

State of Board of Health
Agenda
September 15, 2016 – 9:00 a.m.
Perimeter Center – Boardroom 2

Note: There is limited seating within Boardroom 2, with seats available for 100 members of the public. The meeting will also be viewable in Boardroom 1. There is limited seating within Boardroom 1, with seats available for 80 members of the public. Seating will be available on a first-come, first served basis. The maximum occupancy of Boardroom 2 and 1 is enforced by the Fire Marshal, and cannot be exceeded.

Sign-up sheets for individuals wishing to address the Board during the public comment period will be available in Boardroom 2 and Boardroom 1. Each individual will be allowed to put only one name on the sign-up sheet. Public Comment period 1 is reserved for comments concerning the Regulations for Licensure of Abortion Facilities and related topics. Public Comment Period 2 is reserved for comments for any other topics not previously identified in Public Comment Period 1.

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Faye Prichard
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of June 2, 2016 Minutes	Mr. Edwards
Commissioner’s Report	Marissa Levine, MD, MPH, FAAFP State Health Commissioner
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert

Break

Public Comment Period 1 – Regulations for Licensure of Abortion Facilities and related topics

Working Lunch/Regulatory Action Item

Regulations for the Licensure of Abortion Facilities 12VAC5-412 (Final Amendments)	Dr. Levine
--	------------

Break

Public Comment Period 2 – Any other topics not previously identified in Public Comment Period 1.

Regulations for Alternative Onsite Sewage Systems
12VAC5-613
(Fast Track Amendments)

Allen Knapp, Director
Office of Environmental Health Services

2017 Board Meeting Schedule

Mr. Edwards

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: September 15, 2016

TO: Virginia State Board of Health

FROM: Erik Bodin, Director, Office of Licensure and Certification

SUBJECT: Regulations for the Licensure of Abortion Facilities (12VAC5-412)

Enclosed for your review are final amendments to the Regulations for the Licensure of Abortion Facilities (12VAC5-412).

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: clarify the requirements for parental consent, 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, and make minor technical amendments. The regulations are mandated by § 32.1-127 of the Code of Virginia.

Based on advice received from the Office of Attorney General, additional amendments have been proposed to the regulations to comply with the U.S. Supreme Court decision in *Whole Woman's Health v. Hellerstedt*, 579 U.S. ____ (2016).

Please note that the Governor has asked that the Board consider making the following additional amendments to the regulations:

1. In Part 1, Definitions and Requirements for Licensure, strike the following language: “ ‘First Trimester’ means the first 12 weeks of conception based on an appropriate clinical estimate by a licensed physician as determined in compliance with § 18.2-76 of the Code of Virginia.”

2. In Section 230(A), after “first trimester of pregnancy” insert the following language: “, meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider.”
3. In Section 230(A), after “~~estimate by a licensed physician~~” strike the language: “as determined in compliance with § 18.2-76 of the Code of Virginia.”
4. In Section 230(B), after “authorized person” strike the language: “which shall be notarized as required by § 16.1-241 of the Code of Virginia.”

The Board of Health is requested to approve the final amendments to the Regulations for the Licensure of Abortion Facilities. Should the Board of Health approve the final amendments, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval by the Governor, the final amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin. At the close of the public comment period the final amendments will become effective.



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	8/10/2016

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, clarify the requirements for parental consent, 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, 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 based on advice from the Office of 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.

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.

At a meeting conducted on September 15, 2016 the State Board of Health voted to approve the final amendments to the Regulations for Licensure of Abortion Facilities.

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 are performed per month 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: clarify the requirements for parental consent, 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, 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. In consultation with the Office of Attorney General, additional amendments have been proposed to the Regulations to comply with the U.S. Supreme Court decision in *Whole Woman's Health v. Hellerstedt*, 579 U.S. ____ (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 offered based on advice from the Virginia Office of the Attorney General. .

The term "First trimester" has been amended. It now reads: "First trimester means the first 12 weeks from conception as determined in compliance with §18.2-76 of the Code of Virginia".

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.

12VAC5-412-100(C) Onsite Inspection

Subsection C 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 §§ 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.

It now states: "When the department determines that an abortion facility is (i) in violation of §§ 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." 12VAC5-412-130

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, 32.1-132, 32.1-135.2 or 32.1-137.01 Code of Virginia and applicable state and federal law and regulations hereunder has been obtained."

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 licensed physician. It now states: "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."

Subsection B has been amended to add a notarization requirement for unemancipated minors. It now states: "No person may perform an abortion upon an un-emancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person, which shall be notarized as required by § 16.1-241 of the Code of Virginia. If the un-emancipated 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."

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."

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. 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.” This subsection now states: “All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present. If villi or fetal parts cannot be identified with certainty, the patient shall be notified that pregnancy tissue was not identified 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. The facility shall track and log any specimens sent for further pathologic examination.

12VAC5-412-250 Anesthesia Service

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.”

12VAC5-412-290 Emergency Services

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 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.”

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."

12VAC5-412-350 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 conform to state and local codes and ordinances.”

Documents Incorporated by Reference

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 proposed, based on advice from the Virginia Office of the Attorney General, to comply with 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.

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.

Parental consent safeguards the family unit as well as parental authority. Clarity regarding parental consent will foster family unity and help to preserve the family as a viable social unity.

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*	<p>"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 abortion.</p> <p>"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.</p>	These definitions have been stricken.	At the proposed stage, these two defined terms were used only in Section 370. Given the amendments to Section 370, which were proposed based on advice from the Virginia 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.
12VAC5-412-100 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	Subsection C has been stricken.	This amendment is offered based on advice from the Virginia Office of the Attorney General.

	<p>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.</p>		
<p>12VAC5-412-200 A*</p>	<p>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.</p>	<p>Specific reference to Joint Commission standards has been stricken.</p> <p>Subsection A 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. Reference to Joint Commission standards has been stricken. *</p>	<p>This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>
<p>12VAC5-412-220 A*</p>	<p>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</p>	<p>Specific reference to CDC Guidelines has been stricken.</p> <p>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. Specific reference to CDC Guidelines has</p>	<p>This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>

	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.	been stricken.	
12VAC5-412-350*	<p>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.</p> <p>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.</p>	<p>Subsection A has been stricken.</p> <p>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 testing and maintenance.</p>	This amendment is offered 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	This section has been repealed.	This amendment is offered based on advice from the Virginia Office of the Attorney General.

	<p>applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.</p> <p>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.</p> <p>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).</p>		
<p>12VAC5-412-370*</p>	<p>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, zoning ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). All construction of new buildings and additions, or major renovations to existing buildings 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 2014 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, pursuant to § 32.1-127.001 of the Code</p>	<p>This section has been amended.</p> <p>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 with all applicable state and local codes and ordinances.</p>	<p>This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>

	<p>of Virginia. Abortion facilities that perform only medication induced abortions shall be designed and constructed consistent with Part 1 Section 1.1, 1.3 and 1.4 of the 2014 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute.</p> <p>Abortion procedures may take place in a procedure room, as detailed in Section 3.8-3.1, 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 are not required for abortion facilities. Section 3.7-3.6.13.1(2) shall not apply to facilities that do not have a room designed in accordance with Section 3.8-3.2.</p> <p>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 and be consistent with applicable sections of the 2014 Guidelines for Design and</p>		
--	---	--	--

	<p>Construction of Health Care Facilities of the Facilities Guidelines Institute. The certification shall be forwarded to the OLC.</p> <p>B. In order to determine whether the abortion facility's design and construction is consistent with the applicable sections of the 2014 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines, the commissioner may obtain additional information from the facility or its architect.</p>		
--	---	--	--

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.

Commenter	Comment	Agency response
2479 persons commented via form letter supporting the regulation, but did not cite specific sections for comment. In total there were 240 duplicates. 142 out of state. Actual count of form letters is 2097.	Asking Board of Health to adopt the proposed amendments.	The Board notes the support for the proposed amendments.
6008 submission via public forum supporting the regulation but did not cite specific sections for comment. 2948 duplicates Actual count of Public Forum comments is 3060	Asking Board of Health to adopt the proposed amendments.	The Board notes the support for the proposed amendments.
3 comments did not express support or opposition to the regulation.	N/A	The Board believes that no response is necessary for these comments as they do not speak to the proposed amendments.
The Honorable Barbara A Favola, Virginia State Senate	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 Board notes the support for the proposed amendments.

