



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-412 12VAC5-410 (amendments)
Regulation title	Regulations for Licensure of Abortion Facilities
Action title	Establishes standards for facilities performing five or more first trimester abortions per month (12VAC5-412); deletes references to abortion facilities in the hospital regulations (12VAC5-410).
Date this document prepared	April 25, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Chapter 670 of the 2011 Virginia Acts of Assembly amended and reenacted § 32.1-127 of the Code of Virginia. Chapter 670 (2011) specified that facilities in which five or more first trimester abortions per month are performed shall be classified as a category of hospital and mandated the Board of Health to adopt regulations governing the licensure of such entities within 280 days of its enactment. For that reason, the Board utilized the emergency rulemaking process authorized by the Administrative Process Act for promulgating emergency regulations and filing a Notice of Intended Regulatory Action. Following that regulatory action, the Virginia Department of Health has developed final permanent regulations to replace the emergency regulations upon their expiration. The permanent regulations are necessary to support the implementation of the amendments to § 32.1-127 enacted by Chapter 670 (2011). The final regulations contain provisions pertaining to definitions, procedures for licensure or license renewal, organization and management, infection prevention, patient care, quality assurance, medical records and reports, disaster preparedness, facility security, functional safety and maintenance, and design and construction.

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 or board taking the action, and (3) the title of the regulation.

At its meeting conducted on April 12, 2013, the State Board of Health voted to approve the final Regulations for the 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.

Section 32.1-127 of the Code of Virginia, as amended by Chapter 670 of the 2011 Acts of Assembly, mandated the State Board of Health to promulgate emergency regulations. Chapter 670 further authorizes the Board of Health to continue to regulate facilities in which five or more first trimester abortions per month are performed as a category of hospital after the emergency regulations expire. The Board of Health, in accordance with the Administrative Process Act (§ 2.2-2000 et seq. of the Code of Virginia) has been directed to adopt regulations to implement the provisions of the Act which became effective on March 26, 2011. Having adopted the emergency regulations the Board now seeks to make appropriately revised regulations permanent.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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 intent of this regulatory action is to promote and assure the health and safety of patients who receive first trimester abortion services. The need for these regulations has been extensively and publically articulated over the past several years during the annual sessions of the Virginia General Assembly. The statutory language of § 32.1-127 of the Code of Virginia as amended by Chapter 670 (2011) mandates that the regulatory action include minimum standards for facilities performing five or more first trimester abortions per month. The standards are required to include those for construction and maintenance, operation, staffing and equipping, qualifications and training of staff, and infection prevention, disaster preparedness and facility security.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The majority of the provisions in this regulatory action are currently contained in the Emergency Regulations. No substantive changes have been made since publication of the proposed regulations. The following is a summary of key provisions of the final regulations:

Definitions

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

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

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

"First trimester" means the first twelve weeks from conception based on an appropriate clinical estimate by a licensed physician.

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

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

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

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

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

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

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

Procedures for Licensure or License Renewal

A license is valid for one year.

It is the responsibility of the abortion facility's governing body to maintain a current and accurate license at all times.

The Department may deny, suspend or revoke a license.

The Commissioner may allow a temporary variance to the regulatory provisions.

The Commissioner may rescind or modify a temporary variance.

VDH has a right of entry to any facility that it believes is performing first trimester abortions without a license.

VDH shall make periodic, unannounced onsite inspections not less often than biennially.

VDH employees shall properly identify themselves prior to admission to the facility.

A list of patients receiving services on the day of the inspection, as well as a list of all the abortion facility's patients for the previous 12 months, shall be provided to the inspector within 2 hours of arrival if requested.

A facility must submit a plan of correction within 15 working days to address any deficiencies.

OLC has the responsibility to investigate any complaints regarding violations of the regulations.

The facility has the right to contest the denial, revocation or suspension of a license.

Organization and Management

Each facility shall have a governing body.

Each facility shall develop, implement and maintain policies and procedures, including obtaining informed written consent prior to the initiation of any procedures.

Policies and procedures shall be based on recognized standards and guidelines.

Each facility shall have an administrator, and a staff that is adequately trained and capable of providing appropriate service and supervision to patients.

Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortion procedures.

Clinical privileges of physicians and non-physician health care practitioners shall be clearly defined.

A physician must remain on the premises until all patients are medically stable, must sign the discharge order and be available and accessible until the last patient is discharged.

Licensed health care practitioners trained in post-procedure assessment must remain on the premises until the last patient has been discharged.

Each 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 abortion facility shall establish and maintain complaint handling procedures and any patient seeking an abortion shall be given a copy of the complaint procedures in language or manner she understands at the time of admission to service.

Quality Management and Infection Prevention

The facility shall implement an ongoing assessment program of the quality and appropriateness of care services provided.

The facility shall have an infection prevention plan that encompasses the entire facility and all services provided and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Setting: Minimum Expectations for Safe Care," published by the CDC.

Patient Care

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.

The facility shall offer each patient in a language or manner they understand 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.

Prior to the initiation of any procedure, a medical history and physical examination, to include confirmation of pregnancy, and completion of all the requirements of informed written consent, shall be completed for each patient.

Use of additional medical testing shall be based on an assessment of patient risk.

All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if such verification cannot be made with certainty, the tissue specimen shall be sent for further pathological examination.

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

The 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.).

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

Elective general anesthesia shall not be used.

Controlled substances as defined in the Virginia Drug Control Act, shall be stored, administered, and dispensed in accordance with federal and state laws. The dispensing of drugs shall be in accordance with Regulations Governing the Practice of Pharmacy and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances.

Drugs whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed, or administered by a physician.

A facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's guidelines for Advanced Cardiovascular Life Support.

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

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. 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.[This provision reflects amendments made by the Board of Health at its June 15, 2012 meeting.]

Health Information Records and Reports

An accurate and complete clinical record or chart shall be maintained on each patient.

The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service.

Provisions shall be made for the safe storage of health records or accurate and eligible reproductions thereof according to applicable federal and state law including HIPAA.

The facility shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120).

The abortion facility shall report to the OLC within 24 hours any patient, staff or visitor death, any serious injury to a patient, medication errors that necessitate a clinical intervention other than monitoring, a death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds and any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990.

Records that are confidential under federal or state law shall be maintained as confidential by OLC and shall not be further disclosed except as permitted by law.

Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.

Functional Safety and Maintenance

The facility shall develop, implement and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants.

Each facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters.

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.

When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented.

Design and Construction

Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. 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 Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001.

Entities operating as of the effective date of these regulations 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.

This regulatory action also proposes the following amendments to 12VAC5-410 (Regulations for the Licensure of Hospitals in Virginia.)

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-410-10		Definition of "Outpatient Hospital"	The following text is stricken from the definition: "Outpatient abortion clinics are deemed a category of outpatient hospitals." Rationale - Abortion facilities will be regulated pursuant to 12VAC5-412, not 12VAC5-410.
12VAC5-410-60		Separate License	Deletes the term "outpatient abortions" from the provision authorizing VDH to require a hospital to have separate licenses for different types of services. Rationale - Abortion facilities will be regulated pursuant to 12VAC5-412, not 12VAC5-410.

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 proposed regulatory action to the public are the requirements for health and safety protections at abortion facilities. The primary disadvantage to the public associated with the proposed action is some abortion facilities may need to renovate or relocate their facility in order to comply with the regulations. Section 370 of the proposed regulations allows entities operating as of the effective date of the emergency regulations to be licensed in their current buildings if the abortion facility submits a plan with the application for licensure that will bring the facility into full compliance with the provisions of Section 370 within two years from the date of licensure. The costs of those renovations or

relocations might be passed on to the facilities' patients, or potentially, result in some facilities electing to cease operations at some point in the future. 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 regulations in relation to the agency or the Commonwealth.

At its June 15, 2012 meeting, the Board approved proposed regulations for the licensure of abortion facilities. In approving the proposed regulations, the Board made four amendments to the draft proposed regulations that had been prepared by VDH staff. One of those amendments was to Section 12VAC5-412-370, which stated that:

“All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to 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. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation.”

