to an appropriate provider has been made. Resolution of the pregnancy must be verified and documented. The facility shall track and log any specimens sent for further pathologic examination.	
Josh Hetzler, Esq., The Family Foundation of Virginia via Virginia Regulatory Town Hall	The proposed changes for section 12VAC5-412-130 entitled "Violation of this chapter or applicable law; denial, revocation, or suspension of license" replaces violations applicable throughout all of Article 1, Chapter 5 of Title 32.1 in the Code with only a few of the sections listed therein; namely, § 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2, or 32.1-137.01. Thus, a number of important sections related to patient safety and care are rendered inapplicable for the purpose of denying or suspending the licenses of abortion clinics who may ignore all of those requirements. In essence, it's a "free pass" – a signal to abortion clinics that there is no need to comply with the law because there will be no consequences for violating them. Among the Code sections omitted by the proposed changes are the following: - § 32.1-125.2. Disclosure of other providers of services. - § 32.1-125.5. Confidentiality of complainant's identity. - § 32.1-127.1:01. Record storage. - § 32.1-127.1:03. Health records privacy.	The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127. The proposed amendment integrates Virginia Department of Health Office of Licensure and Certification guidance into the regulation and is a technical amendment.

	- § 32.1-127.1:05. Breach of medical information notification - § 32.1-133. Display of license. - § 32.1-137.02. Hospital discharge procedures. - § 32.1-137.03. Discharge planning; designation of individual to provide care. - § 32.1-137.04. Patient notice of observation or outpatient status. To be sure, even though this proposed change does not give abortion clinics explicit permission to ignore these and other laws, telling them that the Department of Health won't do anything if they do is effectively the same thing. Considering that nearly all of the newly omitted Code sections proscribe basic requirements for ensuring and protecting patient records, confidentiality, awareness, and care, it simply cannot be that this omission "protect[s] the health and safety of patients of these facilities to a higher degree" – the stated purpose of the proposed amendments. Abortion center physicians should be held accountable for the whole law regarding patient care, and not merely a "cherry-picked" few, as this proposal attempts to do. Patients should be able to reasonably expect that their records will be safely handled and that they will be told about how to properly care for themselves upon discharge. If the proposed changes are allowed to take effect, women who use these clinics can feel much less certain of that. I urge the Board of Health to reject this amendment and refuse to signal to abortion providers that when it comes to ensuring compliance with many laws related to basic patient care, they can count on the Department to look the other way.	
Christopher A. Meyer via Virginia Regulatory Town Hall	The rationale given by Commissioner Levine and VDH for removing "post-abortion counseling" from the abortion facility regulations was stated as follows: "The physician's regulatory advisory panel suggested the removal of 'post-abortion	The referenced amendment does not change the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board

	counseling' as the panel stated such counseling is not medically necessary and it's unclear what sort of counseling this would entail." It is unfortunate that the panel of physicians advising the Health Commissioner, VDH and the Board of Health on abortion facility regulations are unaware of the need for emotional healing that might need to take place after having an abortion. The National Abortion Federation's own guidelines regarding "What Should I Expect After the Abortion?" clearly state the need to heal emotionally after having an abortion, and even states that it's member clinics "provide post-abortion counseling or can provide you with referrals to pro-choice counseling services in your community if they do not," offering multiple books and online resources to receive help. The nation's largest abortion provider, Planned Parenthood, details post abortion counseling. They recognize how women "may feel anxious and have concerns about terminating [their] pregnancy" and that some women "do experience extreme negative reactions such as depression, shame, guilt, or regret." Clearly the abortion community is well aware of what constitutes "post-abortion counseling" and sees a medical need for these kinds of services. Furthermore, to be in compliance with existing regulations, all of VA's abortion facilities currently offer "post-abortion counseling." To date, none of these facilities have ever been in non-compliance for failing to provide post-abortion services, nor have they expressed any concern of post-abortion counseling being too burdensome or medically unnecessary. There has been no confusion by these abortion facilities as to what constitutes "post-abortion counseling." To remove "post-abortion counseling" from the regulations would not serve the Purpose of amending the abortion facility regulations as stated in the regulatory action documents…"Upon review, the Department of Health found areas of the	of Medicine, Board of Nursing and other health regulatory boards. The Agency, in its regulation of health care facilities, can reference applicable standards governing health care professionals but does not have the authority to redefine or exceed those standards that are within the purview of other Boards. The Agency notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.

