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Proposed 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 minimum standards for facilities performing five or more first trimester abortions per month.
Date this document prepared	September 17, 2012

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

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 proposed 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 proposed 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.

Acronyms and Definitions

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

The acronyms that appear in this document are as follow:
(i) CDC as an abbreviation of Centers for Disease Control and Prevention
(ii) HIPAA as an abbreviation of Health Insurance Portability and Accountability Act
(iii) NOIRA as an abbreviation of Notice of Intended Regulatory Action
(iv) OLC as an abbreviation of Office of Licensure and Certification
(v) VDH as an abbreviation of Virginia Department of Health

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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, 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 briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The majority of the provisions in this regulatory action are currently contained in the Emergency Regulations. However, some revisions to the provisions of the Emergency Regulations have been proposed as part of this action. The following is a summary of key provisions of the proposed 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, et seq.).

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 15th, 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, not12VAC5-410.
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 the regulatory action poses 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. 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 promulgate these

regulations." Because proposed 12VAC5-412-370 conflicts with Virginia Code § 32.1-127.001, the Board has exceeded its authority. Thus, this Office cannot certify these Regulations."

The amendment to 12VAC5-412-370 approved by the Board on June 15, 2012 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."

Section 32.1-127.001 of the Code of Virginia states: "Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health."

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..." At this time, VDH does not have the memorandum necessary from the OAG. Therefore, in compliance with the provisions of EO14, the proposed regulatory package cannot be submitted 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 are being 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 amended 12VAC5-412-370 to state 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.

Requirements more restrictive than federal

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

There are no applicable federal requirements associated with these regulations.

Localities particularly affected

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

It is not anticipated that any one locality will bear a disproportionate material impact that would not be experienced by other localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Erik Bodin, Director of Office of Licensure and Certification, Virginia Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, (804) 367-2127 (phone), (804) 367-2149 (fax), or erik.bodin@vdh.virginia.gov (email). Written comments must include the name and address of the commenter. In order to be considered, comments must be hand delivered by the close of business on the last date of the public comment period or submitted by fax, email or to the Regulatory Town Hall website by midnight on the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the *Virginia Register of Regulations* and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (**http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi**). Both oral and written comments may be submitted at that time.

Economic impact

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

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	VDH anticipates that the implementation and enforcement of these regulations will require the addition of two full time medical facility inspector positions at an estimated annual cost of $145,600. Funds would be non-general fund licensing fees (1%) and general fund (99%) and would be on-going expenditures. VDH has received additional funding in the 2012 Appropriation Act which will enable it to cover this expense.
Projected cost of the *new regulations or changes to existing regulations* on localities.	VDH anticipates that the implementation of these regulations will not create any cost to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Twenty abortion facilities required to be licensed under the emergency regulations are currently in operation in the Commonwealth. All have submitted

	an application for licensure and a letter expressing their readiness for an onsite survey. VDH will schedule each of the applicant abortion facilities into the weekly licensed/certified facility inspection survey schedule. To date nine of the twenty abortion facilities have had their on-site inspection or are scheduled to be surveyed.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	All twenty of these abortion facilities in operation in the Commonwealth will be affected as all twenty facilities have applied for licensure and thus, must comply with the regulations.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The twenty abortion facilities in operation in the Commonwealth are small businesses. VDH has no data on the square footage size of the abortion facilities or on the amount of renovation or new equipment that will be required to be compliant with the regulations. However, it is expected that the abortion facilities will range in size, the degree of modification, and new equipment required. VDH anticipates that abortion facilities will be able to be grouped into one of three classifications based on the modifications that will be required to meet deficiencies identified on the initial licensure survey: a) none to minor renovations and equipment purchases, at an estimated average cost of $5 per square foot, b) moderate renovations and equipment purchases would have an estimated average cost of $130 per square foot, and c) major renovations and equipment purchases would have, an estimated average cost of $525 per square foot. VDH anticipates that the administrative costs to comply with the regulations (develop application, participate in an onsite inspection survey, develop a plan of correction) will vary but should not require more than 16 man-hours per year on average. Section 370 of the proposed regulations allows entities operating as of the effective date of the emergency regulations to be licensed in the facility's current buildings if the 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.
Beneficial impact the regulation is designed to produce.	This regulation is designed to promote and assure the health and safety of patients who receive first trimester abortion services.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts § 32.1-127 of the Code of Virginia to mandate that the Board of Health promulgate these regulations. Therefore there are no non-regulatory alternatives to this regulatory action.