The Honorable Kaye Kory, Virginia House of Delegates	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 Board notes the support for the proposed amendments.
Sara Shannon	Asking Board of Health to follow the Supreme Court's ruling in Woman's Health v. Hellerstedt.	Additional amendments have been proposed to comply with the Supreme Court's ruling.
John Comerford	Asking the Board to maintain the current Virginia regulations.	The Board notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Masiel G Vergara	Asking the governor to insert new policies that will prevent abortion.	12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Angel A Ruiz	Asking the governor to insert new policies that will prevent abortion.	12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Rodrigo Velasquez	Deep support for the amendment proposed.	The Board notes the support for the proposed amendments.
Maggie Disney, Margarette Botham, Joss Hetzler, Chris Friend, Victoria Cobb, Jeff Caruso, LaDean Barnes, Daniel Howell, Jill Zackrisson, Richard Wiley, Don Blake, and Barry Hodges Public Hearing.	Rejects proposed amendments.	The Board notes the opposition to the proposed amendments. 12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Janice Craft and Janet Dix Public Hearing	Supports the amendments and the Governor's amendments.	The Board notes the support for the proposed amendments as well as support for the Governor's amendments.
Martha Cassell Public Hearing	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.
Pam Messina Public Hearing	Wants strong regulations.	12VAC5-412 is written to comply with Virginia Code § 32.1-127.
Heather Shoemaker, Michael Davis, Anna Sholl, Jill Abbey, Sarena Floyd, Rebecca Gutwalt, Margaret Beth Meyer, Elisa Pharo, Laura Foronda, Ida Dawnhildie, Jurissa Davis, Gail Deady, Cianti Reed, Rachel Robinstein, Nichole Grim, Michelle Wooten Public Hearing	Asking Board of Health to adopt the proposed amendments.	The Board notes the support for the proposed amendments.
Kenneth Oshhanski	Make policies based on science not politics.	The Board believes that no response is necessary for these comments as they do not speak to the proposed amendments.

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.	"First trimester" means the first 12 weeks from conception as determined in compliance with § 18.2-76 of the Code of Virginia. Rationale: Update the definition of first trimester to reflect the requirements of the Code of Virginia.
12VAC5-412.10 Definitions		"Trimester" means a 12-week period of pregnancy.	Definition has been stricken. Rationale: Defining the term "trimester" is unnecessary.
12VAC5-30 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.
12VAC5-412-100(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 offered based on advice from the Virginia Office of the Attorney General.

<p>12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.</p>		<p>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 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.</p> <p>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.</p> <p>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.</p> <p>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).</p>	<p>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 <u>§§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01</u> 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.</p> <p>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 <u>§§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01</u> Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.</p> <p>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.</p> <p>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).</p> <p>Rationale: Technical amendment. Integrate Virginia Department of Health Office of Licensure and Certification guidance into the regulation. Technical amendment.</p>
<p>12VAC5-412-200(A) Patients' Rights</p>		<p>Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint</p>	<p>Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients. The protocol shall include a process reasonably</p>

		<p>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.</p>	<p>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. Reference to Joint Commission standards has been stricken.</p> <p>Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>
<p>12VAC5-412-220(A) Infection Prevention</p>		<p>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.</p> <ol style="list-style-type: none"> 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. 	<p>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.</p> <ol style="list-style-type: none"> 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. <p>Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>
<p>12VAC5-412-230. Patient services; patient counseling.</p>		<p>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.</p> <p>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,</p>	<p>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. <u>as determined in compliance with § 18.2-76 of the Code of Virginia.</u></p> <p>B. No person may perform an abortion upon an unemancipated minor</p>

	<p>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.</p> <p>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.</p> <p>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.</p> <p>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.</p> <p>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.</p>	<p>unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person-, <u>which shall be notarized as required by § 16.1-241 of the Code of Virginia.</u> If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</p> <p>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.</p> <p>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.</p> <p>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 <u>or referral for family planning and post-abortion counseling services</u> to its patients.</p> <p>F. There shall be an organized discharge planning process that includes <u>an evaluation of the patient's capacity for self-care and an assessment of a patient's safety for discharge</u> and discharge instructions for patients to include instructions to call or return if signs of infection develop.</p> <p>Rationale: The amendment to subsection A removes a restriction more stringent than the Code of Virginia and aligns the Regulations more precisely with the Code of Virginia (§ 18.2-76 of the Code). The amendment also aligns part A with the definition of "First trimester" within 12VAC5-412-10. The amendment to subsection B inserts the requirements of parental consent within the Regulations, alerting providers of the necessity of notarization. The amendment to subsection E clarifies that the provider</p>
--	--	--

			<p>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.</p>
<p>12VAC5-412-240. Medical testing and laboratory services.</p>		<p>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.</p> <ol style="list-style-type: none"> 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. <p>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).</p> <ol style="list-style-type: none"> 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. 	<p>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.</p> <ol style="list-style-type: none"> 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. <u>Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.</u> 2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. <u>Use of any additional medical testing shall be based on an assessment of patient risk.</u> 3. The abortion facility shall develop, implement, and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test. 4. 3. A written report of each laboratory test and examination shall be a part of the patient's record. <p>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).</p>

		<p>3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.</p> <p>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.</p> <p>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).</p>	<p>1. Facilities for collecting specimens shall be available on site.</p> <p>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.</p> <p>3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.</p> <p>C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if <u>if</u> villi or fetal parts cannot be identified with certainty, <u>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 facility shall track and log any specimens sent for further pathologic examination.</u></p> <p>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).</p> <p>Rationale: The requirements of subsection A 1 and A 2 were rearranged for greater clarity of the regulations. The physician's regulatory advisory panel suggested the elimination of subsection A 3, as this provision is unrelated to abortion procedures. The list was renumbered due to this suggested elimination. The amendment in 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 performed, so the facility can determine if follow up is necessary.</p>
--	--	--	---

<p>12VAC5-412-250. Anesthesia service.</p>	<p>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.).</p> <p>B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.</p> <p>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.</p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>E. Elective general anesthesia shall not be used.</p> <p>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.</p> <p>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</p>	<p>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.).</p> <p>B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.</p> <p>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 <u>administration and shall be documented in the patient's medical record.</u></p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>E. Elective general anesthesia shall not be used.</p> <p>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.</p> <p>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</p>
--	--	--

	<p>pharmacological agents as required by 18VAC85-20-360C:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 	<p>equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 C:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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
--	---	--

		<p>the anesthesia care and shall occur only when the patient has met specific physician-defined criteria.</p>	<p>move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria <u>and those criteria have been documented within the patient's medical record.</u></p> <p>Rationale: An amendment to subsection C was recommended 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.</p>
<p>12VAC5-290C Emergency services.</p>		<p>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.</p>	<p>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 <u>emergency department staff appropriate receiving facility staff</u> 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.</p> <p>Rationale: 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</p>

			<p>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.</p>
<p>12VAC5-412-350</p>		<p>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.</p> <p>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.</p>	<p>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.</p> <p>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.</p> <p>Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>
<p>12VAC5-412-360</p>		<p>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.</p> <p>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.</p> <p>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</p>	<p>This section has been repealed.</p> <p>Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>

		<p>the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).</p>	
<p>12VAC5-412-370</p>		<p>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 be designed and constructed consistent with Part 1 and sections 3.8 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.</p> <p>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.</p> <p>In order to determine whether the abortion facility's compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.</p>	<p><u>A. All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility.</u></p> <p>Rationale: This amendment is offered based on advice from the Virginia Office of the Attorney General.</p>
<p>Documents Incorporated By Reference (12VAC5-412)</p>		<p>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 3 <u>2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities</u>, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.</p> <p>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/).</p> <p>Sexually Transmitted Diseases</p>	<p>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 3 <u>2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities</u>, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.</p> <p>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/).</p> <p>Sexually Transmitted Diseases</p>

	<p>Treatment Guidelines, 20102015, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (http://www.cdc.gov/std/tg2015/default.htm)</p> <p>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/prevention/prevent_pubs.html) (http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf).</p> <p>2015 Standards for Ambulatory CareStandards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone 1-770-238-04541-877-223-2866, email jrcustomerservice@pbd.com.</p> <p>Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration.</p>	<p>Treatment Guidelines, 20102015, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (http://www.cdc.gov/std/tg2015/default.htm)</p> <p>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/prevention/prevent_pubs.html) (http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf).</p> <p>2015 Standards for Ambulatory CareStandards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone 1-770-238-04541-877-223-2866, email jrcustomerservice@pbd.com.</p> <p>Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration.</p> <p>Rationale: References to the deleted documents have been removed from the Regulations.</p>
--	--	--

DEPARTMENT OF HEALTH

Amend Regulations Following Periodic Review -Chp 412

1 Part I

2 Definitions and Requirements for Licensure

3 **12VAC5-412-10. Definitions.**

4 The following words and terms when used in this regulation shall have the following
5 meanings unless the context clearly indicates otherwise:

6 "Abortion" means the use of an instrument, medicine, drug, or other substance or device
7 with the intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other
8 than a live birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this
9 definition.

10 "Abortion facility" means a facility in which five or more first trimester abortions per month
11 are performed.

12 "Administrator" means the person appointed by the governing body as having responsibility
13 for the overall management of the abortion facility. Job titles may include director, executive
14 director, office manager, or business manager.

15 "Commissioner" means the State Health Commissioner.

16 "Department" means the Virginia Department of Health.

17 "First trimester" means the first 12 weeks from conception as determined in compliance with
18 § 18.2-76 of the Code of Virginia. ~~based on an appropriate clinical estimate by a licensed~~
19 ~~physician.~~

20 "Informed written consent" means the knowing and voluntary written consent to abortion by
21 a pregnant woman of any age in accordance with § 18.2-76 of the Code of Virginia.

22 "Licensee" means the person, partnership, corporation, association, organization, or
23 professional entity who owns or on whom rests the ultimate responsibility and authority for the
24 conduct of the abortion facility.