	regulations which could be improved, therefore protecting the health and safety of patients of these facilities to a higher degree." The health of patients would not be protected or improved by the removal of this requirement. Surely, they would be impacted for the worse if they were no longer offered post-abortion counseling. Therefore I recommend keeping the post-abortion counseling services in the abortion facility regulations.	
Claire G. Gastanaga, ACLU of Virginia via Virginia Regulatory Town Hall	The American Civil Liberties Union of Virginia generally supports the Board's proposed amendments to the Final Regulations for the Licensure of Abortion Facilities, and urges the Board to adopt all of the Governor's recommended changes to the rules. The current licensure rules impose a regime of unprecedented severity, completely out of line with the standards for abortion care and for all other comparable medical procedures – in Virginia and throughout the nation. With no connection whatsoever to improving patient safety, the current rules do nothing but endanger women's health by undermining their ability to access safe legal abortion care from trusted, safe providers, and, as such, fail to meet the constitutional standards affirmed by the Supreme Court in Whole Women's Health v. Hellerstedt. The current licensure rules are about politics, not medicine. Five years ago, the Virginia Dept. of Health (DOH) convened a panel of six top medical experts from across the state to draft regulations to implement Virginia's law requiring those who provide five or more abortions a month to be "classified as a category of 'hospital.'" Those experts recommended evidence-based regulations that protected women's health, but DOH ignored its own doctors' recommendations and drafted regulations designed instead to make it nearly impossible for abortion providers to operate. Under pressure from former Attorney General Cuccinelli, the Board of Health approved final rules that included these restrictions designed to shut down abortion providers rather than protect women's health.	The Agency notes the support for the proposed amendments as well as the Governor's recommendations.

	Now, covered first trimester abortion providers must meet building requirements designed for new ambulatory surgical centers - requirements that no other health care facility in Virginia must meet - despite the fact that first trimester abortion is an extremely safe outpatient procedure. About 88% of the women who obtain abortion care are less than 13 weeks pregnant. Of these women, 97% report no complications; 2.5% have minor complications that can be handled at the medical office or abortion facility; and less than 0.5% have more serious complications that require some additional surgical procedure and/or hospitalization.[1] The current licensure law and implementing rules single out abortion providers even though other procedures, like colonoscopies, commonly performed in outpatient clinics have a much higher rate of complications. Yet those other clinics and doctors are not subject to these types of regulations. Some women's health centers providing abortions in Virginia already have been forced to close, or to stop providing abortion services, due to these burdensome and medically unnecessary regulations. If these burdensome licensure regulations remain unchanged, additional providers will close or cut back on services, further limiting women's access to abortion in Virginia. The real motivation behind the law and current regulations has nothing do to with women's health and everything to do with interfering with a woman's ability to access safe and legal abortion care. Such a scheme is clearly unconstitutional. We urge the Board of Health to adopt the changes in the licensure rules now under consideration and to work with the ACLU of Virginia and other individuals and organizations who truly care about protecting women's health to repeal the statute that imposes on abortion providers licensing requirements that are not justified by medical necessity and serve	

	only to burden women by limiting access to safe, legal abortions.	
Meredith Johnson Harbach, University of Richmond School of Law via Virginia Regulatory Town Hall	I write in support of the Board of Health's proposed amendments to the Regulations for Licensure of Abortion Facilities, as well as Governor McAuliffe's recommendations as reflected in his Approval Memo dated March 6, 2016. As a constitutional matter, the medical basis for statutes regulating abortions must be legitimate, and under existing Supreme Court law they cannot have the purpose or effect of placing a substantial obstacle in the path of Virginia women who seek to have abortions. Courts have looked to the following factors when considering whether these sorts of abortion regulations impose an "undue burden" on women's constitutional rights: the likelihood that regulations will result in clinics closing; whether they will delay or deter patients from obtaining abortions; whether they lead to a significant increase in the cost of abortions; and whether they stigmatize abortion and undermine medical providers' ability to exercise their own medical judgment. Courts consider these factors in light of the lived experiences of the women affected by the regulations and the combination of socioeconomic factors that may make such changes especially impactful for them. As currently drafted, the existing regulations are suspect as a constitutional matter, and harmful to women in the Commonwealth as a practical one. Many of the existing regulations have no clear nexus to women's health, and are not imposed on other medical procedures or practices. Instead, they raise the very real specter of shuttering reproductive health centers, making it difficult, if not impossible, for some women to procure abortions, and increasing costs associated with obtaining them. As we have seen in Texas, the closing of abortion providers can drive women underground, across international and state lines, and can also lead to later-term abortions, which are more costly and dangerous. Clinic closures would also mean that fewer women in the	The Agency notes the support for the proposed amendments as well as the Governor's recommendations.