Executive Order (EO) 14, issued by Governor McDonnell in 2010, pertains to the Development and Review of Regulations Proposed by State Agencies. In pertinent part, EO14 states “In addition to the information required on the regulation background form, the agency shall also include in the regulatory package a memorandum from the Office of the Attorney General (OAG) certifying that the agency has legal authority to promulgate the regulation being proposed...”

On July 16, 2012, the Office of the Attorney General sent a memorandum to the State Health Commissioner stating that “The Board does not have the statutory authority to adopt these Regulations. Because proposed 12 VAC 5-412-370 conflicts with Virginia Code § 32.1-127.001, the Board has exceeded its authority. Thus, this Office cannot certify these Regulations.” Therefore, in compliance with the provisions of EO14, the proposed regulatory package could not be submitted by VDH to the Department of Planning and Budget in order to continue the required Executive Branch review process for the proposed regulations. Consequently, the proposed regulations were reconsidered by the Board of Health on September 14, 2012.

Subsequent to the June 15, 2012 Board meeting, and in preparation for the September 14, 2012 Board meeting, VDH proposed that the Board amend 12VAC5-412-370 by returning to the language contained in the Emergency Regulations and adding a provision stating that in order to determine whether the abortion facility is in compliance with the provisions of that section, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.

At its September 14, 2012 meeting, the Board approved the proposed regulations on a 13-2 vote.

The Department of Planning and Budget completed an Economic Impact Analysis (EIA) on the proposed regulations on January 7, 2013. VDH provided a response to the EIA.

Five bills that addressed abortion facility licensure were introduced during the 2013 General Assembly Session. Three of the bills would have repealed the licensure requirement. Two of the bills would have exempted existing facilities from licensure. All five of these bills were either left in committee or passed by indefinitely.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

None

Section number	Requirement at proposed stage	What has changed	Rationale for change

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.

VDH conducted a 60-day public comment period from January 28, 2013 to March 29, 2013 and conducted two public hearings which were held on March 7, 2013 in Richmond and March 12, 2013 in Alexandria. A total of 6,626 comments were received. Among that total, 2,963 comments were received on the regulatory town hall. In addition, VDH received 167 emails and 3,496 comments in hard copy. VDH has reviewed and summarized all of the public comments received concerning the proposed regulations as part of its work to develop permanent finalized replacement regulations.

Comment	Agency response
Katherine Waddell, President, Women's Strike Force, Former Member, House of Delegates, provided a letter addressed to each member of the Board of Health asking the members: i) to remember the impact on women's lives, ii) asking where is the data showing a need for increased regulation, iii) referencing colonoscopies conducted in doctor's offices, and iv) asking that the members take another good look at the regulations before making them permanent.	The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.
Chris Freund Family Foundation of Virginia stated: We urge [the board] to adopt the abortion center health and safety standards adopted last year...the inspections the abortion industry fought so hard to avoid reveals the industry has no credibility when it comes to which regulations are necessary and which are not.	The Board notes the support for the regulation.
The Honorable Mark Herring, Virginia State Senate, stated that "the enacting legislation makes health care for women more expensive and less accessible through targeted ...	The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first

<p>regulations that provide unnecessary obstacles to any woman seeking access to health care services... The new regulations are wrong and must be fixed to ensure that thousands of Virginia women do not lose access to essential medical care."</p>	<p>trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>Virginia Podboy, Virginia Catholic Conference, stated: Here today to urge you all to implement the proposed permanent regulations. These common sense regulations protect women that make the delicate decision to have an abortion...the facilities that perform these life ending procedures should function as proper health care facilities. This is what women that use them expect. The abortion industry needs to be held accountable.</p>	<p>The Board notes the support for the regulation.</p>
<p>The Honorable Ralph Northam, Virginia State Senate, stated: "As a senator and physician I have grave concerns regarding the TRAP regulations set up for government intervention in medicine. [In legislative committee hearings, proponents of Senate Bill 924] state it was about safety for women, but interestingly nobody came forward with any data that shows that our clinics are unsafe, nor did they come up with data that said these new regulations would make it safer, nor were there any health care providers that said changes were necessary...It is time [to] listen to experienced health care providers, and most importantly it is time for them to listen to women and to keep government out of their lives. That is what our women of Virginia deserve... I urge the board to reject these regulations."</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>Don Blake, Chairman of the Virginia Christian Alliance, supports the regulation stating: we believe this past year has shown clear evidence the need for these regulations, and we appreciate the fact that they have been in use for a year to give us an example of the past need and the present need and future need of those regulations. We ask you, the board, to continue those regulations, make them permanent.</p>	<p>The Board notes the support for the regulation.</p>
<p>The Honorable Barbara Favola, Senate of Virginia, writes: "the cost associated with meeting the building requirements of the proposed TRAP regulations will be so prohibitive - clinics will be forced to close. Women in many parts of the state will be denied access to basic primary and preventive care....If we care about improved health outcomes for women and children and if we care about lowering abortion rates, then women need access to the entire range of reproductive health</p>	<p>The Board notes the opposition to the regulation. The Virginia Department of Planning and Budget completed an Economic Impact Analysis (EIA) of the regulations. VDH provided a response to the EIA.</p> <p>Section 32.1-25 of the Code of Virginia provides the Commissioner or his designee the right to enter onto any property to inspect, investigate, evaluate, conduct tests or take samples for testing as</p>

<p>services offered by these centers...these regulations will allow government inspectors to demand a year's worth of patient lists from women's health clinics that perform abortions. This is government intrusion in the most private decisions...I ask you to not apply the physical requirements contained in the TRAP regulations. Honor your statutory responsibilities and provide a recommendation that improves access to needed health care in the state.</p>	<p>necessary in order to determine compliance with the provisions of any regulations of the Board of Health. Further, VDH has an agency confidentiality policy that applies to all VDH personnel whose jobs require handling of confidential information, including those who are investigating patient care facilities for regulatory purposes. Confidential information includes protected health information and personal information of employees, and clients/patients, as well as other forms of confidential information related to proprietary and/or business information. VDH personnel are required to limit the collection of, use of, access to, and disclosure of confidential information. All VDH personnel must sign the confidentiality policies and procedures acknowledging their intention to adhere to the policy.</p>
<p>The Honorable R. Creigh Deeds The Honorable Barbara Favola The Honorable Mark Herring The Honorable Janet Howell The Honorable L. Louise Luca The Honorable Henry Marsh The Honorable Donald McEachin The Honorable John Edwards The Honorable Phillip Puckett, Virginia State Senate, write: The Board was informed .. that [it] violated its statutory authority in adopting the Regulations for Licensure of Abortion Facilities at the June 15, 2012 Board of Health meeting..The Attorney General's office is incorrect in their interpretation ...that the initial proposed 12VAC5-412-370 conflicted with the Virginia Code 32.1-127.001. But the section has never required existing facilities to need new construction codes, and it was the intent of the General Assembly when it enacted those provisions...The 2010 Guidelines clearly state that they are "intended as minimum standards for designing and constructing new health care facility projects." [The Board's] June 15th [2012] amendment to differentiate between new and existing facilities was "consistent with" the Guidelines and clearly was within the statutory authority the General Assembly has given you.</p>	<p>The Board notes the opposition to the regulation. 12 VAC5-412-370 is written to comply with Virginia Code §32.1-127.001.</p>
<p>The Honorable David Toscano The Honorable Mark D. Sickles The Honorable Rosalyn R. Dance The Honorable Jennifer L. McClellan The Honorable Betsy Carr The Honorable Jeion Ward The Honorable Delores McQuinn The Honorable Charniele Herring</p>	<p>The Board notes the opposition to the regulation. 12 VAC5-412-370 is written to comply with Virginia Code §32.1-127.001.</p>