Regulatory flexibility analysis

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

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts § 32.1-127 of the Code of Virginia and classifies facilities that perform more than five first trimester abortions per month as a category of hospital. In developing these regulations, VDH examined the regulatory provisions of 23 other states that already regulate abortion facilities, reviewed national and international standards, criteria and guidelines, consulted with a panel of OB/GYNs from Virginia's academic medical centers, examined the regulatory provisions governing hospitals and other types of health care facilities in Virginia, and received legal advice from the Office of the Attorney General. Chapter 670 (2011) does not authorize VDH to exempt small businesses from the provisions of the regulations. The proposed regulations are generally consistent with approaches taken by many other states, while also reflecting current best practices and national recommendations in areas such as infection prevention. The regulatory provisions governing facility design and construction are based on Virginia Code § 32.1-127.001.

Small business impact review result

In order to minimize the economic impact of regulations on small businesses, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination of whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

NOTE: If the NOIRA Agency Background Document did not contain an announcement that you were conducting a small business impact review, please delete this entire small business impact review section. Otherwise, report the result of the small business impact review by completing this section.

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts § 32.1-127 of the Code of Virginia to classify facilities that perform five or more first trimester abortions per month as a category of hospital and mandates the Board of Health to promulgate these regulations. Therefore, there is a continued and ongoing need for regulation. All twenty known abortion facilities in the Commonwealth

have applied for licensure although none has yet been licensed. The nature of complaints and comments received concerning the regulation from the public center around the necessity of specific designated construction requirements, exempting existing facilities from building design and construction requirements, and differentiating between facilities that perform medication abortion and those that perform surgical abortion. These comments and complaints are elaborated in more detail below. The regulation is of moderate complexity. The regulation does not overlap, duplicate or conflict with federal or state law or regulation. The emergency regulations went into effect on 12/29/2011.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

A 30-day public comment period was held from January 16, to February 15, 2012. VDH received 1,539 comments during the public comment period. Two public hearings were held during the public comment period, on January 27, 2012 in Richmond and on February 3, 2012 in Alexandria . VDH has reviewed and summarized all of the public comments received concerning the NOIRA as part of its work to develop permanent replacement regulations.

Comment	Agency response
Dr. James B. Kenley on behalf of the Virginia Coalition to Protect Women's Health, Patrick J. Hurd on behalf of Planned Parenthood of Southeastern Virginia, Shelley Abrams on behalf of A Capital Women's Health Clinic, and Jill Abbey on behalf of Richmond Medical Center for Women commented the facility design and construction requirements located in 12VAC5-412-380 are inappropriate. The Emergency Regulations require facilities to comply with Part 1 and Sections 3.1 and 3.7 of the 2010 Guidelines for Design and Construction of Health Care Facilities. The commenters state that the Facility Guidelines Institute (FGI) created the Guidelines as a guide for designing and constructing new health care facility projects, and did not intended for them to apply to existing facilities. The commenters also state that while other VDH regulations for licensure of hospitals, outpatient surgical hospitals and nursing facilities incorporate the Guidelines, those regulations govern only new construction and not existing facilities.	12VAC5-412-370 is written based on Virginia Code § 32.1-127.001. VDH has subsequently issued interpretive guidance concerning the design and construction requirements. Please note in the proposed regulations this provision appears in 12VAC5-412-370.
The Virginia Coalition to Protect Women's Health commented the emergency regulations should distinguish between facilities that offer medication abortion and those that offer medication and/or surgical abortion. The commenter stated that it is medically inappropriate to require facilities that provide only medication abortion to meet the extensive physical plant requirements imposed on abortion facilities under the regulations. According to the commenter, the same is true of the regulations' requirements for anesthesia services, examination of fetal tissue, and certain staffing,	Virginia law does not distinguish between medication and surgical abortions and thus, the Board of Health does not have authority to do so.