	Commonwealth would have access to the affordable, comprehensive reproductive health services they rely on to plan their families and avoid unintended pregnancies. I urge the Board to adopt the proposed amendments, including the Governor's recommendations, to protect the health, safety, and confidentiality of women seeking abortion services in the Commonwealth, and to ensure the availability of safe, high-quality reproductive healthcare providers.	
Heather Shumaker, National Abortion Federation via the Virginia Regulatory Town Hall	NAF supports the amendment of the current regulations for licensure of abortion facilities to reflect evidence-based, medically-appropriate practices. The National Abortion Federation (NAF) is the professional association of abortion providers. Our mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women. Our member facilities care for half of the women who choose abortion in the United States and Canada each year, including Virginia women. NAF is the leading organization offering accredited continuing medical education to health care professionals in all aspects of abortion care. NAF member facilities, including our Virginia members, adhere to our evidence-based Clinical Policy Guidelines (CPGs), which set the standards for quality abortion care in North America. See National Abortion Federation, Clinical Policy Guidelines (2016) [hereinafter NAF CPGs], available at https://prochoice.org/wp-content/uploads/2016-CPGs-web.pdf. Our experience and expertise includes developing evidence-based standards, drafting medically-appropriate regulations for abortion facilities with state health departments, and assisting health care providers in the delivery of high-quality abortion care. NAF is committed to patient health and safety, and evidence-based regulations, but the current regulations do not reflect the safety of abortion care, the needs of patients, or the expertise of providers. As such, we generally support the Board of	The Agency notes the support for the proposed amendments as well as the Governor's recommendations.

	Health's proposed amendments – and strongly support Governor Terry McAuliffe's recommendations. We offer the following specific comments below: 1. NAF supports the governor's recommendation for Section 12VAC5-412-230(A) regarding the definition of "first trimester" and opposes the Board of Health's recommended amendments to Sections 12VAC5-412-10 and 12VAC5-412-230(A) regarding the same. NAF supports the governor's medically-appropriate recommendation that "first trimester" of pregnancy in Section 12VAC5-412-230(A) be defined as "13 weeks and 6 days after the last menstrual period or based on an appropriate clinical estimate by a licensed health care provider." NAF opposes the Board of Health's recommended amendments, including the definition of "first trimester" in Section 12VAC5-412-10 as "the first 12 weeks from conception as determined in compliance with § 18.2-76 of the Code of Virginia" and the requirement in Section 12VAC5-412-230(A) that "[a]bortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy as determined in compliance with § 18.2-76 of the Code of Virginia." Medical professionals measure pregnancy using trimesters from the first day of a woman's last menstrual period (LMP), totaling 40 weeks. And while the definition of first and second trimester can vary, it is generally accepted that the first trimester goes to 14 weeks LMP. NAF CPGs do not directly define trimesters, but reference the premise that the second trimester begins after 14 weeks LMP. See NAF CPGs, page 29. "[Twelve] weeks from conception," on the other hand, is a less technically accurate measure of the first trimester of pregnancy. Additionally, NAF supports the inclusion of health care providers broadly in the definition of "first trimester," and the medically-appropriate recommendation states "13 weeks and 6 days after the last menstrual period or based on an	