<p>The Honorable Eileen Filler-Corn The Honorable Mamyé BaCote The Honorable Robert Brink The Honorable Patrick Hope The Honorable Mark Keam The Honorable Robert Krupicka The Honorable Alfonso Lopez The Honorable Kenneth Plum The Honorable James Scott The Honorable Scott Surovell The Honorable Roslyn Tyler The Honorable Onzlee Ware The Honorable Vivian Watts The Honorable Kaye Kory, Virginia House of Delegates, write: "Your June 15th amendment to differentiate between new and existing facilities was "consistent with" the Guidelines, and clearly within the statutory authority the General Assembly has given [the Board]. Indeed, your June 15th amendments were also consistent with regulations promulgated in the past...We are aware of no other instance in which Virginia has forced existing healthcare facilities to satisfy standards designed for new construction...We, the undersigned members of the Virginia House of Delegates, strongly urge you to reconsider abandoning your June 15 [2012] amendments, and adopt final regulations that exempt existing facilities to move forward and avoid certain litigation with respect to your decision to establish disparate treatment for these clinics under the law.</p>	
<p>M. Casey Maddox, Senior Counsel of the Alliance Defending Freedom, and their allied attorneys representing a number of abortion clinic workers "encourage the Board of Health to adopt the proposed abortion clinic regulations that will protect the health and safety of the women of the Commonwealth."</p>	<p>The Board notes the support for the regulation.</p>
<p>Fred Hannett, Former Chair, Virginia State Board of Health; Wendy S., Klein, MD, FACP, Andrew M. Klein, MD, Holly S, Puritz, MD, James E. Ferguson II, MD, MBA, write that [E. O. 14] (2010) was clearly signed to prevent the sometimes-heavy hand of government from arbitrarily stifling small businesses and enterprise or interfering with personal freedom without achieving any compelling government interest...regulations currently proposed under [SB924] merely pay lip service to these mandates and ideals...these regulations fail to offer any</p>	<p>The Board notes the opposition to the regulation. The Virginia Department of Planning and Budget completed an Economic Impact Analysis (EIA) of the regulations. VDH provided a response to the EIA. The EIA includes a section titled "Small Businesses: Costs and Other Effects."</p>

<p>reasonable alternatives that might achieve the same goals...We urge the Virginia government to follow its own principles of regulation and to stand up for everyone's rights. When our leaders break their own rules for regulatory procedures in order to pick winners and losers, we all lose.</p>	
<p>Karen Remley, MD, MBA, FAAP, Former Commissioner of Health addressed §32.1-127.001 regarding building standards stating: "For all health care facilities, including abortion facilities, rigidity in interpretation will potentially decrease access to safe and quality care" and urged VDH "to retain the consistent with language [in regulation], aligning with the language in the Code of Virginia as written by the General Assembly, signed into law by the Governor, as is the norm for other health facility regulations and numerous other health department regulations...balancing the promotion of safety and quality care in a context of application of these regulations that rely on evidence and professionalism, without over-reaching interpretations that exceed the Code language."</p>	<p>The Board notes the interpretation offered.</p>
<p>Kathy Greenier, Director, Women's Rights Project ACLU of Virginia, commented that [Virginia] law does not give the AG's Office veto power over the Board's policy decisions about what to include in the final rules. There is no credible legal basis for the Attorney General's assertion that the Board does not have the authority to grandfather in existing women's health care centers....While the regulatory process may stall as a result of the AG's refusal to certify, the Board has the authority and statutory obligation to create regulations for health care facilities that conform solely to standards established by medical and health professionals.</p>	<p>The Board notes the opposition to the regulation.</p> <p>The Code of Virginia requires the Board of Health to receive legal service only from the Office of the Attorney General.</p>
<p>Stephan Bendheim, MD, writes "the draft permanent regulations are not grounded in medical facts or sound medical practices. The regulations require health care facilities that only perform first-trimester abortion procedures to unnecessarily overhaul their existing facilities and comply with the building and construction requirements applicable to new hospitals. Such onerous and expensive structural facility requirements are not rationally related to enhancing the safety of first-trimester abortion procedure, nor prevent potential patient complications...A hospital grade facility is not required, and I am not aware of any credible medical opinion holding that it is.</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital. The Virginia Department of Planning and Budget completed an Economic Impact Analysis (EIA) of the regulations.</p>
<p>James Ferguson II, MD, MBA, writes: The draft regulations should not be adopted in their current</p>	<p>The Board notes the opposition to the regulation. The Virginia Department of Planning and Budget</p>

<p>form. They will impose unnecessary and unreasonable financial and compliance burdens on providers of first trimester abortion services that are neither necessary or reasonably calculated to promote patient health and safety...Many provisions in the [draft] have nothing to do with patient care and safety, do not improve patient outcomes, and do not serve to better and/or protect the health of women undergoing first trimester abortions, which are outpatient procedures.</p>	<p>completed an Economic Impact Analysis (EIA) of the regulations. VDH provided a response to the EIA.</p>
<p>Tarina Keene, Executive Director, NARAL Pro-Choice Virginia Foundation, writes: "the hospital-like construction requirements being placed on existing doctor's offices that perform first trimester abortion are overly burdensome, unnecessary and put Virginia women's health and lives at risk...NEVER has the commonwealth required existing facilities to retroactively meet regulatory construction guidelines. The [current] facilities must be grandfathered... The people of Virginia demand comprehensive health care and a fair approach to regulation - not politically motivated requirements designed to restrict abortion access and close exemplary medical providers...NARAL Pro-Choice asks the Board of Health to put medicine before politics and ideology and vote to exempt existing abortion providers from forced and unnecessary hospital construction requirements and help ensure safe and accessible healthcare for the women of Virginia.</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>The Virginia Coalition to Protect Women's Health writes: The Board of Health has been led to believe that its decisions of June 15th [2012] were not legal... this is not true on any level. The Board acted precisely within its jurisdiction, its mission, and its expertise - independently. The Attorney General and his office have no legal authority to dictate the precise, explicit letter of public health regulations that uphold patient safety in Virginia. The Board acted appropriately...the public health board cannot succumb to bullying and intimidation by one government office - the slippery slope and political and ideological intrusion into medical and public-health decision making is far too perilous.</p>	<p>The Board notes the opposition to the regulation. The Code of Virginia requires the Board of Health to receive legal service only from the Office of the Attorney General.</p>
<p>Mallory Quigley, Communications Director of the Susan B. Anthony List, urged the adoption of the abortion center health and safety standards passed last year and referenced the violations found in abortion clinics that applied for licensing.</p>	<p>The Board notes the support for the Regulation.</p>

<p>Rosemary Wilber Coddling, Director Patient Services, Falls Church Healthcare Center, stated that "regulations should embrace evidence-based medical best-practices that advance public health to insure women in [Virginia] can maintain access to vital health care from her trusted medical provider" so that there is not a return to "illegal abortions through unneeded restrictive regulations that medical practices cannot meet...making these temporary regulations a permanent code will not increase access to improve safety which is what VDH's mission is."</p>	<p>The Board notes the opposition to the regulation.</p>
<p>Brenda Seward, State Director - UniteWomen.org, stated "the decision should be decided based on real medical concerns and not from ideological standpoint and that does not appear to be the case...there is a real and imminent danger in limiting, or potentially removing the access that women in Virginia have to safe, carefully operated abortion services."</p>	<p>The Board notes the opposition to the regulation.</p>
<p>Marjorie Signer, Legislative Vice President, Va. chap. National Organization for Women, states "the pending TRAP regulations for Virginia clinics that provide first trimester abortions are not reasonable and most likely will have serious negative consequences on the provision and availability of women's health care in Virginia...[and] ask the Board to reconsider the proposed regulations... to become mini-hospitals...These clinics have a critical preventive care role that will be lost if and when they shut down because they cannot meet the hospital-like standards required by the regulations...there is no data indicating that our clinics are unsafe or that these new regulations would make them safer...[the violations found] must be addressed - but treating clinics that provide first trimester abortions and reproductive health services as mini-hospitals is not the way to do that.</p>	<p>The Board notes the opposition to the proposed regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital. The Virginia Department of Planning and Budget completed an Economic Impact Analysis (EIA) of the regulations. VDH provided a response to the EIA.</p>
<p>Margaret Vanderhye, Former member, House of Delegates, Chair of the FCDC Women's Action Committee, Founding member of the Women's Strike Force, writes that §32.1-127.001 calls for "minimum standards <i>consistent with</i> the current Guidelines for design and construction, offering discretion because to do otherwise would create barriers to essential health care services for many different kinds of needs... safe and appropriate health care standards and practices are available to patients now...and gives authority to make informed, considered decisions on behalf of all our health</p>	<p>The Board notes the opposition to the regulation. ,</p>