equipment and emergency services requirements.	
The Virginia Coalition to Protect Women's Health, A Women's Clinic, and the Richmond Medical Center for Women commented that the regulatory provisions concerning issuance of variances should be consistent with comparable regulations for all other health care facilities licensed by VDH. The Emergency Regulations only authorize the Commissioner to issue "temporary" variances, and only upon a showing that the requirement "would be an impractical hardship unique to the abortion facility." The commenters stated the authority of the Commissioner to issue a variance from regulatory requirements for an abortion facility is different from the Commissioner's variance authority with respect to general hospitals, outpatient surgical hospitals and nursing facilities. In those cases, the Commissioner has the authority to issue a "permanent" variance if the enforcement of a regulation would be "clearly impractical."	As VDH completes periodic reviews of the regulations governing hospitals, outpatient surgical hospitals and nursing facilities, it will work to develop a consistent approach to the issuance of variances.
Dr. James B. Kenley on behalf of the Virginia Coalition to Protect Women's Health, Patrick J. Hurd on behalf of Planned Parenthood of Southeastern Virginia, Shelley Abrams on behalf of A Capital Women's Health Clinic, and Jill Abbey on behalf of Richmond Medical Center for Women commented the regulatory provisions pertaining to patient and provider confidentiality need strengthening. The commenters state that the permanent regulations should allow VDH to access patient records and related materials only after health care facilities have a reasonable period of time to redact the records and other materials of all identifying information. The commenters also state that VDH should revise the regulations to specify that 1) VDH employees should not remove patient records from the premises of the facility, and 2) VDH employees may not interview current patients without their explicit permission. In addition, the commenters state the permanent regulations should provide stringent confidentially protections for all information concerning health care facilities that provide abortion care and concerning individuals who provide that care. For example, VDH should accept redacted disaster and other emergency plans, facility operations policies and protocols, and require disclosure of abortion patients to VDH representatives only for those patients scheduled on the day of the onsite survey.	VDH disagrees. Section 32.1-25 of the Code of Virginia provide the Commissioner or his designee the right to enter onto any property to inspect, investigate, evaluate, conduct tests or take samples for testing as 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 addresses these concerns. This policy applies to all VDH personnel whose jobs require handing 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, clients/patients and public 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. VDH has subsequently issued interpretative guidance to abortion facilities concerning treatment of confidential information. (http://www.vdh.virginia.gov/OLC/AcuteCare/documents/2012/pdf/Abortion%20facility%20FAQs%20revised%202%2010%2012.pdf)
The Richmond Medical Center for Women and A Capital Women's Health clinic commented that required transfer agreements between abortion facilities and general hospitals are not necessary. If a person comes to a hospital's emergency department with an emergency medical condition, the Emergency Medical Treatment and Labor Act (EMTALA) requires the hospital to treat and	VDH disagrees. The purpose of EMTALA is to prevent facilities from refusing to treat patients due to their inability to pay. EMTALA requires a hospital to provide treatment "within its capacity" and if the hospital does not have the capability to treat a patient's condition to make an "appropriate" transfer. Thus, although EMTALA requires hospitals to admit and treat patients presenting with

stabilize the patient or transfer the patient to another facility. As a result, the commenters state, "it adds nothing to patient safety to force individual health care providers to arrange transfer agreements with local hospitals…." According to the commenters, the permanent regulations should eliminate the required transfer agreement provision.	an emergency medical condition, if the hospital does not have the equipment or personnel necessary to treat the patient EMTALA requires the hospital to transfer the patient to a medical facility that can. Thus, if VDH were to rely solely on EMTALA, a patient who presents with an emergency medical condition in an abortion facility could potentially be transferred twice before receiving the medical care they need, once from the abortion facility to a nearby hospital and again to a hospital that is qualified to treat the patient. The "transfer agreement" provision, 12VAC5-412-290 (C), not only ensures needed emergency treatment of abortion patients but is intended to have a clinic determine the closest hospital with the necessary and appropriate equipment and personnel before an emergency presents to prevent a patient from undergoing multiple transfers.
The Virginia Coalition to Protect Women's Health, A Capital Women's Clinic and Richmond Medical Center for Women commented that VDH should eliminate from the permanent regulations the incorporation of "Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia." Section 12VAC5-412-130 of the Emergency Regulations allows for denial, suspension or revocation of a license for any violation of any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation. According to the commenters, VDH can take such action no matter "however minor and unrelated to patient safety" a violation may be. The commenters also state that the regulations are unclear about which statutes and regulations abortion facilities must comply with in order to obtain a license and remain licensed. The commenters recommend that the permanent regulations only require abortion facilities to comply with applicable sections of the statute.	This section is written in conformance with Virginia Code § 32.1-135. VDH has subsequently issued interpretative guidance to abortion facilities identifying specific Code sections for which it will take enforcement action against abortion facilities in the event of violations. (http://www.vdh.virginia.gov/OLC/AcuteCare/documents/2012/pdf/Abortion%20facility%20FAQs%20revised%202%2010%2012.pdf)
Planned Parenthood of Southeastern Virginia commented that guidance and interpretive information provided by the VDH Office of Licensure and Certification should be incorporated into the permanent regulations. A comment provided recommended amending language, which would incorporate guidance provided by VDH subsequent to approval of the Emergency Regulations, for the following sections 12VAC5-412: 20, 110C, 170G, 210D, and 240B.	VDH has proposed amendments to the emergency regulations to address this comment. VDH has proposed the following changes: • 12VAC5-412-100(C)- Clarification of the meaning of current patients, by adding the language "A list of patients receiving services on the day of survey as well as a list of all the abortion facility's patients for the previous 12 months shall be provided to the surveyor within 2 hours of arrival if requested." . • 12VAC5-412-180(F) - Addition of the language "Electronic availability of the personnel files to the OLC surveyor will meet this requirement." This clarifies the record requirements of the facility. • 12VAC5-412-200(D) - Addition of the language "Any patient seeking an abortion," clarifying which patients must receive