25 ~~["Medication induced abortion" means any abortion caused solely by the administration of
26 any medication or medications given to a woman in the first trimester of pregnancy with the
27 intent to produce abortion.]~~

28 "Minor" means a patient under the age of 18.

29 "Patient" means any person seeking or obtaining services at an abortion facility.

30 "Physician" means a person licensed to practice medicine in Virginia.

31 "Spontaneous miscarriage" means the expulsion or extraction of a product of human
32 conception resulting in other than a live birth and which is not an abortion.

33 ~~["Surgical abortion" means any abortion caused by any means other than solely by the
34 administration of any medication or medications given to a woman in the first trimester of
35 pregnancy with the intent to produce abortion.]~~

36 ~~"Trimester" means a 12-week period of pregnancy.~~

37 **12VAC5-412-30. Classification. (Repealed.)**

38 ~~Abortion facilities shall be classified as a category of hospital.~~

39 **12VAC5-412-100. on-Site Inspection.**

40 A. An OLC representative shall make periodic unannounced on-site inspections of each
41 abortion facility as necessary, but not less often than biennially. If the department finds, after
42 inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a
43 written licensing report of such findings. The abortion facility shall submit a written plan of
44 correction in accordance with provisions of 12VAC5-412-110.

45 B. The abortion facility shall make available to the OLC's representative any requested
46 records and shall allow access to interview the agents, employees, contractors, and any person
47 under the abortion facility's control, direction, or supervision. If copies of records are removed

48 from the premises, patient names and addresses contained in such records shall be redacted
49 by the abortion facility before removal.

50 ~~[C. If the OLC's representative arrives on the premises to conduct a survey and the~~
51 ~~administrator, the nursing director, or a person authorized to give access to patient records is~~
52 ~~not available on the premises, such person or the designated alternate shall be available on the~~
53 ~~premises within one hour of the surveyor's arrival. A list of patients receiving services on the day~~
54 ~~of the survey as well as a list of all of the abortion facility's patients for the previous 12 months~~
55 ~~shall be provided to the surveyor within two hours of arrival if requested. Failure to be available~~
56 ~~or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia~~
57 ~~and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-~~
58 ~~130.]~~

59 **12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or**
60 **suspension of license.**

61 A. When the department determines that an abortion facility is (i) in violation of any provision
62 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,
63 32.1-135.2 or 32.1-137.01 of the Code of Virginia or of any applicable regulation, or (ii) is
64 permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the
65 department may deny, suspend, or revoke the license to operate an abortion facility in
66 accordance with § 32.1-135 of the Code of Virginia.

67 B. If a license or certification is revoked as herein provided, a new license or certification
68 may be issued by the commissioner after satisfactory evidence is submitted to him that the
69 conditions upon which revocation was based have been corrected and after proper inspection
70 has been made and compliance with all provisions of Article 1 of Chapter 5 of Title 32.1 of
71 ~~the~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01 Code of Virginia and
72 applicable state and federal law and regulations hereunder has been obtained.

73 C. Suspension of a license shall in all cases be for an indefinite time. The commissioner
74 may restore a suspended license when he determines that the conditions upon which
75 suspension was based have been corrected and that the interests of the public will not be
76 jeopardized by resumption of operation. No additional fee shall be required for restoring such
77 license.

78 D. The abortion facility has the right to contest the denial, revocation, or suspension of a
79 license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.
80 of the Code of Virginia).

81 Part II
82 Organization and Management

83 **12VAC5-412-200. Patients' Rights.**

84 A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of
85 patients [~~consistent with the current edition of the Joint Commission Standards of Ambulatory~~
86 ~~Care~~]. The protocol shall include a process reasonably designed to inform patients of their rights
87 and responsibilities, in a language or manner they understand. Patients shall be given a copy of
88 their rights and responsibilities upon admission.

89 B. The abortion facility shall establish and maintain complaint handling procedures which
90 specify the:

- 91 1. System for logging receipt, investigation, and resolution of complaints; and
- 92 2. Format of the written record of the findings of each complaint investigated.

93 C. The abortion facility shall designate staff responsible for complaint resolution, including:

- 94 1. Complaint intake, including acknowledgment of complaints;
- 95 2. Investigation of the complaint;
- 96 3. Review of the investigation findings and resolution for the complaint; and
- 97 4. Notification to the complainant of the proposed resolution within 30 days from the date of
98 receipt of the complaint.

99 D. Any patient seeking an abortion shall be given a copy of the complaint procedures, in a
100 language or manner she understands, at the time of admission to service.

101 E. The abortion facility shall provide each patient or her designee with the name, mailing
102 address, and telephone number of the:

103 1. Abortion facility contact person; and

104 2. OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit
105 complaints anonymously to the OLC. The abortion facility shall display a copy of this
106 information in a conspicuous place.

107 F. The abortion facility shall maintain documentation of all complaints received and the status of
108 each complaint from date of receipt through its final resolution. Records shall be maintained for
109 no less than three years.

110 Part III

111 Quality Management and Infection Prevention

112 **12VAC5-412-220. Infection Prevention.**

113 A. The abortion facility shall have an infection prevention plan that encompasses the entire
114 abortion facility and all services provided~~[, and which is consistent with the provisions of the~~
115 ~~current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations~~
116 ~~for Safe Care," published by the U.S. Centers for Disease Control and Prevention].~~ An individual
117 with training and expertise in infection prevention shall participate in the development of
118 infection prevention policies and procedures and shall review them to assure they comply with
119 applicable regulations and standards.

120 1. The process for development, implementation, and maintenance of infection
121 prevention policies and procedures and the regulations or guidance documents on which
122 they are based shall be documented.

123 2. All infection prevention policies and procedures shall be reviewed at least annually by
124 the administrator and appropriate members of the clinical staff. The annual review
125 process and recommendations for changes/updates shall be documented in writing.

126 3. A designated person in the abortion facility shall have received training in basic
127 infection prevention, and shall also be involved in the annual review.

128 B. Written infection prevention policies and procedures shall include, but not be limited to:

129 1. Procedures for screening incoming patients and visitors for acute infectious illnesses
130 and applying appropriate measures to prevent transmission of community-acquired
131 infection within the abortion facility;

132 2. Training of all personnel in proper infection prevention techniques;

133 3. Correct hand-washing technique, including indications for use of soap and water and
134 use of alcohol-based hand rubs;

135 4. Use of standard precautions;

136 5. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety
137 and Health Administration;

138 6. Use of personal protective equipment;

139 7. Use of safe injection practices;

140 8. Plans for annual retraining of all personnel in infection prevention methods;

141 9. Procedures for monitoring staff adherence to recommended infection prevention
142 practices; and

143 10. Procedures for documenting annual retraining of all staff in recommended infection
144 prevention practices.

145 C. Written policies and procedures for the management of the abortion facility, equipment,
146 and supplies shall address the following:

147 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based
148 hand rubs, disposable towels or hot air driers);

- 149 2. Availability of utility sinks, cleaning supplies, and other materials for cleaning,
150 disposal, storage, and transport of equipment and supplies;
- 151 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals
152 used for cleaning) and product-specific instructions for use of cleaning agents (e.g.,
153 dilution, contact time, management of accidental exposures);
- 154 4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies,
155 and equipment;
- 156 5. Procedures for handling/temporary storage/transport of soiled linens;
- 157 6. Procedures for handling, storing, processing, and transporting regulated medical
158 waste in accordance with applicable regulations;
- 159 7. Procedures for the processing of each type of reusable medical equipment between
160 uses on different patients. The procedure shall address: (i) the level of
161 cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process
162 (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying
163 that the recommended level of disinfection/sterilization has been achieved. The
164 procedure shall reference the manufacturer's recommendations and any applicable state
165 or national infection control guidelines;
- 166 8. Procedures for appropriate disposal of nonreusable equipment;
- 167 9. Policies and procedures for maintenance/repair of equipment in accordance with
168 manufacturer recommendations;
- 169 10. Procedures for cleaning of environmental surfaces with appropriate cleaning
170 products;
- 171 11. An effective pest control program, managed in accordance with local health and
172 environmental regulations; and

173 12. Other infection prevention procedures necessary to prevent/control transmission of
174 an infectious agent in the abortion facility as recommended or required by the
175 department.

176 D. The abortion facility shall have an employee health program that includes:

177 1. Access to recommended vaccines;

178 2. Procedures for assuring that employees with communicable diseases are identified
179 and prevented from work activities that could result in transmission to other personnel or
180 patients;

181 3. An exposure control plan for bloodborne pathogens;

182 4. Documentation of screening and immunizations offered/received by employees in
183 accordance with statute, regulation, or recommendations of public health authorities,
184 including documentation of screening for tuberculosis and access to hepatitis B vaccine;
185 and

186 5. Compliance with requirements of the U.S. Occupational Safety and Health
187 Administration for reporting of workplace-associated injuries or exposure to infection.

188 E. The abortion facility shall develop, implement, and maintain policies and procedures for
189 the following patient education, follow up, and reporting activities:

190 1. A procedure for surveillance, documentation, and tracking of reported infections; and

191 2. Policies and procedures for reporting conditions to the local health department in
192 accordance with the Regulations for Disease Reporting and Control (12VAC5-90),
193 including outbreaks of disease.