<p>care facilities, rather than to "trap" those that include abortions among their services... misapplications of current law do not serve the interests of our private or corporation citizens, but [VDH] has the tools needed to protect both."</p>	
<p>Jim Edmondson, Consumer Representative, Virginia Board of Health, writes "the state has an interest in such matters as cleanliness, emergency arrangements, record-keeping, and the qualifications of staff... All the clinics in Virginia subject to these regs have been operating for many years very safely. In fact abortions have fewer problems than births. Yet the state has decided to impose requirements on the physical plans of the clinic's buildings that are wholly unreasonable...the department may exercise some discretion in its inspections of clinics, giving them latitude to waive specific requirements, such as hallway widths, if patient safety is not jeopardized...The object is to keep Virginia citizens safe. And the truth is that the clinics as is have done that. I urge [VDH] to exercise reasonableness in the use of regs of these clinics.</p>	<p>The Board notes the opposition to the regulation.</p>
<p>Anna Franzonello, Staff Counsel, Americans United for Life, writes: Virginia's proposed abortion clinic regulations comport with legal precedent and reflect medically appropriate standards for patient care including those adopted in other states' abortion clinic regulations...Virginia's proposed abortion clinic regulations are substantially similar to those that have been upheld in other states and are important and necessary safeguards of women's health and safety.</p>	<p>The Board notes the support for the regulation.</p>
<p>Noah Mamber, Public and Legislative Affairs Manager, Planned Parenthood Metropolitan Washington, writes: Application of the [FGI Guidelines] that are unrelated to the services provided and have no proven medical benefit will reduce or eliminate Virginia women's access to health care because of the burdens they impose on health centers... the text of SB924 provides zero support for regulations that subject abortion facilities to standards in the areas that are substantially more stringent than those applicable to hospitals and other facilities mentioned in §32.1-127(B)1. Not only do the FGI Guidelines themselves note that they are only applicable to new healthcare facilities but the Board itself has never previously applied the Guidelines to existing facilities since §32.1-127.001 was enacted</p>	<p>The Board notes the opposition to the regulation.</p>

<p>in 2005...It is my hope that the regulations will be amended to be based purely on medicine and science and not designed to impede women's access to essential health care.</p>	
<p>Alena Yarmosky, NARAL PRO Choice Virginia, stated: For nearly 2 years NARAL PRO Choice has worked [with others] to help insure that the redrafted regulation to be imposed upon first trimester abortion providers are based on sound science and medical evidence. Unfortunately politics seems to rule the day and despite ...best efforts to work with the administration and the [Board], the regulations are being pushed through without consideration for the advice of medical experts or evidence of the real impact on womens' health and safety. .. All 20 [clinics in Virginia] are inspected and given unconditional licenses, and I'd like to request that you adhere to medical advice and grandfather in the state's top notch abortion providers from having to meet 2010 requirements for new hospitals...I hope the Board will draw on the medical and health expertise that's been presented to you today when considering how far these regulations should go and the long term impact they will have on the women of Virginia.</p>	<p>The Board notes the opposition to the regulation.</p> <p>Neither the Code of Virginia nor the regulations provide for an "unconditional" license. A facility is either licensed or it isn't.</p>
<p>Cianti Stewardt-Reid, Planned Parenthood Advocate for Virginia, stated: As the representative here of all our centers which includes the medical professionals who practice there who hold themselves to the highest standards of care, I implore the board to reconsider these regulations again before approval...It is well within the board's authority to reject these regulations as written and listen to expert opinion of fellow physicians and professionals in your field who will testify here today who indicate that these regulations are unnecessary.</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>James B. Kenley, Former State Health Commissioner, stated: I share the concerns of abortion rights activists that a legal ban could endanger the health and the lives of women by driving abortions underground without much reducing their numbers...I urge the members of the [department] and the [board] to adhere to their charge to protect the public health and safety of the people of the Commonwealth by adopting only those regulations that are medically appropriate and based in science.</p>	<p>The Board notes the opposition to the regulation</p>
<p>Andrew Klein, MD, and 177 health care professionals & the Virginia Chapter of the</p>	<p>The Board notes the opposition to the regulation. The State Board of Health is a board appointed by</p>

<p>American College of Gynecologists oppose the regulation stating: political forces have challenged the independence of the Board. We appeal to the Board to resist these outside influences and urge the Board to make its decision on the basis of impartial, professional and scientific information as its relates to the women's health clinic regulations. The reputation and credibility of the Board are at stake... Although the purported intent of these regulations is to protect women's health, the safety record of these clinics in the Commonwealth of Virginia has been exemplary...We all understand that abortion has supporters and detractors and we must respect those views. The issue here is not and should not be about abortion. It is about the Virginia Board of Health as an independent, objective, public health advisory group that acts with impartiality in weighing scientific evidence. We must not travel down a dangerous slippery slope where we allow political forces to dictate medical care."</p>	<p>the Governor with specific statutory authority and responsibilities. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>Anna Higgins, J.D., Family Research Council, states: the FRC supports enhanced abortion clinic regulations and asks the Board to adopt regulations consistent with the entire statute passed by the Virginia General Assembly, which required all clinics to meet the same standards as new hospital construction.</p>	<p>The Board notes the support for the regulation.</p>
<p>Michael Mitchell, Religious Coalition for Reproductive Choice, and 107 signatories write: We believe that our state laws should protect access to all forms of reproductive healthcare, including abortion. It is wrong to adopt unnecessary and judgmental policies that place cumbersome restrictions on Virginia women and health care providers.</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p>
<p>Tammy Fuller, Charlottesville Chapter - NOW, asks [the Board] to reject the proposed final regulations for licensure of abortion facilities...which do not grandfather existing facilities and are not grounded in evidence-based medicine, will jeopardize the continued operation of an estimated 75% of abortion clinics in the Commonwealth.</p>	<p>The Board notes the opposition to the regulation. The 2011 General Assembly mandated that the Board of Health promulgate regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. Those facilities are required to be classified as a category of hospital.</p> <p>The Virginia Department of Planning and Budget completed an Economic Impact Analysis (EIA) of the regulations. VDH provided a response to the EIA.</p>
<p>28 persons commented that existing abortion facilities should be grandfathered in and that the construction guideline be applied to new construction.</p>	<p>12 VAC5-412-370 is written to comply with Virginia Code §32.1-127.001.</p>

<p>144 persons commented via email stating general opposition to the proposed regulations which seek "to impose unnecessary hurdles for women in Virginia seeking reproductive health care including not only abortion but also birth control, cancer screens, and routine reproductive health exams by forcing clinics to close." These commenters urge the Board of Health to "reject these unnecessary and harmful restrictions."</p>	<p>The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>3,379 persons commented via form letter opposing the regulation stating the regulations should be based on health care needs, not politics, and that the proposed regulations will limit access to safe and legal abortion.</p>	<p>The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>5 persons submitted form letters in support of the regulations stating the proposed regulations are reasonable, common sense measures to ensure that life-saving equipment is on hand, infections are prevented, and that clear written policies and building guidelines are in place.</p>	<p>The Board notes the support for the regulation.</p>
<p>1,120 persons commented via Townhall supporting the regulation, but did not cite specific sections for comment.</p>	<p>The Board notes the support for the regulation.</p>
<p>1,273 persons commented via Townhall opposing the regulation, but did not cite specific sections for comment.</p>	<p>The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>337 comments did not express support or opposition to the regulation. Some of these comments encouraged a complete ban on abortion, some were incomprehensible, and some were the result of difficulty using the comment page of the TH (i.e., title but no comment).</p>	<p>The Board believes that no response is necessary for these comments as they do not speak to the regulation itself. The difficulty completing the comment was reported to the TH program management.</p>

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.