	appropriate clinical estimate by a licensed health care provider" (emphasis added). It is widely accepted within the medical community that health care providers other than physicians can accurately date a pregnancy. Additionally, Virginia Code § 18-2-76 is not relevant for defining "first trimester." Code § 18-2-76 does not define "first trimester" and instead discusses informed consent, and should not be referenced in regard to dating a pregnancy. 2. NAF supports the Board of Health's recommended amendments, and in particular, the governor's additional recommended amendments to Section 12VAC5-412-370, regarding design and construction standards for abortion facilities. Any physical plant requirements for health care facilities should be based on the medical needs for the services provided as well as the safety record of services provided. Abortion care is a simple procedure that is typically provided in office-based settings. Abortion care is one of the safest and most commonly provided medical procedures in the United States. Serious complications are extremely rare. See Facts on Induced Abortion in the United States, Guttmacher Institute, https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#9 (last updated May 2016). Credit for the outstanding safety record of abortion care is attributed to the specialized care given and received in outpatient facilities, which currently provide 95% of the abortion care in the United States. See Rachel K. Jones and Kathryn Kooistra, Guttmacher Institute, Abortion Incidence and Access to Services in the United States, 2008, 43 Perspectives on Sexual and Reproductive Health, no. 1, at 42 (March 2011). As a result, the standard of care for abortion procedures does not require an ambulatory surgical center setting – which is the setting for a variety of complicated and invasive surgical procedures. NAF CPGs do not discuss the setting for first trimester abortion care, but state that	

	second trimester abortion care can safely be provided in medical offices and freestanding clinics. See page 29. Requiring first trimester abortion care to be provided in a hospital-like setting is extraordinarily burdensome, medically unnecessary and inappropriate – and does nothing to advance patient health and safety. Because first trimester abortion care can safely be provided in an office-based setting, abortion providers should not have to adhere to any portion of the hospital design and construction standards outlined by the Facilities Guidelines Institute (FGI). So while we would like to see the amendments go further, the Board and Governor's recommendations for design and construction are an important first step, given the limitations of the Virginia statutes, to bring the regulations for the licensure of abortion facilities in line with the medical reality of first trimester abortion care. 3. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-230(E) regarding counseling. NAF supports the removal of the requirement of "post-abortion counseling" in Section 12VAC5-412-230(E) of the Board of Health's recommendations, which would provide that, "[t]he 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 to its patients." NAF fully supports medically-accurate and appropriate informed consent, patient education, and counseling. NAF CPGs state "[o]btaining informed consent and assessing that the decision to have an abortion is made freely by the patient are essential parts of the abortion process." See page 2. However, requirements for so-called "post-abortion counseling" originate from false anti-choice claims that women face long-term distress following an abortion	

	procedure. Counseling requirements for health care should be grounded in medicine and evidence-based practices, and as such, the removal of this language is appropriate. 4. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-230(F) regarding discharge planning. The Board of Health's recommended amendment to Section 12VAC5-412-230(F) edits the language related to "an organized discharge planning process." NAF supports the deletion of the requirement that the organized discharge planning process include "an evaluation of the patient's capacity for self-care," and instead require "an assessment of a patient's safety for discharge." NAF CPGs reflect the importance of an assessment of a patient's safety for discharge. See pages 46-47. For example, NAF CPGs require a provider to document that a patient is stable and require that a patient be given post-procedure instructions regarding self-care, what to expect, and emergency contacts. See page 46. The Board of Health's recommended amendment replaces the existing TRAP regulation with a more medically-appropriate requirement. 5. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-240 regarding medical testing, laboratory services, and ectopic pregnancy. The Board of Health's recommended amendments to Section 12VAC5-412-240 are consistent with NAF CPGs related to laboratory practice and Rh status, management of pregnancy of uncertain location, and evaluation of evacuated uterine contents. See pages 6, 9, 25-26, and 49-50. 6. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-250 regarding documentation of anesthesia services. The Board of Health's recommended	

	amendments to Section 12VAC5-412-250 add the requirement that "[t]he administration of sedation and monitoring of the patient shall be documented in the patient's medical record." This requirement is consistent with NAF CPGs, Standard 11.9, which requires monitoring to be documented. See page 40. 7. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-290 regarding emergency services. NAF supports the Board of Health's recommended amendments to Section 12VAC5-412-290, which eliminate the requirement for a written transfer agreement with a hospital for emergency treatment. NAF CPGs do not require our members to have transfer agreements with local hospitals. There are many reasons why a facility providing abortion care would not routinely have a transfer agreement, none of which have to do with the standard of care. Requirements for transfer agreements vary from hospital to hospital. As such, hospitals may refuse to grant facilities these agreements because of outside pressure. More so, women can obtain emergency care in hospitals in the rare cases they need it without their facility having a transfer agreement. In the unusual instance when a woman must seek emergency care, she would likely visit the hospital nearest to her, which in any case is not necessarily the hospital with which her facility has a transfer agreement, particularly given the significant distances many women travel to access abortion care. In conclusion, NAF thanks you for your time in reviewing our comments and in amending the regulations to reflect the reality of abortion care. We urge you to adopt medically-appropriate amendments, including the governor's recommendations.	