	counseling. • 12VAC5-412-230(E) -Addition of the language "Patient seeking abortion services," clarifying which patients must receive copies of complaint procedures.
The Virginia Coalition to Protect Women's Health commented that the permanent regulations should not derive standards from external sources. The Emergency Regulations require abortion facilities to comply with a number of outside statutes, guidelines and other materials, which is problematic for a number of reasons. First, the regulations require compliance with "current" versions. Second, some of the referenced material does not seem to exist or is difficult to find. Third, the referenced materials may not be the most medically appropriate or the only source of guidance on the particular issue.	VDH disagrees. Incorporation by reference is a common practice in Virginia state regulations. However, VDH acknowledges that some of this information may not appear readily accessible to entities coming under licensure for the first time. Therefore, a dedicated page has been established on the agency web site at: http://www.vdh.virginia.gov/OLC/AcuteCare/abortionfacilities.htm that contains a variety of information of use to providers and interested persons. This web page is updated frequently. VDH welcomes meaningful suggestions or additions to this page.
The Institute for Policy Integrity commented the Board has failed to consider reasonable regulatory alternatives. The commenter states "the current administrative record indicates that the Board has thus far failed to adequately identify and consider viable alternatives to the proposed regulations." While tacitly acknowledging that legislation mandated the Board to promulgate regulations, the comments also stated "The notion that Senate Bill 924 precluded the Board from considering a range of alternatives strains basic rules of interpretation." This commenter also stated the Board has not yet considered economic impacts nor relied upon the best available information. The commenter also stated, "The lack of analysis conducted during the emergency rulemaking stage suggests that the Board has engaged in, and may be continuing to engage in, an incomplete, cursory and inadequate rulemaking process."	VDH disagrees. In preparing the emergency regulations VDH analyzed regulatory provisions from twenty-three other states which already regulated abortion facilities. Also, VDH consulted with a panel of OB/GYNs and reviewed standards and criteria from numerous other entities, international guidelines and recommendations, and ensured the regulations adhered to CDC guidelines for infection prevention. The building design and construction provisions are written based on Virginia Code § 32.1-127.001. Finally, the expedited emergency regulation process, pursuant to the Virginia Administrative Process Act, does not require production of an economic impact analysis prior to promulgation of emergency regulations.
268 commenters submitted a form comment, which stated the regulations threaten the availability of safe, legal first-trimester abortion and preventive reproductive health care in multiple locations throughout the state. These commenters stated requirements for clinic buildings were extensive and burdensome and further that they are unrelated to the services health centers provide and have no proven medical benefit. These commenters are concerned that the building requirements will reduce or eliminate patient access to health care by increasing the financial hurdles to health care for patients. These commenters believe the high standard of care provided by women's health centers is proven by their impressive safety record. They go on to state overregulation will limit access to a wide range of preventive reproductive health care services provided by women's health clinics, including life-saving cancer screenings, family planning, and	This comment does not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent). The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.