194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217

Part IV

Patient Care Management

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 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, which shall be notarized as required by § 16.1-241 of the Code of Virginia. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

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

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

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

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

218 **12VAC5-412-240. Medical testing and laboratory services.**

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

223 1. Medical testing shall include a recognized method to confirm pregnancy and
224 determination or documentation of Rh factor. ~~Use of any additional medical testing shall~~
225 ~~be based on an assessment of patient risk. The clinical criteria for such additional testing~~
226 ~~and the actions to be taken if abnormal results are found shall be documented.~~

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

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

234 4. 3. A written report of each laboratory test and examination shall be a part of the
235 patient's record.

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

239 1. Facilities for collecting specimens shall be available on site.

240 2. If laboratory services are provided on site they shall be directed by a person who
241 qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88
242 standards.

243 3. All laboratory supplies shall be monitored for expiration dates, if applicable, and
244 disposed of properly.

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

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

256 **12VAC5-412-250. Anesthesia service.**

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

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

262 C. When moderate sedation or conscious sedation is administered, the licensed health care
263 practitioner who administers the anesthesia shall routinely monitor the patient according to
264 procedures consistent with such administration and shall be documented in the patient's
265 medical record.

266 D. An abortion facility administering moderate sedation/conscious sedation shall maintain
267 the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-
268 360 B:

- 269 1. Appropriate equipment to manage airways;
- 270 2. Drugs and equipment to treat shock and anaphylactic reactions;
- 271 3. Precordial stethoscope;
- 272 4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen
- 273 saturation;
- 274 5. Continuous electrocardiograph;
- 275 6. Devices for measuring blood pressure, heart rate, and respiratory rate;
- 276 7. Defibrillator; and
- 277 8. Accepted method of identifying and preventing the interchangeability of gases.
- 278 E. Elective general anesthesia shall not be used.
- 279 F. If deep sedation or a major conductive block is administered or if general anesthesia is
- 280 administered in an emergent situation, the licensed health care practitioner who administers the
- 281 anesthesia service shall remain present and available in the facility to monitor the patient until
- 282 the patient meets the discharge criteria.
- 283 G. In addition to the requirements of subsection D of this section, an abortion facility
- 284 administering deep sedation or a major conductive block, or administering general anesthesia in
- 285 an emergent situation, shall maintain the following equipment, supplies, and pharmacological
- 286 agents as required by 18VAC85-20-360 C:
- 287 1. Drugs to treat malignant hyperthermia, when triggering agents are used;
- 288 2. Peripheral nerve stimulator, if a muscle relaxant is used; and
- 289 3. If using an anesthesia machine, the following shall be included:
- 290 a. End-tidal carbon dioxide monitor (capnograph);
- 291 b. In-circuit oxygen analyzer designed to monitor oxygen concentration within
- 292 breathing circuit by displaying oxygen percent of the total respiratory mixture;

- 293 c. Oxygen failure-protection devices (fail-safe system) that have the capacity to
294 announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to
295 discontinue other gases when the pressure of the supply of oxygen is reduced;
- 296 d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and
297 therefore only a single anesthetic agent can be actualized on any anesthesia
298 machine at one time;
- 299 e. Pressure-compensated anesthesia vaporizers, designed to administer a constant
300 nonpulsatile output, which shall not be placed in the circuit downstream of the
301 oxygen flush valve;
- 302 f. Flow meters and controllers, which can accurately gauge concentration of oxygen
303 relative to the anesthetic agent being administered and prevent oxygen mixtures of
304 less than 21% from being administered;
- 305 g. Alarm systems for high (disconnect), low (subatmospheric), and minimum
306 ventilatory pressures in the breathing circuit for each patient under general
307 anesthesia; and
- 308 h. A gas evacuation system.

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

315 **12VAC5-412-290. Emergency services.**

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

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

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

335 Part VI. Functional Safety and Maintenance

336 **12VAC5-412-350. Maintenance.**

337 A. ~~[The abortion facility's structure, its component parts, and all equipment such as elevators,~~
338 ~~heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating~~
339 ~~condition. Areas used by patients shall be maintained in good repair and kept free of hazards.~~
340 ~~All wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that~~
341 ~~will allow sanitization.~~

342 ~~B.]~~When patient monitoring equipment is utilized, a written preventive maintenance program
343 shall be developed and implemented. This equipment shall be checked and/or tested in
344 accordance with manufacturer's specifications at periodic intervals, not less than annually, to

345 ensure proper operation and a state of good repair. After repairs and/or alterations are made to
346 any equipment, the equipment shall be thoroughly tested for proper operation before it is
347 returned to service. Records shall be maintained on each piece of equipment to indicate its
348 history of testing and maintenance.

349 **12VAC5-412-360. Firefighting Equipment and Systems. [(Repealed)]**

350 ~~A. Each abortion facility shall establish a monitoring program for the internal enforcement of~~
351 ~~all applicable fire and safety laws and regulations and shall designate a responsible employee~~
352 ~~for the monitoring program.~~

353 ~~B. All fire protection and alarm systems and other firefighting equipment shall be inspected~~
354 ~~and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code~~
355 ~~(§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.~~

356 ~~C. All corridors and other means of egress or exit from the building shall be maintained clear~~
357 ~~and free of obstructions in accordance with the current edition of the Virginia Statewide Fire~~
358 ~~Prevention Code (§ 27-94 et seq. of the Code of Virginia).]~~

359 Part VII

360 Design and Construction

361 **12VAC5-412-370. Local and state codes and standards.**

362 [A. All construction of new buildings and additions, or major renovations to existing buildings
363 for occupancy as an abortion facility. Abortion facilities shall comply ~~conform~~ with all
364 applicable ~~to with~~ state and local codes, and zoning, and building ordinances, and the Virginia
365 Uniform Statewide Building Code (13VAC5-63) ~~All construction of new buildings and additions,~~
366 ~~or major renovations to existing buildings for occupancy as an abortion facility. In addition,~~
367 ~~abortion facilities that perform only surgical abortions or a combination of surgical and~~
368 ~~medication induced abortions shall comply ~~be designed and constructed consistent with~~ Part 1~~
369 ~~and sections ~~3.8~~ 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the ~~2014~~ 2010 Guidelines for~~
370 ~~Design and Construction of ~~Hospitals and Outpatient~~ Health Care Facilities of the Facilities~~

371 ~~Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building~~
372 ~~Code pursuant to § 32.1-127.001 of the Code of Virginia. Abortion facilities that perform only~~
373 ~~medication induced abortions shall be designed and constructed consistent with Part 1 Section~~
374 ~~1.1, 1.3 and 1.4 of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient~~
375 ~~Facilities of the Facilities Guidelines Institute.]~~

376 ~~[Abortion procedures may take place in a procedure room, as detailed in Section 3.8-3.1,~~
377 ~~except that minimum square footage requirements for procedure rooms used for the provision of~~
378 ~~surgical abortion do not need to be greater than 120 square feet, with a minimum room~~
379 ~~dimension of 10 feet and a minimum clear dimension of 3 feet at each side and at the foot of the~~
380 ~~bed. Rooms designed in accordance with Section 3.8-3.2 are not required for abortion facilities.~~
381 ~~Section 3.7-3.6.13.1(2) shall not apply to facilities that do not have a room designed in~~
382 ~~accordance with Section 3.8-3.2.]~~

383 ~~[Architectural drawings and specifications for all new construction or for additions,~~
384 ~~alterations, or renovations to any existing building shall be dated, stamped with professional~~
385 ~~seal, and signed by the architect. The architect shall certify that the drawings and specifications~~
386 ~~were prepared to conform to the Virginia Uniform Statewide Building Code and be consistent~~
387 ~~with the applicable sections of the 2014 Guidelines for Design and Construction of Hospitals~~
388 ~~and Outpatient Facilities of the Facilities Guidelines Institute. The certification shall be forwarded~~
389 ~~to the OLC.]~~

390 ~~[Entities operating as of the effective date of this chapter as identified by the department~~
391 ~~through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-~~
392 ~~120 or other means and that are now subject to licensure may be licensed in their current~~
393 ~~buildings if such entities submit a plan with the application for licensure that will bring them into~~
394 ~~full compliance with this provision within two years from the date of licensure.]~~

395 ~~[B. In order to determine whether the abortion facility's design and construction~~
396 ~~is consistent in compliance with the applicable sections of the 2014 Guidelines for Design and~~

397 ~~Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute~~
398 ~~provision, the commissioner may obtain additional information from the facility or its architect~~
399 ~~concerning the design and construction of the facility.]~~

400

401 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-412)

402 ~~Guidelines for Design and Construction of Health Care Facilities, 2010 Edition, Part 1 and~~
403 ~~Sections 3.1-1 through 3.1-8 and 3.7 of Part 3~~~~[2014 Guidelines for Design and Construction of~~
404 ~~Hospitals and Outpatient Facilities, Facilities Guidelines Institute (formerly of the American~~
405 ~~Institute of Architects), Washington, D.C.]~~

406 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.
407 Circulation. November 2, 2010, Volume 122, Issue 18 Suppl 3, American Heart Association,
408 7272 Greenville Avenue, Dallas, TX 75231-4596
409 (http://circ.ahajournals.org/content/vol122/18_suppl_3/).