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-412-10 Definitions		“First trimester" means the first 12 weeks from conception as determined in compliance based on an appropriate clinical estimate by a licensed physician.	Remove the definition of "First trimester" Rationale: At a special meeting of the Board of Health on October 24th, a Board member suggested this amendment. Defining the term is unnecessary within the definition section as it is defined by the Board in the only section it is utilized.
12VAC5-412-10 Definitions		"Trimester" means a 12-week period of pregnancy.	Definition has been stricken. Rationale: Defining the term “trimester” is unnecessary.
12VAC5-412-30 Classification		Abortion facilities shall be classified as a category of hospital.	This section has been repealed. Rationale: This language is contained in the Code of Virginia, therefore it is unnecessary to restate it in the Regulations.
12VAC5-412-80 Allowable variances		A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.	This section has been amended to align with the hospital licensure regulations. Rationale: This amendment was suggested by a Board member at a special meeting of the Board of Health on October 24th. This section has been aligned and made consistent with provisions for allowable variances in the hospital licensure regulations.

		B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients. C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients. D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.	
12VAC5-412-100(C) Onsite Inspection		C. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within two hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-130.	Subsection C has been stricken. Rationale: This amendment is proposed after review by the Department based on advice from the Virginia Office of the Attorney General.
12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or		A. When the department determines that an abortion facility is (i) in violation of any provision of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the	A. When the department determines that an abortion facility is (i) in violation of ~~any provision of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1~~ §§ 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or

suspension of license.		abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provisions of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).	abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with ~~all provisions of Article 1 of Chapter 5 of Title 32.1 of the~~ §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). Rationale: Integrate Virginia Department of Health Office of Licensure and Certification guidance into the regulation. A technical amendment was suggested by a Board member at a special meeting of the Board of Health on October 24th to remove reference to Code sections that pertain to licensure of hospitals and nursing homes.
12VAC5-412-180		A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document appropriate	Subsection H has been amended. H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the

		staffing by licensed clinicians based on the level, intensity, and scope of services provided. B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable. C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility. D. The abortion facility shall develop, implement, and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties and appropriate to the level, intensity, and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. E. Job descriptions. 1. Written job descriptions that adequately describe the duties of every position shall be maintained. 2. Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. 3. Job descriptions shall be reviewed at least annually, kept current, and given to each employee and volunteer when assigned to the position and when revised. F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the	employee's personnel file. Unless redacted, copies of personnel files shall not be removed from the premises. Rationale: This amendment was suggested by a Board member at a special meeting of the Board of Health on October 24th, in order to protect the privacy of abortion facility employees.

		person's in-service education, and professional licensure, if applicable. G. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file.	
12VAC5-412-190		A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined. B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience. C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order, and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-	A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined. B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience. C. A physician shall remain on the premises until all patients are medically stable ~~, sign the discharge order, and be readily available and accessible until the last patient is discharged~~ . Licensed health care practitioners trained in post-

		procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility. D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.	procedure assessment shall remain on the premises until the last patient has been discharged. ~~The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge.~~ The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that ~~adequate~~adequately trained health care practitioners remain with the patient until she is discharged from the abortion facility. D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff. Rationale: This amendment removes the requirement for the physician to remain on the premises until the last patient is discharged. The amendment also removes the requirement that the physician give a discharge order. Language is retained requiring that a physician remain on the premises until all patients are medically stable. This amendment was suggested by a Board member at a special meeting of the Board of Health on October 24th, stating that the stricken language provided no medical benefit.
12VAC5-412-200(A) Patients' Rights		Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.	Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission. Rationale: Reference to Joint Commission standards has been stricken. This amendment is proposed after review by the Department based on