The emergency regulations for Licensure of Abortion Facilities were published on December 29, 2011. The final regulations for Licensure of Abortion Facilities are substantially similar to the emergency regulations but some changes have been made. The chart below summarizes provisions of the final regulations and clarifies any changes made to the emergency regulations.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-410-10. Definitions	N/A	"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization.	N/A
12VAC5-410-60. Separate license.	N/A	A. A separate license shall be required by hospitals maintained on separate premises even though they are operated under the same management. Separate license is not required for separate buildings on the same grounds or within the same complex of buildings. B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, and outpatient surgery.)	N/A
12VAC5-412-10. Definitions.	N/A	The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise: "Abortion" means the use of an instrument, medicine, drug, or other substance or device with the intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than a live birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this definition.	The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise: "Abortion" means the use of an instrument, medicine, drug, or other substance or device with the intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than a live birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this definition. "Abortion facility" means a facility in

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>"Abortion facility" means a facility in which five or more first trimester abortions per month are performed.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"First trimester" means the first twelve weeks from conception based on an appropriate clinical estimate by a licensed physician.</p> <p>"Informed written consent" means the knowing and voluntary written consent to abortion by a pregnant woman of any age in accordance with Virginia Code § 18.2-76.</p> <p>"Licensee" means the person, partnership, corporation, association, organization, or professional entity who owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.</p> <p>"Minor" means a patient under the age of 18.</p> <p>"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns and/or manages or operates an abortion facility.</p> <p>"Patient" means any person seeking or obtaining services at an abortion facility.</p> <p>"Physician" means a person licensed to practice medicine in Virginia.</p> <p>"Trimester" means a 12-week period of pregnancy.</p>	<p>which five or more first trimester abortions per month are performed.</p> <p><u>"Administrator" means the person appointed by the governing body as having responsibility for the overall management of the abortion facility. Job titles may include director, executive director, office manager, or business manager.</u></p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"First trimester" means the first twelve weeks from conception based on an appropriate clinical estimate by a licensed physician.</p> <p>"Informed written consent" means the knowing and voluntary written consent to abortion by a pregnant woman of any age in accordance with Virginia Code § 18.2-76.</p> <p>"Licensee" means the person, partnership, corporation, association, organization, or professional entity who owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.</p> <p>"Minor" means a patient under the age of 18.</p> <p>"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns and/or manages or operates an abortion facility.</p> <p>"Patient" means any person seeking or obtaining services at an abortion facility.</p> <p>"Physician" means a person licensed to practice medicine in Virginia.</p> <p><u>"Spontaneous miscarriage" means the expulsion or extraction of a product of human conception resulting in other than a live birth and which is not an abortion</u></p> <p>"Trimester" means a 12-week period of pregnancy.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p>Rationale: The Board has added the term and definition of the term "Administrator" in order to remain consistent with other VDH Health Care Facility Regulations.</p> <p>The Board removed the term "Ownership/person" as it was duplicative of the definition of "Licensee"</p> <p>The Board has added the term and definition of the term "Spontaneous miscarriage."</p>
12VAC5-412-20. General.	N/A	<p>A license to establish or operate an abortion facility shall be issued only when the abortion facility is in compliance with all applicable federal, state and local statutes and regulations, the provisions of this chapter, and when the application fee has been received by the department.</p> <p>No ownership/person, as defined in 12VAC5-412-10, shall establish, conduct, maintain, or operate in this state, any abortion facility as defined and included within provisions of this chapter without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.</p>	N/A
12VAC5-412-30. Classification.	N/A	Abortion facilities shall be classified as a category of hospital.	N/A
12VAC5-412-40. Separate license.	N/A	<p>An abortion facility operating at more than one location shall be required to obtain separate licenses for each location in which abortion services are provided.</p> <p>Abortion facilities which have separate organized sections,</p>	N/A