sexually transmitted infection testing and treatment.	
234 commenters submitted a form comment, which stated they strongly support the current regulations on abortion centers approved last year. These commenters believe regulations should be made permanent and should continue to include the strongest standards. These commenters went on to say Virginia's abortion centers must be licensed, regulated, and inspected to protect women's health and safety and they reject the premise that abortion is "health care" because it ends lives instead of healing them, but as long as the abortion industry is allowed to operate within the health care system it must be required to adhere to well-defined health and safety standards.	VDH notes the support for the emergency regulations that are currently in effect. For the permanent regulations, VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent).
50 commenters submitted a form comment, which stated they wished the Board to enact the strongest possible regulations on abortion clinics.	VDH notes the support for the emergency regulations that are currently in effect. VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent).
20 commenters submitted a form comment, which stated Virginians want these regulations to be permanent for the protection of women, and the prevention of heinous incidences like the kind linked with Dr. Brigham. These commenters further expressed concern that Dr. Brigham owns abortion facilities in the state of Virginia.	VDH notes the support for the emergency regulations that are currently in effect. VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent).
Andrea Alford, Ellen Shapiro and Joe Laughton Fields-Johnson representing Medical Students for Choice - Blacksburg Chapter commented these	This comment does not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to

regulations will not make abortion care safer, but will just make it more difficult for abortion providers to remain open and for women to continue to access the abortion care they need. These commenters went on to state that the emergency regulations are being supported by a minority of Virginians with an ideological agenda, and not the medical community. They went on to argue that the Board of Health heard testimony from abortion providers and members of the medical community opposing these medically unnecessary regulations and they still chose to reject numerous amendments offered to protect the safety and confidentiality of both providers and patients with little to no debate.	the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent). The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.
Joanne Merrifield R.N and Donald Schwab commented abortion centers should be held to the same strict regulations as Out Patient Surgical Centers and have to be inspected and follow OSHA standards.	The regulations (12VAC5-412-220) require abortion facilities to comply with OSHA's blood-borne pathogen requirements and with the OSHA requirements for reporting of workplace associated with injuries or exposure to infection. The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.
264 commenters expressed general support for the emergency regulations as written.	VDH notes the support for the emergency regulations that are currently in effect. VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and • Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent).
567 commenters expressed general opposition to the emergency regulations as written.	These comments do not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to the emergency regulations based on: • Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments; • OLC's review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC's other health care facility regulations; and

	• Ensuring that the regulatory provisions are consistent with the provisions of § 18.2-76 of the Code of Virginia (informed consent). The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.
131 comments did not express support or opposition to the regulations. Some of these comments encouraged a complete ban on abortion, some were individuals who believed they were commenting concerning the ultrasound bill (HB 462 of 2012) or the personhood bill (HB 1 of 2012), some were incomprehensible and some were the result of an individual improperly filling out the comment page on the Town Hall website (i.e. title but no comment)	VDH believes that no response is necessary for these comments, as they do not speak to the regulations.

Family impact

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

The proposed regulatory action will not have any impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

The proposed regulations are intended to replace emergency regulations. Listed below are 1) all differences between the pre-emergency regulation and this proposed regulation:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
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	Proposed change: "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

		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. Outpatient abortion clinics are deemed a category of outpatient hospitals.	medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. ~~Outpatient abortion clinics are deemed a category of outpatient hospitals.~~ Intent: Abortion facilities will be governed by 12VAC5-412, not 12VAC5-410.
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, outpatient surgery, outpatient abortions)	Proposed change: 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, <u>and</u> outpatient ~~surgery, outpatient abortions)~~ <u>surgery)</u>. Intent: Abortion facilities will be governed by 12VAC5-412, not 12VAC5-410.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-412-10. Definitions.	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 which five or more first trimester abortions per month are performed. "Administrator" means the person appointed by the	N/A	Intent: Define key terms used in the regulations. Likely impact: Clear understanding of terms used in the regulations.

	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. "Commissioner" means the State Health Commissioner. "Department" means the Virginia Department of Health. "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.		
12VAC5-412-20. General.	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. No person or entity shall establish, conduct, maintain, or operate in this state, any abortion facility 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.	§ 32.1-27 of the Code of Virginia. Penalties, injunctions, civil penalties and charges for violations.	Intent: Establish licensure requirements for abortion facilities. Likely impact: Facilitate identification and oversight of licensed abortion facilities.
12VAC5-412-30. Classification.	Abortion facilities shall be classified as a category of hospital.	N/A	Intent: Compliance with statutory mandate established by SB 924 of 2011. Likely impact: Increase in the health and safety protections at