			advice from the Virginia Office of the Attorney General.
12VAC5-412-220(A) Infection Prevention		A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation, and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review.	A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation, and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review. Rationale: Reference to CDC Guidelines has been stricken. This amendment is proposed after review by the Department based on advice from the Virginia Office of the Attorney General.
12VAC5-412-230. Patient services; patient counseling.		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 a 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. 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	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 a licensed physician.~~ Meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider. 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. 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 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 family planning and post-abortion counseling to its patients. F. There shall be an organized discharge planning process that includes 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.	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 ~~and post-abortion counseling~~services to its patients. F. There shall be an organized discharge planning process that includes ~~an evaluation of the patient's capacity for self-care and~~ an assessment of a patient's safety for discharge and discharge instructions for patients to include instructions to call or return if signs of infection develop. Rationale: The amendment to subsection A utilizes a more clinically accurate time frame for first trimester. The amendment to subsection E clarifies that the provider need not provide the family planning services but rather simply make referrals. The physician's regulatory advisory panel suggested the removal of "post-abortion counseling" as the panel stated such counseling is not medically necessary and it's unclear what sort of counseling this would entail. The amendment to subsection F was also suggested by the physician's regulatory advisory panel and is a technical amendment for clarity. It is the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and

			other health regulatory boards.
12VAC5-412-240. Medical testing and laboratory services.		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. 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 tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic	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.~~ Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 2. ~~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. 3. The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to clinics that provide such testing. ~~The policies and procedures shall address appropriate responses to a positive screening test.~~ 4. 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

		pregnancy, and referred appropriately. 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).	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 tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.~~ The abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion, and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy. 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). Rationale: The requirements of subsection A 1 and A 2 were rearranged for greater clarity of the regulations. Subsection 3 was amended slightly to clarify that facilities need not offer STD screening themselves. The amendment in subsection C removes mandatory additional testing and instead requires the facility to have policies and procedures for patient reevaluation in the event that the evaluation of tissue is insufficient to confirm termination of pregnancy. It is the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards.
12VAC5-412-250. Anesthesia service.		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	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 who is certified in advanced resuscitative

		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 18VAC85-20-360C: 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	techniques and has met the continuing education requirements. 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 The administration of sedation and monitoring of the patient shall be documented in the patient's medical record. 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

		(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.	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 those criteria have been documented within the patient's medical record. Rationale: At a special meeting of the Board of Health on October 24, 2016,an amendment to subsection B was suggested by a Board member to bring an office-based anesthesia requirement into the regulations to make facilities aware of the requirement. An amendment to subsection C was suggested by a Board of Health member to stress the importance of documentation of a patient's status. An amendment to subsection H restates a requirement located in 12VAC5-412-300 (5) (h). The restatement here stresses the importance of this documentation requirement. It is the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards.
12VAC5-280 Emergency Equipment and Supplies		An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions: 1. Cardiopulmonary arrest; 2. Seizure; 3. Respiratory distress; 4. Allergic reaction; 5. Narcotic toxicity; 6. Hypovolemic shock; and 7. Vasovagal shock.	An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. ~~Drugs shall include, at a minimum, those to treat the following conditions:~~ ~~1. Cardiopulmonary arrest;~~ ~~2. Seizure;~~ ~~3. Respiratory distress;~~ ~~4. Allergic reaction;~~ ~~5. Narcotic toxicity;~~ ~~6. Hypovolemic shock; and~~ ~~7. Vasovagal shock.~~

			Rationale: Removal of specific conditions for emergency drugs must be available to treat; language is retained which requires the supplies be consistent with the American Heart Association's Guidelines for CPR and ECC. This amendment was suggested by a Board member with the rationale that treating the conditions listed would be unnecessary in most cases and that each facility should have the ability to determine what type of emergency drugs to have on hand.
12VAC5-290 Emergency services.		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 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.	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~~ Cardiopulmonary Resuscitation and Emergency Cardiovascular ~~Life Support~~ Care. 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. Rationale: Insert updated reference to American Heart Association guidelines.

			A written agreement is not necessary due to the Emergency Medical Treatment and Labor Act (EMTALA). 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 regulatory advisory panel suggested the additional amendment stating that emergency department staff may not always be the appropriate staff for the provider to be communicating with in the case of emergency transfer. It is the Agency's expectation that a physician, nurse or other health care professional will adhere to established standards of practice. Those standards of practice are regulated by the Virginia Board of Medicine, Board of Nursing and other health regulatory boards. The Board of Medicine's regulations for the use of office-based anesthesia currently require physicians to have a transfer agreement if they use moderate or greater sedation, and that is the Agency's expectation.
12VAC5-412-300		An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physicians' and nurses' progress notes; h. Condition at time of discharge; i. Patient instructions (preoperative and postoperative); and j. Names of referral physicians or	An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. ~~It~~ If medically indicated, it shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physicians' and nurses' progress notes;