410 Sexually Transmitted Diseases Treatment Guidelines, ~~2010~~2015, Centers for Disease
411 Control and Prevention, U.S. Department of Health and Human Services.
412 (<http://www.cdc.gov/std/tg2015/default.htm>)

413 [~~Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care,~~
414 ~~Centers for Disease Control and Prevention, U.S. Department of Health and Human~~
415 ~~Services (http://www.cdc.gov/HAI/prevent/prevent_pubs.html) (<http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf>).~~]

417 [~~2015 Standards for Ambulatory Care~~Standards for Ambulatory Care, Rights and
418 Responsibilities of the Individual, 2011, [The Joint Commission, 1515 W. 22nd Street, Suite
419 1300W, Oak Brook, IL 60523, telephone 1-770-238-0454 1-877-223-2866, email
420 jrcustomerservice@pbd.com.]

421 Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and
422 Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: September 15, 2016

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health Services

SUBJECT: Fast-track amendments; performance requirements for direct dispersal for repair and voluntary upgrade applications.

The Regulations for Alternative Onsite Sewage Systems (12VAC5-613, AOSS Regulations) provide performance and operation and maintenance requirements for alternative onsite sewage systems. The Board is seeking to amend the definition of “direct dispersal of effluent to groundwater,” also known as “direct dispersal,” (12VAC5-613-10) and to add a new section (12VAC5-613-90.E) permitting less stringent performance and monitoring requirements for repairs and voluntary upgrades of installed onsite sewage systems. The requirements for direct dispersal contained in the AOSS Regulations have proved to be an economic stumbling block for owners who want to repair failing sewage systems or upgrade older septic systems with newer technology. The proposed less restrictive requirements would only be available to owners of onsite sewage systems already directly dispersing effluent to groundwater with a capacity of 10,000 gallons/day or less.

Since the AOSS Regulations became effective, the Commissioner has granted more than 20 variances to property owners who could not afford to comply with direct dispersal requirements for repairs and voluntary upgrades of older septic systems. The older septic systems discharge partially treated effluent to the groundwater. The current AOSS Regulations inadvertently discourage more complete upgrades and repairs as the requirements for direct dispersal are too stringent when applied to previously developed properties. The Board seeks to improve the regulation by providing a clearer definition of direct dispersal, identifying exclusions, and by specifying more reasonable treatment and performance requirements for direct dispersal when an owner needs to repair or upgrade an installed sewage system. The changes will still be protective of public health.

Staff does not believe the fast-track amendments will be viewed as controversial. VDH estimates that compliance with direct dispersal requirements can cost over \$30,000 for many owners with previously developed properties. With the changes, costs will be significantly reduced, perhaps by 50% or more. The new amendments will provide a more financially attainable level of treatment for developed properties, while still providing a high level of public health protection. The amendments will also eliminate the need for an individualized variance for most situations.

Upon approval by the Board of Health, the fast track amendments will undergo executive branch review and approval. Following publication of the fast track amendments after executive branch approval, the amendments will take effect 15 days after the close of a 30-day comment period unless 10 or more persons object or any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules objects. In the event of a qualified objection, the fast track amendments would revert to the normal and routine regulatory adoption process.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-613
Regulation title(s)	Regulations for Alternative Onsite Sewage Systems
Action title	Amend performance requirements for direct dispersal for repair and voluntary upgrade applications
Date this document prepared	June 10, 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 (preferably no more than 2 or 3 paragraphs) 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.

The Regulations for Alternative Onsite Sewage Systems (12VAC5-613, AOSS Regulations) provide performance and operation and maintenance requirements for alternative onsite sewage systems. The Board is seeking to amend the definition of “direct dispersal of effluent to

groundwater,” also known as “direct dispersal,” (12VAC5-613-10) and to add a new section (12VAC5-613-90.E) permitting less stringent performance and monitoring requirements for repairs and upgrades of installed onsite sewage systems. The requirements for direct dispersal contained in the AOSS Regulations have proved to be an economic stumbling block for owners who want to repair failing sewage systems or upgrade older septic systems with newer technology. The proposed less restrictive requirements would only be available to owners of onsite sewage systems already directly dispersing effluent to groundwater with a capacity of 10,000 gallons/day or less.

Since the AOSS Regulations became effective, the Commissioner has granted more than 20 variances to property owners who could not afford to comply with direct dispersal requirements for repairs and voluntary upgrades of older septic systems. The older septic systems discharge partially treated effluent to the groundwater. The current AOSS Regulations inadvertently discourage more complete upgrades and repairs as the requirements for direct dispersal are too stringent when applied to previously developed properties. The Board seeks to improve the regulation by providing a clearer definition of direct dispersal, identifying exclusions, and by specifying more reasonable treatment and performance requirements for direct dispersal when an owner needs to repair or upgrade an installed sewage system. The changes will still be protective of public health.

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.

“AOSS” means Alternative Onsite Sewage System

“BMP” means Best Management Practice

“Board” means Board of Health

“BOD₅” Biochemical Oxygen Demand 5-day

“GPD” means gallons per day

“TN” means Total Nitrogen

“TP” means Total Phosphorous

“TMDL” means Total Maximum Daily Load

“TSS” Total Suspended Solids

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.

1. September 15, 2016
2. Virginia Department of Health
3. The Regulations for Alternative Onsite Sewage Systems

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.

Va. Code § 32.1-12 authorizes the Board to make, adopt, promulgate, and enforce regulations that protect, improve, and preserve public health and the environment for the general welfare of the citizens of the Commonwealth. Va. Code §§ 32.1-164 A. and B. authorize the Board to adopt regulations governing the collection, conveyance, transportation, treatment, and disposal of sewage, including sewerage systems and treatment works as they affect public health and welfare. Va. Code § 32.1-20 vests the Commissioner with all of the authority of the Board when not in session, and Va. Code § 32.1-16 provides that the Virginia Department of Health shall be under the supervision and management of the Commissioner of Health.

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.

The AOSS Regulations took effect on December 7, 2011, and defined “direct dispersal,” set performance requirements for direct dispersal, and established a program for operation and maintenance of AOSS that directly disperse effluent to groundwater. In regulating direct dispersal of treated effluent to groundwater, 12VAC5-613-90.D.4 established a discharge limit of 3 mg/l TN and 0.3 mg/l TP in the Chesapeake Bay Watershed, which is the limit of technology. However, the limit of technology is economically infeasible for many owners with developed property who need or want to repair or upgrade an older sewage system that already disperses septic tank effluent directly into groundwater. VDH estimates that compliance with direct dispersal requirements can cost over \$30,000 for many owners with previously developed properties.

Section 12VAC5-613-90.C sets stringent performance and operational requirements for all sewage systems that result in direct dispersal. These stringent requirements include: 1) quarterly sampling and remote monitoring; 2) BOD₅ and TSS equal to or less than 5 mg/l; 3) fecal coliform concentration less than or equal to 2.2 col/100 ml with no sample exceeding 14 col/100 ml; 4) Total Nitrogen less than 5 mg/l; high level disinfection; average turbidity of less than or equal to 2 Nephelometric turbidity units prior to disinfection; 5) a renewable operating permit; and 6) a hydrogeologic analysis of the receiving groundwater. These stringent requirements, while appropriate for new construction, present a significant financial barrier to repairing or voluntarily upgrading existing sewage systems that directly disperse effluent to ground water.

Since promulgation of the AOSS Regulations on December 7, 2011, the Commissioner of Health has granted more than 20 variances to owners claiming financial hardship for repairs and voluntary upgrades. The amendments will provide a more financially attainable level of treatment for developed properties, while still providing a high level of public health protection. The amendments will eliminate the need for an individualized variance for most situations.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The amendments will allow more owners to affordably repair failing sewage systems or upgrade old sewage systems already dispersing effluent to ground water. The action will not be controversial as it reduces a financial burden to homeowners and small business owners while still protecting public health and the environment.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of changes” section below.

The amendment to the definition of direct dispersal of effluent to ground water at 12VAC5-613-10 will clarify that excavation excludes any pre-existing soil disturbance not designed to create a direct conduit or preferential path to groundwater. The amendment to 12VAC5-613-90 will add subsection (E) to allow for a repaired or voluntarily upgraded direct dispersal system to provide a 50% reduction of TN as compared to a conventional gravity drainfield system, and provide TL-3 treatment and standard disinfection in accordance with 12VAC5-613-80 (13), Table 2, for systems with less than 12 inches separation to groundwater.

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 advantage to the public is a reduced financial burden to repair or upgrade sewage systems when requirements for direct dispersal apply. The public will also receive faster permitting because a variance to the regulation would no longer be necessary in most cases. The advantage to the agency is it will reduce staff time spent granting individual variances to the regulations and, in most cases, the regulatory amendments will lead to more clearly defined expectations for repairing and upgrading sewage systems. Currently, the Commissioner has granted over 20 variances to allow for the repair or voluntary upgrade of existing direct dispersal systems. The variances, while having less stringent requirements for treatment and monitoring, are still protective of public health in context of the cost, exceed the level of treatment provided by the existing sewage system, are within the requirements of the EPA’s model program for the TMDL, and ease the financial burden on the homeowner or small business owner while streamlining the agency’s processing of applications.