			Virginia's abortion facilities.
12VAC5-412-40. Separate license.	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. Abortion facilities which have separate organized sections, 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.	N/A	Intent: Each abortion facility must have its own license. Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-50. Request for issuance.	A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to the 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 abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of 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 application for licensure shall be made at least 30 days in advance of a change of ownership or location.	N/A	Intent: Specify process for issuing abortion facility licenses Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-60. License expiration and renewal.	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. 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	N/A	Intent: Specify process for license expiration and renewal. Likely impact: Effective VDH oversight of abortion facilities.

	accepted. C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal. 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.		
12VAC5-412-70. Return and/or Reissuance of License.	A. It is the responsibility of the facility's governing body to maintain a current and accurate license at all times. B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes: 1. Change of location. 2. Change of ownership. 3. Change of name. 4. Voluntary closure. 5. Change of administrator. 6. Change of operator. Notices shall be sent to the attention of the director of the OLC. 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 license shall be returned to the OLC within 5 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. 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 facility during the process of evaluating a change. E. The facility will be notified in writing by the OLC whether a license can be re-issued or a new application is needed.	N/A	Intent: Specify process for return and/or reissuance of a license. Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-80. Allowable variances.	A. The commissioner may authorize a temporary variance only to a specific regulation 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 regulation or requirements contained in a particular regulation 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 regulation constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the requirements that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to	N/A	Intent: Specify process for issuance of temporary variances. Likely impact: Temporary variances may be granted if the Commissioner deems appropriate.

	general applicability. The abortion facility may withdraw a request for a temporary variance at any time. B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision;(iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well being of patients. C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients. D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation to which the temporary variance was granted shall be resumed.		
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 abortion 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 in charge shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.	§ 32.1-25 of the Code of Virginia. Right of entry to inspect, etc.; warrants.	Intent: Incorporate the authority granted by Section 32.1-25 of the Code of Virginia into the regulations and specify process by which such authority may be used. Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-100. On-site inspection.	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 12VAC5-412-110. B. The abortion facility shall make available to the	§ 32.1-27 of the Code of Virginia. Penalties, injunctions, civil penalties and charges for violations.	Intent: Specify provisions governing on-site inspections of abortion facilities. Likely impact: Effective VDH

	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. 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 patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within 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 denial, suspension or revocation of the facility's license in accordance with 12VAC5-412-130.		oversight of abortion facilities.
12VAC5-412-110. Plan of correction.	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. 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: 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. 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 denial, revocation or suspension of a license in accordance with 12VAC5-412-130. D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.	§ 32.1-27 of the Code of Virginia. Penalties, injunctions, civil penalties and charges for violations. Regulation of Medical Care Facilities and Services	Intent: Specify process and timeline for submission of plan of correction and for review of the plan. Likely impact: Facilitate VDH oversight of abortion facilities.
12VAC5-412-120. OLC complaint investigations.	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. B. As required by the OLC, the administrator shall	N/A	Intent: Define responsibilities of OLC and facility administrator pertaining to

	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.		complaint investigations. Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-130. Violation of this chapter or applicable law; Denial, revocation or suspension of license.	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. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provisions of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The abortion facility has the right to contest the denial, revocation or suspension of a license in accordance with the provisions of the Administrative Process Act (Virginia Code § 2.2-4000 et seq.).	Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) Regulation of Medical Care Facilities and Services. § 32.1-135 of the Code of Virginia - Revocation or suspension of license or certification; restriction or prohibition of new admissions to nursing home. § 2.2-4000 of the Code of Virginia - Administrative Process Act	Intent: Specify process for denial, revocation or suspension of an abortion facility license. Likely impact: Effective VDH oversight of abortion facilities.
12VAC5-412-140. Management and administration	A. The abortion facility shall comply with: 1. This chapter (12VAC5 412); 2. Other applicable federal, state or local laws and regulations; and 3. The abortion facility's policies and procedures. B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law. C. The abortion facility shall permit OLC inspectors to conduct inspections to: 1. Verify application information; 2. Determine compliance with this chapter and applicable law; 3. Review necessary records and documents; and 4. Investigate complaints. D. An abortion facility shall give written notification	Other applicable federal, state or local laws and regulations.	Intent: Specify requirements for management and administration of abortion facilities. Likely impact: Effective VDH oversight of abortion facilities.