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>units or buildings to provide services of a classification covered by provisions of other state statutes or regulations shall be required to have any additional applicable license required for that type or classification of service. Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of these regulations.</p>	
<p>12VAC5-412-50. Request for issuance.</p>	<p>N/A</p>	<p>A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to Department's Office of Licensure and Certification (OLC). B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days. C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the facility's certificate of use and occupancy. D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee is submitted. E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC. F. A license shall not be assigned or transferred. A new</p>	<p>A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to Department's Office of Licensure and Certification (OLC). B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days. C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the facility's certificate of use and occupancy <u>or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.</u> D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee is submitted. E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC. F. A license shall not be assigned or</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		application for licensure shall be made at least 30 days in advance of a change of ownership or location.	transferred. A new application for licensure shall be made at least 30 days in advance of a change of ownership or location. Rationale: 12VAC-412-50 (C) was amended to reflect an amendment approved by the Board of Health at its June 15th, 2012 meeting.
12VAC5-412-60. License expiration and renewal.	N/A	<p>A. Licenses shall expire at midnight April 30th following the date of issue, and shall be renewable annually, upon filing of a renewal application and payment of the appropriate nonrefundable renewal application fee. Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter.</p> <p>B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.</p> <p>C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-120 shall not be eligible for license renewal.</p> <p>D. Any license issued before April 30, 2012 shall not expire until April 30, 2013. No additional fee will be required for the period from May 1, 2012 until April 30, 2013.</p>	N/A
12VAC5-412-70. Posting of license.	12VAC5-412-140. Management and administration.	The abortion facility license issued by the commissioner shall at all times be posted in a place readily visible and accessible to the public.	<p>The abortion facility license issued by the commissioner shall at all times be posted in a place readily visible and accessible to the public.</p> <p>Rationale: The Board has amended 12VAC5-412-70 in order to be consistent with other VDH health care facility regulations. This</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			provision was moved to 12VAC5-412-140. Management and administration.
12VAC5-412-80. Return of license.	12VAC5-412-70. Return and/or reissuance of license.	<p>A. It is the responsibility of the facility's governing body to maintain a current and accurate license.</p> <p>B. The license issued by the commissioner shall be returned to the OLC when any of the following changes occur which may require reissuance of a license during the licensing year:</p> <ol style="list-style-type: none"> 1. Revocation or suspension. 2. Change of location. 3. Change of ownership. 4. Change of name. 5. Voluntary closure. <p>C. The facility shall give written notification 30 working days in advance of any proposed changes that may require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC.</p> <p>D. The OLC will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the facility during the process of evaluating a proposed change.</p> <p>E. The facility will be notified in writing whether a new application is needed.</p>	<p>A. It is the responsibility of the abortion facility's governing body to maintain a current and accurate license <u>at all times.</u></p> <p>B. The license issued by the commissioner shall be returned to the OLC when any of the following changes occur which may require reissuance of a license during the licensing year:</p> <ol style="list-style-type: none"> 1. Revocation or suspension. 2. Change of location. 3. Change of ownership. 4. Change of name. 5. Voluntary closure. <p><u>B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</u></p> <ol style="list-style-type: none"> <u>1. Change of location.</u> <u>2. Change of ownership.</u> <u>3. Change of name.</u> <u>4. Voluntary closure.</u> <u>5. Change of administrator.</u> <u>6. Change of operator.</u> <p><u>Notices shall be sent to the attention of the director of the OLC.</u></p> <p>C. The facility shall give written notification 30 working days in advance of any proposed changes that may require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC.</p> <p><u>C. The license issued by the commissioner shall be returned to the OLC when any of the changes listed in subsection B of this section occur. In addition, if the abortion facility is no longer operational, or the license has been suspended or revoked, the</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p><u>license shall be returned to the OLC within five calendar days of the abortion facility closing. The abortion facility's patients and the OLC shall be notified where all patient records will be located.</u></p> <p>D. The OLC will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the facility during the process of evaluating a proposed change.</p> <p><u>D. The OLC shall determine if any changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the abortion facility during the process of evaluating a change.</u></p> <p><u>E. The abortion facility will be notified in writing by the OLC whether a license can be reissued or a new application is needed.</u></p> <p>Rationale: The Board has amended 12VAC5-412-70 in order to be consistent with other VDH health care facility regulations. The Board has added to sub-section C to 12VAC5-412-70 Return and/or Reissuance of a License to be consistent with other VDH health care facility regulations. This addition was moved from the section 320 of the Emergency Regulations "Records Storage" with some additions and clarifications.</p>
12VAC5-412-90. Allowable variances.	12VAC5-412-80. Allowable variances.	Upon finding that the enforcement of a specific regulation would be an impractical hardship unique to the abortion facility, the commissioner may grant a variance temporarily waiving the enforcement of the specific regulation, provided patient safety, patient care, and	<p>Upon finding that the enforcement of a specific regulation would be an impractical hardship unique to the abortion facility, the commissioner may grant a variance temporarily waiving the enforcement of the specific regulation, provided patient safety, patient care, and services are not adversely affected.</p> <p><u>A. The commissioner may authorize a</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>services are not adversely affected.</p>	<p><u>temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.</u></p> <p><u>B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.</u></p> <p><u>C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.</u></p> <p><u>D. If a temporary variance is denied,</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p><u>expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed</u></p> <p>Rationale: The Board has amended 12VAC5-412-80. Allowable variances. This was done in order to be consistent with other VDH health care facility regulations. This amendment provides more detail and creates more thorough regulations. This section was further amended by the Board of Health at its June 15th 2012 meeting.</p>
12VAC5-412-100. Right of entry	12VAC5-412-90. Right of entry	Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any such employee shall properly identify himself or herself as an inspector designated by OLC; the facility may verify the identity of the inspector prior to his or her admission. Such entries and inspections shall be made with the permission of the owner or person in charge, unless an inspection warrant is obtained after denial of entry from an appropriate circuit court. If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate revocation or suspension of the license. If the entity is unlicensed, the owner or person	Rationale: The Board has renumbered this section however; the provisions are unchanged.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		in charge shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.	
12VAC5-412-110. On-site inspection.	12VAC5-412-100. On-site inspection	<p>A. An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than biennially. If the department finds, after inspection, non-compliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-120.</p> <p>B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the facility's control, direction or supervision. If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the facility before removal.</p> <p>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 1 hour of the surveyor's arrival. A list of current patients shall be provided to the surveyor within 2 hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-27 and</p>	<p>A. An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than biennially. If the department finds, after inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-120, <u>12VAC5-412-110</u>.</p> <p>B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction, or supervision. If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the abortion facility before removal.</p> <p>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 current patients <u>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</u> 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>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		denial, suspension or revocation of the facility's license in accordance with 12VAC5-412-130.	Rationale: Correcting citations due to renumbering of the regulations the Board amended 12VAC5-412-100. On-site inspection. This amendment incorporates certain interpretative guidance previously issued by VDH, thereby creating more thorough, comprehensive and transparent regulations. This change clarifies the meaning of current patients, as well as what materials must be available to surveyors.
12VAC5-412-120. Plan of correction.	12VAC5-412-110. Plan of correction.	<p>A. Upon receipt of a written licensing report each abortion facility shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.</p> <p>B. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan of correction as determined by the OLC. The plan of correction shall contain for each violation cited:</p> <ol style="list-style-type: none"> 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date, not to exceed 30 working days from the exit date of the survey; 3. A description of the measures implemented to prevent a recurrence of the violation; and 4. The signature of the person responsible for the validity of the report. <p>C. The administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with Virginia Code § 32.1-27 or in</p>	Rationale: The Board has renumbered this section however; the provisions are unchanged.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>denial, revocation or suspension of a license in accordance with 12VAC5-412-130.</p> <p>D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p>	
N/A	12VAC5-412-120. OLC complaint investigations	N/A	<p><u>A. The OLC shall investigate any complaints regarding alleged violations of this chapter and applicable law. When the investigation is complete, the abortion facility and the complainant, if known, will be notified of the findings of the investigation.</u></p> <p><u>B. As required by the OLC, the administrator shall submit a plan of correction for any deficiencies found during a complaint investigation in accordance with 12VAC5-412-110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</u></p> <p>Rationale: The Board has added 12VAC5-412-120. OLC complaint investigations in order to be consistent with other VDH health care facility regulations.</p>
12VAC5-412-130. Denial, revocation or suspension of license.	12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.	<p>A. When the department determines that an abortion facility is (i) in violation of any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) 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</p>	Rationale: This section has been renamed for clarity however the provisions are unchanged.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>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 facility has the right to contest the denial, revocation or suspension of a license in accordance with the provisions of the Administrative Process Act (Virginia Code § 2.2-4000 et seq.).</p>	
N/A	12VAC5-412-140. Management and administration	N/A	<p><u>A. The abortion facility shall comply with:</u></p> <ol style="list-style-type: none"> <u>1. This chapter (12VAC5-412);</u> <u>2. Other applicable federal, state, or local laws and regulations; and</u> <u>3. The abortion facility's policies and procedures.</u> <p><u>B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.</u></p> <p><u>C. The abortion facility shall permit OLC inspectors to conduct inspections to:</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p>1. <u>Verify application information;</u></p> <p>2. <u>Determine compliance with this chapter and applicable law;</u></p> <p>3. <u>Review necessary records and documents; and</u></p> <p>4. <u>Investigate complaints.</u></p> <p><u>D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</u></p> <p>1. <u>Change of location.</u></p> <p>2. <u>Change of ownership.</u></p> <p>3. <u>Change of name.</u></p> <p>4. <u>Voluntary closure.</u></p> <p>5. <u>Change of administrator.</u></p> <p>6. <u>Change of operator.</u></p> <p><u>Notices shall be sent to the attention of the director of the OLC.</u></p> <p><u>E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.</u></p> <p>Rationale: The Board has added 12VAC5-412-140. Management and administration. This was done in order to be consistent with other VDH health care facility regulations.</p>
<p>12VAC5-412-140. Governing body.</p>	<p>12VAC5-412-150. Governing body.</p>	<p>A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility.</p> <p>B. There shall be disclosure of facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.</p>	<p>Rationale: The Board has renumbered this section however; the provisions are unchanged.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.</p> <p>D. The governing body shall have a formal organizational plan with written bylaws. These shall clearly set forth organization, duties and responsibilities, accountability, and relationships of professional staff and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.</p> <p>E. The bylaws shall include at a minimum the following:</p> <ol style="list-style-type: none"> 1. A statement of purpose; 2. Description of the functions and duties of the governing body, or other legal authority; 3. A statement of authority and responsibility delegated to the administrator and to the clinical staff; 4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and 5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff. 	
<p>12VAC5-412-150. Policy and procedures manual.</p>	<p>12VAC5-412-160. Policies and procedures.</p>	<p>Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering, at a minimum, the following topics:</p> <ol style="list-style-type: none"> 1. Personnel; 2. Types of elective and emergency procedures that may be performed in the facility; 	<p><u>A.</u> Each abortion facility shall develop, implement, and maintain an appropriate policy and procedures manual. <u>documented policies and procedures, which shall be readily available on the premises and</u> The manual shall be reviewed annually and updated as necessary by the <u>licensee governing body.</u> The manual shall include provisions covering, at a minimum, the following topics: <u>The policies and procedures shall include but shall not be limited to the</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>3. Types of anesthesia that may be used;</p> <p>4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;</p> <p>5. Obtaining written informed consent of the patient prior to the initiation of any procedures;</p> <p>6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;</p> <p>7. Infection prevention;</p> <p>8. Risk and quality management;</p> <p>9. Management and effective response to medical and/or surgical emergency;</p> <p>10. Management and effective response to fire;</p> <p>11. Ensuring compliance with all applicable federal, state, and local laws;</p> <p>12. Facility security;</p> <p>13. Disaster preparedness;</p> <p>14. Patient rights;</p> <p>15. Functional safety and facility maintenance; and</p> <p>16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable.</p> <p>These policies and procedures shall be based on recognized standards and guidelines. A copy of the approved policies and procedures and revisions thereto shall be made available to the OLC upon request.</p>	<p><u>following topics:</u></p> <p>1. Personnel;</p> <p>2. Types of elective and emergency procedures that may <u>services</u> performed in the abortion facility;</p> <p>3. Types of anesthesia that may be used;</p> <p>4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;</p> <p>5. Obtaining <u>informed</u> written consent of the patient <u>pursuant to § 18.2-76 of the Code of Virginia</u> prior to the initiation of any procedures;</p> <p>6. <u>When to use sonography to assess patient risk; When to use ultrasound to determine gestational age and when indicated to assess patient risk;</u></p> <p>7. Infection prevention;</p> <p>8. <u>Quality and risk management; Risk and quality management;</u></p> <p>9. Management and effective response to medical and/or surgical emergency;</p> <p>10. Management and effective response to fire;</p> <p>11. Ensuring compliance with all applicable federal, state, and local laws;</p> <p>12. <u>Abortion</u> facility security;</p> <p>13. Disaster preparedness;</p> <p>14. Patient rights;</p> <p>15. Functional safety and abortion facility maintenance; and</p> <p>16. Identification the person to whom responsibility for operation and maintenance of the facility is delegated <u>of the administrator and methods established by the governing</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p>body for holding the administrator <u>the licensee</u> responsible and accountable.</p> <p><u>B.</u> These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved <u>by the governing body</u> and revisions thereto shall be made available to the OLC upon request.</p> <p>Rationale: The Board has made several changes to 12VAC5-412-160. Policies and procedures. The first change was removing the term manual. Removal of this term allows for on-line or electronic policies and procedures. Next, the Board made some amendments in order to be consistent with the amendment to Virginia Code § 18.2-76. Finally the Board made amendments in order to be consistent with other VDH health care facility regulations.</p>
<p>12VAC5-412-160. Administrator.</p>	<p>12VAC5-412-170. Administrator.</p>	<p>A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.</p> <p>B. Any change in the position of the administrator shall be reported immediately by the licensee to the department in writing.</p> <p>C. A qualified individual shall be appointed in writing to act in the absence of the administrator.</p>	<p><u>A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility, including but not limited to:</u></p> <ol style="list-style-type: none"> <u>1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;</u> <u>2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;</u> <u>3. Ensuring the accuracy of public information materials and activities;</u> <u>4. Ensuring an effective budgeting and accounting system is implemented; and</u> <u>5. Maintaining compliance with applicable laws and regulations and</u>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p><u>implementing corrective action.</u></p> <p>B. Any change in the position of the administrator shall be reported immediately by the licensee <u>governing body</u> to the department in writing.</p> <p>C. A qualified individual shall be appointed in writing to act in the absence of the administrator</p> <p>Rationale: The Board made several changes to 12VAC5-412-170. Administrator in order to be consistent with other VDH health care facility regulations.</p>
<p>12VAC5-412-170. Personnel.</p>	<p>12VAC5-412-180. Personnel.</p>	<p>A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.</p> <p>B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.</p> <p>C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.</p> <p>D. When abortions are being performed, a staff member</p>	<p>Rationale: VDH has renumbered this section however; the provisions are unchanged.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.</p> <p>E. The facility shall develop, implement and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.</p> <p>F. Job Descriptions.</p> <ol style="list-style-type: none"> 1. Written job descriptions that adequately describe the duties of every position shall be maintained. 2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications. 3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised. <p>G. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.</p> <p>H. Personnel policies and procedures shall include, but not be limited to:</p>	