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.

The proposed amendments to the regulations are not more restrictive than any federal requirement. There is no federal requirement with respect to onsite sewage systems.

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 localities within the Chesapeake Bay Watershed and coastal plain physiographic province of the Commonwealth are most affected by these substantive changes. Localities within the coastal plain physiographic province are more likely to have shallow groundwater and sewage systems dispersing effluent close to, or into, the shallow groundwater.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The amendments would (1) establish less stringent compliance and reporting requirements; (2) establish a less stringent sampling frequency (yearly instead of quarterly); (3) have no effect on compliance and reporting requirements; (4) establish less stringent performance standards for treatment (e.g., 10 mg/l or less BOD₅, standard disinfection, 50% TN reduction instead of 5 mg/l or less BOD₅ with high level disinfection, 3 mg/l or less TN, and 0.3 mg/l or less P); and (5) have no negative impact on small businesses.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>The amendments will not add cost to the state, but will decrease the cost as staff will not have to individually process variance requests.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>The amendments will add no additional cost to localities.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new</p>	<p>Owners of AOSS systems, especially in the Chesapeake Bay Watershed will be able to</p>

<p>regulations or changes to existing regulations.</p>	<p>more affordably repair and voluntarily upgrade their AOSS systems.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Each year, the Department receives about 2,500 to 3,500 applications for repairs and voluntary upgrades. Of these requests, approximately 1,000 could be associated with direct dispersal. Of these, the Department estimates 1 to 25 could be associated with a small business.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>There is no additional reporting requirement or cost for real estate development.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The amendments will reduce the financial burden on homeowners and small business to repair or voluntarily upgrade an existing onsite sewage system.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The agency could choose not to amend the regulations; in which case, homeowners or small business owners would need to fully comply with the more stringent regulations for repairs and voluntary upgrades, or request a variance. This is the current reality and many owners seek a variance from the regulatory requirements for direct dispersal. Without a regulation change, property owners would continue to apply for and receive variances for a repair or voluntary upgrade when direct dispersal requirements apply.

The number of variance requests granted to owners for voluntary upgrades and repairs demonstrates that many owners cannot financially comply with the regulations for direct dispersal. The limit of currently available technology is not always feasible for repairs and voluntary upgrades. The best alternative is to amend the regulation and make the need for a variance and case-by-case evaluation no longer necessary.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

-
- (1) This fast-track is not the specific result of a periodic review or small business impact review. This regulatory initiative specifically results from an internal assessment that took place before the periodic review. However, a periodic review of the regulation concluded on February 25, 2016, and the Board received 34 comments asking for various changes to the regulations. The Board plans a separate action to address all of the comments received during the periodic review. The Board recognizes that two commenters asked for a change to the requirements for direct dispersal (see comments from Ms. Janet Swords, dated February 9, 2016, and Mr. Joel Pinnix, dated February 24, 2016). The Board considered these two comments when finalizing this proposal.

Other comments received addressed field testing (12VAC5-613-70), requirements for soil evaluation (12VAC5-613-40.G), general approval and other definitions (12VAC5-613-10), adding additional standards of practice and ethical requirements, and updating or changing performance requirements (12VAC5-613-80).

- (2) The AOSS Regulations are necessary to protect public health, safety, and welfare. Additional changes to the regulations is expected to improve clarity and understanding of the performance requirements (12VAC5-613-80), field testing (12VAC5-613-70), site characterization (12VAC5-613-40.G), and definitions (12VAC5-613-10).

Discussion of the agency’s consideration:

- (1) The Board believes the regulations are necessary to ensure that AOSS do not adversely impact surface water, groundwater, and public health. The regulations remain necessary to implement Va. Code §§32.1-163.5 and 163.6.
- (2) The concerns raised from the public generally address performance requirements and evaluation for TL-3 general approval.
- (3) The regulation is necessary to implement performance requirements for AOSS. The agency believes the regulation is not too complex, but additional edits can improve clarity and understanding.
- (4) Because there are no other federal or state requirements for AOSS, and because the AOSS Regulations supersede the Sewage Handling and Disposal Regulations (12VAC5-610) if any conflict existed, the agency finds the AOSS Regulations do not conflict with other federal or state regulations.
- (5) The AOSS Regulations were promulgated on December 7, 2011, and VDH has gained considerable experience working with the relatively new regulation. Technology continues to improve, including nascent ideas for treating and dispersing treated effluent.

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 substantive regulatory changes will allow more families to affordably repair their failing onsite sewage systems. The less stringent requirements will have no impact on the authority or

rights of parents to educate, nurture or supervise their children. The amendments will reduce the cost to repair or voluntarily upgrade a sewage system that is subject to direct dispersal requirements, which could encourage self-sufficiency. The amendments will likely have no impact on marital commitment, but could have a positive impact on disposable family income since repairs and voluntary upgrades for direct dispersal will be less expensive with the amendments.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-613-10		Direct dispersal of effluent to ground water means less than six inches of vertical separation between the point of effluent application or the bottom of a trench or other excavation and ground water.	Direct dispersal of effluent to ground water means less than six inches of vertical separation between groundwater and the point of effluent application or the bottom of an effluent-dispersal trench or other excavation. Other excavation excludes minor tillage of the soil surface without soil removal; replacement of fill material; house foundations; tank excavations; force main and header line excavations; and pre-existing soil disturbances, including, but not limited to, percolation trenches, utility line excavations, or other excavations not designed for surface or groundwater drainage.

			<p>The proposed change clarifies what direct dispersal means and explains what is specifically excluded from the definition. A repair or voluntary upgrade located over an older sewage system’s footprint would no longer be considered direct dispersal. Currently, such designs are considered direct dispersal even though the design improves the existing situation and reduces threats to public health. The broad language of the current regulatory definition could encompass such activities as augering a soil boring, or excavation for a tank, which has never been considered a site feature that requires adherence to direct dispersal requirements.</p> <p>The updated definition will provide specific exclusions from the definition and make clear what site features and conditions initiate direct dispersal requirements.</p>
N/A	12VAC5-613-90.E		<p><u>When an application is filed to repair or voluntarily upgrade an existing sewage system with capacity of 10,000 gallons per day or less, and the existing sewage system already disperses effluent to groundwater as defined in 12VAC5-613-10, then the repair or upgrade shall provide a minimum 50% reduction of TN as compared to a conventional gravity drainfield system and shall provide TL-3 effluent and standard disinfection in accordance with 12VAC5-613-80 (13), Table 2, for systems with less than 12 inches separation to groundwater. For systems greater than 1,000 gallons per day and up to, and including, 10,000 gallons per day, the sewage system shall also adhere to 12VAC5-613-90.B; and the following requirements</u></p>

			<p><u>are not applicable to repair or voluntary upgrade applications that result in direct dispersal: 12VAC5-613-90.C(1) through C(7) and 12VAC5-613-100. G. The repair or voluntary upgrade shall be monitored pursuant to 12VAC5-613-100.D, 12VAC5-613.100.E, or 12VAC5-613.100.F, as appropriate.</u></p> <p>For repairs and voluntary upgrades that directly disperse effluent to groundwater, the new regulation would eliminate or reduce the performance and operation and maintenance requirements of 12VAC5-613-90.C. The intent is to reduce the financial burden to owners seeking to repair or voluntarily upgrade their older sewage systems, which already disperse septic tank effluent into the watertable.</p>
--	--	--	---

DEPARTMENT OF HEALTH

Amend Alternative Onsite Regulations

Part I

General

1 **12VAC5-613-10. Definitions.**

2 The following words and terms used in this chapter shall have the following meanings.
3 Terms not defined in this chapter shall have the meanings prescribed in Chapter 6 (§ 32.1-163
4 et seq.) of Title 32.1 of the Code of Virginia or in 12VAC5-610 unless the plain reading of the
5 language requires a different meaning.

6 "Alternative onsite sewage system," "AOSS," or "alternative onsite system" means a
7 treatment works that is not a conventional onsite sewage system and does not result in a point
8 source discharge.

9 "Best management practice" means a conservation or pollution control practice approved by
10 the division, such as wastewater treatment units, shallow effluent dispersal fields, saturated or
11 unsaturated soil zones, or vegetated buffers, that manages nutrient losses or other potential
12 pollutant sources to minimize pollution of water resources.

13 "Biochemical oxygen demand, five-day" or "BOD₅" means the quantitative measure of the
14 amount of oxygen consumed by bacteria while stabilizing, digesting, or treating biodegradable
15 organic matter under aerobic conditions over a five-day incubation period; BOD₅ is expressed in
16 milligrams per liter (mg/l).

17 "Board" means the State Board of Health.