		agencies; and 6. Any other information required by law to be maintained in the health information record.	h. Condition at time of discharge; i. Patient instructions (preoperative and postoperative); and j. Names of referral physicians or agencies; and 6. Any other information required by law to be maintained in the health information record. Rationale: At a special meeting of the Board of Health held on October 24, 2016, a Board member suggested this amendment, stating that the listed information is not always medically indicated or relevant.
12VAC5-412-320		A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). B. The abortion facility shall report the following events to OLC: 1. Any patient, staff, or visitor death; 2. Any serious injury to a patient; 3. Medication errors that necessitate a clinical intervention other than monitoring; 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and 5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629). C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies.	A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). B. The abortion facility shall report the following events to OLC: 1. Any patient, staff, or visitor death; 2. Any serious injury to a patient; 3. Medication errors that necessitate a clinical intervention other than monitoring;and 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; ~~and~~ ~~5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629).~~ C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. D. Compliance with this section does not relieve the abortion facility from complying with any other applicable

		E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.	reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies. E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia. Rationale: At a special meeting of the Board of Health held on October 24, 2016, a Board member suggested this amendment, stating that the reporting required by subsection B5 can be an act to intimidate an abortion provider.
12VAC5-412-330		The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: 1. Abortion facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and 3. Provisions for disseminating safety-related information to employees and users of the abortion facility.	The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: ~~1. Abortion facility security;~~ ~~2.~~ Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and ~~3. Provisions for disseminating safety-related information to employees and users of the abortion facility.~~ Rationale: At a special meeting of the Board of Health held on October 24, 2016, this amendment was suggested by a Board member, with the rationale of wanting to prevent this material from being obtained by someone trying to compromise the security of an abortion facility.
12VAC5-412-350		A. The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating	A. ~~The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating~~

		condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that will allow sanitization. B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.	~~condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that will allow sanitization.~~ ~~B~~. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. Rationale: This amendment is proposed after review by the Department based on advice from the Virginia Office of the Attorney General.
12VAC5-412-360		A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. C. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).	This section has been repealed. Rationale: This amendment was proposed after consultation with the Virginia Office of the Attorney General because compliance with applicable fire and safety laws and regulations is required by 12 VAC 5-412-370 as amended.
12VAC5-412-370		Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63).In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the	All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall comply with all applicable state and local codes and ordinances.

		2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia. Entities operating as of the effective date of this chapter as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.	Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.
Documents Incorporated By Reference (12VAC5-412)		Guidelines for Design and Construction of Health Care Facilities, 2010 Edition, Part 1 and Sections 3.1-1 through 3.1-8 and 3.7 of Part, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C. Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. November 2, 2010, Volume 122, Issue 18 Suppl 3, American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596 (http://circ.ahajournals.org/content/vol122/18_suppl_3/). Sexually Transmitted Diseases Treatment Guidelines, 2010, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (http://www.cdc.gov/std/tg2015/default.htm~~)~~ Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, Centers for Disease Control and Prevention, U.S. Department of Health and Human	~~Guidelines for Design and Construction of Health Care Facilities, 2010 Edition, Part 1 and Sections 3.1-1 through 3.1-8 and 3.7 of Part~~ 32014 ~~Guidelines for Design and Construction of Hospitals and Outpatient Facilities, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.~~ Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. November 2, 2010, Volume 122, Issue 18 Suppl 3, American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596 (http://circ.ahajournals.org/content/vol122/18_suppl_3/). Sexually Transmitted Diseases Treatment Guidelines, [~~2010~~2015], Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (http://www.cdc.gov/std/tg2015/default.htm) ~~Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, Centers for Disease Control and Prevention, U.S. Department of Health and Human~~

		Services (http://www.cdc.gov/HAI/prevent/prevent_pubs.html) Standards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone 1-877-223-2866, email jcrcustomerservice@pbd.com. Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration.	~~Services [(http://www.cdc.gov/HAI/prevent/prevent_pubs.html) (http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf).]~~ ~~[2015 Standards for Ambulatory Care]Standards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone [1-770-238-0454]1-877-223-2866, email jcrcustomerservice@pbd.com.~~ Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration. Rationale: References to the deleted documents have been removed from the Regulations.