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;</p> <p>2. Process for verifying current professional licensing or certification and training of employees or independent contractors;</p> <p>3. Process for annually evaluating employee performance and competency;</p> <p>4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and</p> <p>5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.</p> <p>I. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.</p>	
12VAC5-412-180. Clinical staff.	12VAC5-412-190. Clinical staff.	<p>A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and non-physician health care practitioners shall be clearly defined.</p> <p>B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only</p>	Rationale: The Board has renumbered this section however; the provisions are unchanged.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>performed by physicians who are qualified by training and experience.</p> <p>C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the facility.</p> <p>D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.</p>	
12VAC5-412-190. Consent of the patient.	N/A	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.	Rationale: The Board has moved the Consent of the Patient and Minors provisions to the Patient Care Management section beginning at 12VAC5-412-230.
12VAC5-412-200. Minors.	N/A	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	Rationale: The Board has moved the Consent of the Patient and Minors provisions to the Patient Care Management section beginning at 12VAC5-412-230.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>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>12VAC5-412-210. Patients' rights.</p>	<p>12VAC5-412-200. Patients' rights.</p>	<p>A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of 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>B. The facility shall establish and maintain complaint handling procedures which specify the:</p> <ol style="list-style-type: none"> 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. <p>C. The facility shall designate staff responsible for complaint resolution, including:</p> <ol style="list-style-type: none"> 1. Complaint intake, including acknowledgment of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. 	<p>Rationale: The Board has renumbered this section however; the provisions are unchanged.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>D. The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service.</p> <p>E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> 1. Facility contact person; and 2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place. <p>F. The facility shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained for no less than three years.</p>	
<p>12VAC5-412-300. Quality assurance.</p>	<p>12VAC5-412-210. Quality management</p>	<p>A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.</p> <p>B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:</p> <ol style="list-style-type: none"> 1. Staffing patterns and performance; 2. Supervision appropriate to 	<p>Rationale: The Board moved Section 300 of the Emergency Regulations "Quality assurance" to section 210 and renamed this section Quality management. This change was made in order to be consistent with other VDH health care facility regulations. No changes were made to the regulatory text.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>the level of service;</p> <ol style="list-style-type: none"> 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and 7. Staff concerns regarding patient care. <p>C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:</p> <ol style="list-style-type: none"> 1. A physician; 2. A non-physician health care practitioner; 3. A member of the administrative staff; and 4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff. <p>In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.</p> <p>D. Measures shall be implemented to resolve problems or concerns that have been identified.</p> <p>E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.</p>	

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-412-220. Infection prevention.	N/A	<p>A. The abortion facility shall have an infection prevention plan that encompasses the entire 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 facility shall have received training in basic infection prevention, and shall also be involved in the annual review. <p>B. Written infection prevention policies and procedures shall include, but not be limited to:</p> <ol style="list-style-type: none"> 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate 	N/A

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>measures to prevent transmission of community-acquired infection within the facility;</p> <ol style="list-style-type: none"> 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. <p>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:</p> <ol style="list-style-type: none"> 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of 	

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>cleaning agents (e.g., dilution, contact time, management of accidental exposures);</p> <p>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;</p> <p>5. Procedures for handling/temporary storage/transport of soiled linens;</p> <p>6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;</p> <p>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;</p> <p>8. Procedures for appropriate disposal of non-reusable equipment;</p> <p>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</p> <p>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</p> <p>11. An effective pest control program, managed in accordance with local health and environmental regulations;</p>	

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>and</p> <p>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.</p> <p>D. The facility shall have an employee health program that includes:</p> <ol style="list-style-type: none"> 1. Access to recommended vaccines; 2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients; 3. An exposure control plan for blood borne pathogens; 4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; 5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection. <p>E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities:</p> <ol style="list-style-type: none"> 1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop; 2. A procedure for surveillance, documentation and tracking of reported infections; and 3. Policies and procedures for reporting conditions to the local health department in accordance with the 	

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.	
12VAC5-412-230. Limitation of services offered by abortion facilities.	12VAC5-412-230. Patient services; patient counseling	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>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. <u>No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</u></p> <p>C. <u>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.</u></p> <p>D. <u>When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.</u></p> <p>E. <u>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.</u></p> <p>F. <u>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</u></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p><u>infection develop.</u></p> <p>Rationale: Section 230 Patient services; patient counseling the beginning of Part IV Patient Care Management has several additions taken from elsewhere in the emergency regulations including Sections 190 and 200. These amendments were made in order to be consistent with other VDH health care facility regulations.</p>
<p>12VAC5-412-240. Medical testing, patient counseling and laboratory services.</p>	<p>N/A</p>	<p>A. Prior to the initiation of any abortion, a medical history and physical examination, to include confirmation of pregnancy, shall be completed for each patient.</p> <ol style="list-style-type: none"> 1. Use of any additional medical testing, including but not limited to ultrasonography, 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 pregnancy test and determination or documentation of Rh factor. 3. The 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. The abortion facility shall offer each patient, in a language or manner they understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies</p>	<p>A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, <u>and completion of all the requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia.</u> shall be completed for each patient.</p> <ol style="list-style-type: none"> 1. Use of any additional medical testing including but not limited to ultrasonography, 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 <u>abortion</u> 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. The abortion facility shall offer each patient, in a language or manner they understand, appropriate counseling and</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>and procedures for the provision of family planning and post-abortion counseling to its patients.</p> <p>C. 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).</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. 3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly. <p>D. 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>E. 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 (9 VAC20-120).</p>	<p>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>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. 3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly. <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>Rationale: The Board made a few minor changes to section 240 Medical testing and laboratory services due to the amendment to the Informed Consent statute.</p>
12VAC5-412-	N/A	A. The anesthesia service shall	A. The anesthesia service shall