18 "Chesapeake Bay Watershed" means the following Virginia river basins: Potomac River
19 Basin (see 9VAC25-260-390 and 9VAC25-260-400), James River Basin (see 9VAC25-260-410,
20 9VAC25-260-415, 9VAC25-260-420, and 9VAC25-260-430), Rappahannock River Basin (see
21 9VAC25-260-440), Chesapeake Bay and small coastal basins (see 9VAC25-260-520, Section 2
22 through Section 3g), and the York River Basin (see 9VAC25-260-530).

23 "Conventional onsite sewage system" means a treatment works consisting of one or more
24 septic tanks with gravity, pumped, or siphoned conveyance to a gravity distributed subsurface
25 drainfield.

26 "Department" means the Virginia Department of Health.

27 "Direct dispersal of effluent to ground water" means less than six inches of vertical
28 separation between ground water and the point of effluent application or the bottom of a an
29 effluent-dispersal trench or other excavation ~~and ground water~~. Other excavation excludes the
30 following: minor tillage of the soil surface without soil removal; replacement of fill material with
31 better quality fill material as determined by the Department to improve the ability of the site to
32 treat wastewater; house foundations; tank excavations; force main and header line excavations;
33 and soil disturbances, including pre-existing drainfields installed prior to _____ (effective date of
34 regulatory change), that are not designed for surface or ground water drainage, and do not
35 create a direct conduit to ground water.

36 "Disinfection" means a process used to destroy or inactivate pathogenic microorganisms in
37 wastewater to render them non-infectious.

38 "Dissolved oxygen" or "DO" means the concentration of oxygen dissolved in effluent,
39 expressed in mg/l or as percent saturation, where saturation is the maximum amount of oxygen
40 that can theoretically be dissolved in water at a given altitude and temperature.

41 "Division" means the Division of Onsite Sewage and Water Services, Environmental
42 Engineering, and Marina Programs within the department .

43 "Effluent" means sewage that has undergone treatment.

44 "General approval" means that a treatment unit has been evaluated in accordance with the
45 requirements of this chapter and 12VAC5-610 and approved for TL-2 or TL-3 in accordance
46 with this chapter.

47 "GPD/sf" means gallons per day per square foot.

48 "Ground water" means any water, except capillary moisture, beneath the land surface in the
49 zone of saturation or beneath the bed of any stream, lake, reservoir, or other body of surface
50 water wholly or partially within the boundaries of this Commonwealth, whatever the subsurface
51 geologic structure in which such water stands, flows, percolates, or otherwise occurs. Ground
52 water includes a seasonal or perched water table.

53 "High-level disinfection" means a disinfection method that results in a fecal coliform
54 concentration less than or equal to 2.2 colonies/100 ml. Chlorine disinfection requires a
55 minimum total residual chlorine (TRC) concentration at the end of a 30 minute contact time of
56 1.5 mg/l. Ultraviolet disinfection requires a minimum dose of 50,000 $\mu\text{W}\cdot\text{sec}/\text{cm}^2$. Influent
57 turbidity to the disinfection unit shall be less than or equal to 2 Nephelometric turbidity units
58 (NTU) on average.

59 "Ksat" means saturated hydraulic conductivity.

60 "Large AOSS" means an AOSS that serves more than three attached or detached single-
61 family residences with a combined average daily sewage flow greater than 1,000 GPD or a
62 structure with an average daily sewage flow in excess of 1,000 GPD.

63 "Limiting feature" means a feature of the soil that limits or intercepts the vertical movement
64 of water, including seasonal, perched or permanent water table, pans, soil restrictions, and
65 pervious or impervious bedrock.

66 "Local health department" means the local health department having jurisdiction over the
67 AOSS.

68 "Maintenance" means performing adjustments to equipment and controls and in-kind
69 replacement of normal wear and tear parts such as light bulbs, fuses, filters, pumps, motors, or
70 other like components. Maintenance includes pumping the tanks or cleaning the building sewer
71 on a periodic basis. Maintenance shall not include replacement of tanks, drainfield piping, and
72 distribution boxes or work requiring a construction permit and an installer.

73 "MGD" means million gallons per day.

74 "MPI" means minutes per inch.

75 "Operate" means the act of making a decision on one's own volition to (i) place into or take
76 out of service a unit process or unit processes or (ii) make or cause adjustments in the
77 operation of a unit process at a treatment works.

78 "Operation" means the biological, chemical, and mechanical processes of transforming
79 sewage or wastewater to compounds or elements and water that no longer possess an adverse
80 environmental or health impact.

81 "Operator" means any individual employed or contracted by any owner who is licensed or
82 certified under Chapter 23 (§ 54.1-2300 et seq.) of Title 54.1 of the Code of Virginia as being
83 qualified to operate, monitor and maintain an alternative onsite sewage system.

84 "Organic loading rate" means the biodegradable fraction of chemical oxygen demand (BOD,
85 biodegradable fats, oils, and grease and volatile solids) delivered to a treatment component in a

86 specified time interval expressed as mass per time or area; examples include pounds per day,
87 pounds per cubic foot per day (pretreatment), or pounds per square foot per day (infiltrative
88 surface or pretreatment). For a typical residential system, these regulations assume that
89 biochemical loading (BOD₅) equals organic loading.

90 "Owner" means the Commonwealth or any of its political subdivisions, including sanitary
91 districts, sanitation district commissions and authorities, or any individual, any group of
92 individuals acting individually or as a group, or any public or private institution, corporation,
93 company, partnership, firm, or association that owns or proposes to own a sewerage system or
94 treatment works.

95 "pH" means the measure of the acid or base quality of water that is the negative log of the
96 hydrogen ion concentration.

97 "Pollution" means such alteration of the physical, chemical, or biological properties of any
98 state waters as will or is likely to create a nuisance or render such waters (i) harmful or
99 detrimental or injurious to the public health, safety, or welfare or to the health of animals, fish, or
100 aquatic life; (ii) unsuitable with reasonable treatment for use as present or possible future
101 sources of public water supply; or (iii) unsuitable for recreational, commercial, industrial,
102 agricultural, or other reasonable uses. Pollution shall include any discharge of untreated sewage
103 into state waters.

104 "Point source discharge" means any discernible, confined, and discrete conveyance
105 including, but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure,
106 container, rolling stock, concentrated animal feeding operation, landfill leachate collection
107 system, vessel, or other floating craft from which pollutants are or may be discharged. This term
108 does not include return flows from irrigated agriculture or agricultural storm water run-off.

109 "Project area" means one or more recorded lots or a portion of a recorded lot owned by the
110 owner of an AOSS or controlled by easement upon which an AOSS is located or that is
111 contiguous to a soil treatment area and that is designated as such for purposes of compliance
112 with the performance requirements of this chapter. In the case of an AOSS serving multiple
113 dwellings, the project area may include multiple recorded lots as in a subdivision.

114 "Project area boundary" or "project boundary" means the physical limits of the three-
115 dimensional length, width, and depth of the project area, whereby each dimension is identified
116 as follows: (i) the horizontal component is the length and width of the project area; (ii) the upper
117 vertical limit is the ground surface in and around the AOSS; and (iii) the lower vertical limit is the
118 limiting feature.

119 "Renewable operating permit" means an operation permit that expires and must be
120 revalidated at a predetermined frequency or schedule in accordance with this chapter.

121 "Reportable incident" means one or more of the following: an alarm event lasting more than
122 24 hours; an alarm event that reoccurs; any failure to achieve one or more performance
123 requirements; removal of solids; replacement of media; or replacement of any major component
124 of the system including electric and electronic components, pumps, blowers, and valves. The
125 routine cleaning of effluent filters is not a reportable incident.

126 "Saturated hydraulic conductivity" means a quantitative measure of a saturated soil's
127 capacity to transmit water when subjected to a hydraulic gradient.

128 "Settleable solids" means a measure of the volume of suspended solids that will settle out of
129 suspension within a specified time, expressed in milliliters per liter (ml/l).

130 "Sewage Handling and Disposal Regulations" means 12VAC5-610 or its successor.

131 "Small AOSS" means an AOSS that serves no more than three attached or detached single-
132 family residences with a combined average flow of less than or equal to 1,000 GPD, or a
133 structure with an average daily sewage flow of less than or equal to 1,000 GPD.

134 "Soil treatment area" means the physical location in the naturally occurring soil medium
135 where final treatment and dispersal of effluent occurs.

136 "Standard disinfection" means a disinfection process that results in a fecal coliform
137 concentration of less than or equal to 200 colonies/100 ml. Chlorine disinfection requires a
138 minimum TRC concentration at the end of a 30 minute contact time of 1.0 mg/l. Influent TSS to
139 the disinfection unit shall average 30 mg/l or less.

140 "Standard engineering practice" means the care, diligence, competence, and judgment that
141 a reasonably prudent and experienced professional engineer licensed in the Commonwealth of
142 Virginia would exercise given the circumstances, including site and soil conditions, of a
143 particular AOSS design.

144 "State waters" means all water, on the surface and under the ground, wholly or partially
145 within or bordering the Commonwealth or within its jurisdiction, including wetlands.

146 "Subsurface drainfield" means a system installed within the soil and designed to
147 accommodate treated sewage from a treatment works.

148 "Surface waters" means: (i) all waters that are currently used, were used in the past, or may
149 be susceptible to use in interstate or foreign commerce, including all waters that are subject to
150 the ebb and flow of the tide; (ii) all interstate waters, including interstate wetlands; (iii) all other
151 waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats,
152 sandflats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds and
153 the use, degradation, or destruction of which would affect or could affect interstate or foreign
154 commerce including any such waters: (a) that are or could be used by interstate or foreign

155 travelers for recreational or other purposes; (b) from which fish or shellfish are or could be taken
156 and sold in interstate or foreign commerce; or (c) that are used or could be used for industrial
157 purposes by industries in interstate commerce; (iv) all impoundments of waters otherwise
158 defined as surface waters under this definition; (v) tributaries of waters identified in clauses (i)
159 through (iv) of this definition; (vi) the territorial sea; and (vii) wetlands adjacent to waters (other
160 than water that are themselves wetlands) identified in clauses (i) through (vi) of this definition.

161 "Total nitrogen" or "TN" means the measure of the complete nitrogen content of wastewater
162 including all organic, inorganic, and oxidized forms expressed in mg/l as nitrogen.

163 "Total residual chlorine" or "TRC" means a measurement of the combined available chlorine
164 and the free available chlorine available in a sample after a specified contact time.

165 "Total suspended solids" or "TSS" means a measure of the mass of all suspended solids in
166 a sample typically measured in milligrams per liter (mg/l).

167 "Treatment level 2 effluent" or "TL-2 effluent" means secondary effluent as defined in
168 12VAC5-610-120 that has been treated to produce BOD₅ and TSS concentrations equal to or
169 less than 30 mg/l each.

170 "Treatment level 3 effluent" or "TL-3 effluent" means effluent that has been treated to
171 produce BOD₅ and TSS concentrations equal to or less than 10 mg/l each.

172 "Treatment unit" or "treatment system" means a method, technique, equipment, or process
173 other than a septic tank or septic tanks used to treat sewage to produce effluent of a specified
174 quality before the effluent is dispersed to a soil treatment area.

175 "Turbidity" means a measurement of the relative clarity of effluent as a result of the
176 presence of varying amounts of suspended organic and inorganic materials or color.

177 "Vertical separation" means the vertical distance between the point of effluent application to
178 the soil or the bottom of a trench or other excavation and a limiting feature of the soil treatment
179 area such as seasonal high ground water, bedrock, or other restriction.

180 "Wetlands" means those areas that are inundated or saturated by surface or ground water at
181 a frequency and duration sufficient to support, and that under normal circumstances do support,
182 a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands
183 generally include swamps, marshes, bogs, and similar areas .

184 **12VAC5-613-90. Performance requirements; ground water protection.**

185 A. The AOSS shall not pose a greater risk of ground water pollution than systems otherwise
186 permitted pursuant to 12VAC5-610. After wastewater has passed through a treatment unit or
187 septic tank and through the soil in the soil treatment area, the concentration of fecal coliform
188 organisms shall not exceed 2.2 cfu/100 ml at the lower vertical limit of the project area
189 boundary.

190 B. Each large AOSS shall comply with TN limit of 5 mg/l at the project area boundary. Prior
191 to the issuance of a construction permit, the designer shall demonstrate compliance with this
192 requirement through modeling or other calculations. Such demonstration may incorporate
193 multiple nitrogen removal methods such as pretreatment, vegetative uptake (only for AOSSs
194 with shallow soil treatment areas), denitrification, and other viable nitrogen management
195 methods. Ground water and other monitoring may be required at the department's discretion.

196 C. AOSSs with direct dispersal of effluent to ground water are subject to the following
197 requirements:

198 1. If the concentration of any constituent in ground water is less than the limits set forth
199 at 9VAC25-280, the natural quality for the constituent shall be maintained; natural quality
200 shall also be maintained for all constituents not set forth in 9VAC25-280. If the

201 concentration of any constituent in ground water exceeds the limit in the standard for
202 that constituent, no addition of that constituent to the naturally occurring concentration
203 shall be made. The commissioner shall consult with the Department of Environmental
204 Quality prior to granting any variance from this subsection.

205 2. Ground water and laboratory sampling in accordance with 12VAC5-613-100 G.

206 3. The treatment unit or system shall comply with the following at a minimum:

207 a. The effluent quality from the treatment unit or system shall be measured prior to
208 the point of effluent application to the soil treatment area and shall be as follows:
209 BOD₅ and TSS concentrations each equal to or less than 5 mg/l; fecal coliform
210 concentrations less than or equal to 2.2 col/100 ml as a geometric mean with no
211 sample exceeding 14 col/100 ml; and TN concentration of less than 5 mg/l;

212 b. High level disinfection is required; and

213 c. Treatment systems shall incorporate filtration capable of demonstrating
214 compliance with an average turbidity of less than or equal to 2 NTU prior to
215 disinfection.

216 4. Gravity dispersal to the soil treatment area is prohibited.

217 5. Loading rates to the soil treatment area shall not exceed the loading rates in Table 1
218 of this section.

219 6. A renewable operating permit shall be obtained and maintained in accordance with
220 12VAC5-613-60 C.

221 7. The designer shall provide sufficient hydrogeologic analysis to demonstrate that a
222 proposed AOSS will function as designed for the life of the structure served without

223 degradation of the soil treatment area. This shall include a determination of ground water
224 flow direction and rate.

225 D. The following additional nutrient requirements apply to all AOSSs in the Chesapeake Bay
226 Watershed:

227 1. All small AOSSs shall provide a 50% reduction of TN as compared to a conventional
228 gravity drainfield system; compliance with this subdivision may be demonstrated through
229 the following:

230 a. Compliance with one or more best management practices recognized by the
231 division such as the use of a NSF 245 certified treatment; or

232 b. Relevant and necessary calculations provided to show one or both of the
233 following:

234 (1) Effluent TN concentration of 20 mg/l measured prior to application to the soil
235 dispersal field; or

236 (2) A mass loading of 4.5 lbs N or less per person per year at the project
237 boundary provided that no reduction for N is allotted for uptake or denitrification
238 for the dispersal of effluent below the root zone (>18 inches below the soil
239 surface).

240 2. All large AOSSs up to and including 10,000 gallons per day shall provide a 50%
241 reduction of TN at the project boundary as compared to a conventional gravity drainfield
242 system. Compliance with this subdivision may be demonstrated as follows:

243 a. A demonstrated effluent quality of less than or equal to 20 mg/l TN measured prior
244 to application to the soil treatment area; or

245 b. In situ monitoring of the treatment works within 24 vertical inches of the point of
246 effluent application to the soil treatment area to demonstrate the effluent leaving the
247 treatment works has a TN concentration of less than or equal to 20 mg/l. The
248 designer shall identify an intermediate compliance point within the treatment system
249 and a corresponding TN concentration for use in the event that a representative in
250 situ sample cannot be obtained. The intermediate compliance point and the
251 corresponding TN concentration for use must be approved by the department and
252 shall be conditions of the operation permit.

253 The AOSS operation permit shall be conditioned upon compliance with the constituent
254 concentrations approved pursuant to this subdivision.

255 3. All large AOSSs over 10,000 gallons per day shall comply with the following TN
256 requirements:

257 a. A demonstrated effluent quality of less than or equal to 8 mg/l TN measured prior
258 to application to the soil treatment area; or

259 b. In situ monitoring of the treatment works within 24 vertical inches of the point of
260 effluent application to the soil treatment area to demonstrate the effluent leaving the
261 treatment works has a TN concentration of less than or equal to 5 mg/l. The designer
262 shall identify an intermediate compliance point within the treatment system and a
263 corresponding TN concentration for use in the event that a representative in situ
264 sample cannot be obtained. The intermediate compliance point and the
265 corresponding TN concentration for use must be approved by the department and
266 shall be conditions of the operation permit.

267 The AOSS operation permit shall be conditioned upon compliance with the constituent
268 concentrations approved pursuant to this subdivision.

269 4. For direct dispersal of effluent to groundwater in the Chesapeake Bay Watershed, TN
270 concentration shall be less than or equal to 3 mg/l and total phosphorus concentration
271 shall be less than or equal to 0.3 mg/l.

272 E. When an application is filed to repair or voluntarily upgrade an existing sewage system
273 with capacity of 10,000 gallons per day or less, and the existing sewage system already
274 disperses effluent to groundwater as defined in 12VAC5-613-10, then the repair or upgrade
275 shall provide a minimum 50% reduction of TN as compared to a conventional gravity drainfield
276 system and shall provide TL-3 effluent and standard disinfection in accordance with 12VAC5-
277 613-80 (13), Table 2, for systems with less than 12 inches separation to groundwater. For
278 systems greater than 1,000 gallons per day and up to, and including, 10,000 gallons per day,
279 the sewage system shall also adhere to 12VAC5-613-90.B; and the following requirements are
280 not applicable to repair or voluntary upgrade applications that result in direct dispersal: 12VAC5-
281 613-90.C(1) through C(7) and 12VAC5-613-100. G. The repair or voluntary upgrade shall be
282 monitored pursuant to 12VAC5-613-100.D, 12VAC5-613.100.E, or 12VAC5-613.100.F, as
283 appropriate.