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
250. Anesthesia service.		<p>be managed in accordance 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. The 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.</p> <p>D. 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>E. 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; 	<p>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. The 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.</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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>3. Precordial stethoscope;</p> <p>4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;</p> <p>5. Continuous electrocardiograph;</p> <p>6. Devices for measuring blood pressure, heart rate and respiratory rate;</p> <p>7. Defibrillator; and</p> <p>8. Accepted method of identifying and preventing the interchangeability of gases.</p> <p>F. When deep sedation, general anesthesia or a major conductive block is administered, 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 E of this section, an abortion facility administering general anesthesia, deep sedation or major conductive blocks shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 C:</p> <p>1. Drugs to treat malignant hyperthermia, when triggering agents are used;</p> <p>2. Peripheral nerve stimulator, if</p>	<p>8. Accepted method of identifying and preventing the interchangeability of gases.</p> <p><u>E. Elective general anesthesia shall not be used.</u></p> <p><u>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.</u></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 pharmacological agents as required by 18VAC85-20-360 C:</p> <p>1. Drugs to treat malignant hyperthermia, when triggering agents are used;</p> <p>2. Peripheral nerve stimulator, if a muscle relaxant is used; and</p> <p>3. If using an anesthesia machine, the following shall be included:</p> <p>a. End-tidal carbon dioxide monitor (capnograph);</p> <p>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;</p> <p>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;</p> <p>d. Vaporizer exclusion (interlock)</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>a muscle relaxant is used; and</p> <p>3. If using an anesthesia machine, the following shall be included:</p> <p>a. End-tidal carbon dioxide monitor (capnograph);</p> <p>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;</p> <p>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;</p> <p>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;</p> <p>e. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;</p> <p>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;</p> <p>g. Alarm systems for high</p>	<p>system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;</p> <p>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;</p> <p>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;</p> <p>g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and</p> <p>h. A gas evacuation system.</p> <p>H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria</p> <p>I. Elective general anesthesia shall not be used.</p> <p>Rationale: The Board made changes to this section to provide clarifying language and to be consistent with best practices.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>(disconnect), low (subatmospheric) and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and</p> <p>h. A gas evacuation system.</p> <p>H. 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.</p> <p>I. Elective general anesthesia shall not be used.</p>	
<p>12VAC5-412-260. Administration, storage and dispensing of drugs.</p>	<p>N/A</p>	<p>A. Controlled substances, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).</p> <p>B. Drugs, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed or administered by a physician.</p> <p>C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures</p>	<p>N/A</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.</p> <p>D. The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.).</p> <p>E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Drug Control Act of the Code of Virginia.</p>	
<p>12VAC5-412-270. Equipment and supplies.</p>	<p>N/A</p>	<p>An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:</p> <ol style="list-style-type: none"> 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; 5. Emergency medications, 	<p>N/A</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light; 8. Containers for soiled linen and waste materials with covers; and 9. Refrigerator.	
12VAC5-412-280. Emergency equipment and supplies.	N/A	An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support. Drugs shall include, at a minimum, those to treat the following conditions: 1. Cardiopulmonary arrest; 2. Seizure; 3. Respiratory distress; 4. Allergic reaction; 5. Narcotic toxicity; 6. Hypovolemic shock; and 7. Vasovagal shock.	N/A

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
<p>12VAC5-412-290. Emergency services.</p>	<p>N/A</p>	<p>A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for resuscitation and control of hemorrhage and other complications.</p> <p>B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support.</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.</p>	<p>A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, and related items for resuscitation and control of hemorrhage and other complications.</p> <p>B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support.</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. <u>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.</u></p> <p>Rationale: The Board amended 12VAC5-412-290 to reflect an amendment approved by the Board of Health at its June 15th, 2012 meeting. The amendment is designed to increase patient health and safety.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-412-300. Quality assurance.	12VAC5-412-210. Quality management	<p>A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.</p> <p>B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:</p> <ol style="list-style-type: none"> 1. Staffing patterns and performance; 2. Supervision appropriate to the level of service; 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and 7. Staff concerns regarding patient care. <p>C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:</p> <ol style="list-style-type: none"> 1. A physician; 2. A non-physician health care practitioner; 3. A member of the administrative staff; and 4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff. 	Section 300 as stated earlier was moved to section 210 and renamed Quality Management in order to be consistent with other VDH health care facility regulations. No changes were made to the regulatory text.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.</p> <p>D. Measures shall be implemented to resolve problems or concerns that have been identified.</p> <p>E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.</p>	
<p>12VAC5-412-310. Medical records.</p>	<p>12VAC5-412-300. Health information records.</p>	<p>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:</p> <ol style="list-style-type: none"> 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: <ol style="list-style-type: none"> a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; 	<p>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:</p> <ol style="list-style-type: none"> 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: <ol style="list-style-type: none"> a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes;

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes; h. Condition at time of discharge; i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies.	g. Physicians' and nurses' progress notes; h. Condition at time of discharge; i. Patient instructions (preoperative and postoperative); and j. Names of referral physicians or agencies; and <u>6. Any other information required by law to be maintained in the health information record.</u> Rationale: The Board made this change in order to reflect the change made in the Informed Consent statute.
12VAC5-412-320. Records storage.	12VAC5-412-310. Records storage.	Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored.	Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored. Rationale: The Board has moved this requirement 12VAC5-412-70. Return and/or reissuance of license.
12VAC5-412-330. Reports.	12VAC5-412-320. Required reporting.	A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence.	A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120). B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence. B. <u>The abortion facility shall report the following events to OLC:</u> <u>1. Any patient, staff, or visitor death;</u> <u>2. Any serious injury to a patient;</u> <u>3. Medication errors that necessitate a clinical intervention other than monitoring;</u> <u>4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs</u>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p><u>within or on the abortion facility grounds; and</u></p> <p><u>5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629).</u></p> <p><u>C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the:</u></p> <ol style="list-style-type: none"> <u>1. Abortion facility name;</u> <u>2. Type and circumstance of the event being reported;</u> <u>3. Date of the event; and</u> <u>4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.</u> <p><u>D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies.</u></p> <p><u>E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law.</u></p> <p><u>F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.</u></p> <p>Rationale: The Board made several changes to 12VAC5-412-320. Required Reporting. This was done in order to be consistent with other VDH health care facility regulations. The Board also added provision F in this section which requires abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.
12VAC5-412-340. Policies and procedures.	12VAC5-412-330. Abortion facility security and safety	The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: 1. Facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and 3. Provisions for disseminating safety-related information to employees and users of the facility.	The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to: 1. <u>Abortion</u> facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and 3. Provisions for disseminating safety-related information to employees and users of the <u>abortion</u> facility. Rationale: Technical changes
12VAC5-412-350. Disaster preparedness.	12VAC5-412-340. Disaster preparedness.	A. Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster. B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.	Rationale: The Board has renumbered this section however; the provisions are unchanged.
12VAC5-412-360. Maintenance.	12VAC5-412-350. Maintenance.	A. The 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	A. The <u>abortion</u> 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,

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		<p>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>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: Technical change.</p>
<p>12VAC5-412-370. Fire-fighting equipment and systems.</p>	<p>12VAC5-412-360. Fire-fighting equipment and systems.</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. Corridor Obstructions. 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</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. Corridor Obstructions. 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>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).	Rationale: Technical change
12VAC5-412-380. Local and state codes and standards.	12VAC5-412-370. Local and state codes and standards	<p>Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. 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 Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001. Entities operating as of the effective date of these regulations 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>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.</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><u>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.</u></p> <p>Rationale: The Board amended 12VAC5-412-370 to state that, in order to determine whether the abortion facility is in compliance with the provisions of this section, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility</p>