	30 calendar days in advance of implementing any of the following planned changes: 1. Change of location. 2. Change of ownership. 3. Change of name. 4. Voluntary closure. 5. Change of administrator. 6. Change of operator. Notices shall be sent to the attention of the director of the OLC. E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.		
12VAC5-412-150. Governing body.	A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the abortion facility. B. There shall be disclosure of abortion 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. C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs. 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. E. The bylaws shall include at a minimum the following: 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.	N/A	Intent: Specify the requirements and responsibilities of a facility's governing body. Likely impact: Facilitate VDH oversight of abortion facilities.
12VAC5-412-160. Policies and procedures.	A. Each abortion facility shall develop, implement and maintain documented policies and procedures, which shall be readily available on the premises, and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but shall not be limited to the following topics: 1. Personnel; 2. Types of elective services performed in the abortion facility;	§ 18.2-76 of the Code of Virginia-Informed written consent required; civil penalty.	Intent: Specify the required policies and procedures abortion facilities must implement, develop and maintain.

	3. Types of anesthesia that may be used; 4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge; 5. Obtaining informed written consent of the patient pursuant to § 18.2-76 prior to the initiation of any procedures; 6. When to use sonography to assess patient risk; 7. Infection prevention; 8. Quality and risk management; 9. Management and effective response to medical and/or surgical emergency; 10. Management and effective response to fire; 11. Ensuring compliance with all applicable federal, state, and local laws; 12. Abortion facility security; 13. Disaster preparedness; 14. Patient rights; 15. Functional safety and abortion facility maintenance; and 16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable. B. These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request.		Likely impact: Clarity of requirements and facilitation of VDH oversight of abortion facilities.
12VAC5-412-170. Administrator.	A. The governing body shall select an administrator who shall be responsible for the managerial, operational, financial and reporting components of the abortion facility, including but not limited to: 1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights; 2. Employing qualified personnel and ensuring appropriate personnel orientation, training education and evaluation; 3. Ensuring the accuracy of public information materials and activities; 4. Ensuring an effective budgeting and accounting system is implemented; and 5. Maintaining compliance with applicable laws and regulations and implementing corrective action. B. Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing. C. A qualified individual shall be appointed in writing to act in the absence of the administrator.	N/A	Intent: Specify the responsibilities the administrator. Likely impact: Clarity of process, requirements and facilitation of VDH oversight of abortion facilities.
12VAC5-412-180. Personnel.	A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services	§ 32.1-126.02 Hospital pharmacy employees; criminal records check required.	Intent: Specify requirements for selection and management of abortion facility

	provided. B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable. C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility. D. The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. E. Job Descriptions. 1. Written job descriptions that adequately describe the duties of every position shall be maintained. 2. Each job description shall include position title, authority, specific responsibilities and minimum qualifications. 3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised. F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable. G. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.		personnel and staff. Likely impact: Clarity of process, requirements and facilitation of VDH oversight of abortion facilities.

	H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.		
12VAC5-412-190. Clinical staff.	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. B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience. C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility. D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.	N/A	Intent: Specify requirements and responsibilities of clinical staff of abortion facilities. Likely impact: Clarity of requirements and responsibilities of clinical staff. Promotion of patient health and safety.
12VAC5-412-200. Patients' rights.	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. B. The abortion facility shall establish and maintain complaint handling procedures which specify the: 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. C. The abortion facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgment of	N/A	Intent: Specify the required protocol regarding patients' rights, including the requirements regarding the handling of complaints. Likely impact: Clarity of process, requirements and procedure regarding

	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. D. Any patient seeking an abortion shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service. E. The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the: 1. Abortion 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 abortion facility shall display a copy of this information in a conspicuous place. F. The abortion 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.		patient rights, specifically for handling of complaints. Facilitation of VDH oversight of abortion facilities.
12VAC5-412-210. Quality management.	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. B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences: 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. C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of: 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. In selecting members of this committee,	N/A	Intent: Specify the requirements and process for quality management. Likely impact: Clarity of requirements and process for quality management. Promotion of patient health and safety.

	consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients. D. Measures shall be implemented to resolve problems or concerns that have been identified. 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.		
12VAC5-412-220. Infection prevention.	A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review. B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility; 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;	Regulations for Disease Reporting and Control 12VAC5-90 OSHA Blood Borne Pathogen Requirements 29 CFR 1910.1030 OSHA Reporting of workplace-associated Injuries or Exposure to Infection Requirements 29 CFR 1952.4	Intent: Specify the requirements for abortion facilities' infection prevention plans and the process for implementing these plans. Likely impact: Clarity of process and requirements regarding infection prevention plans. Prevention of infectious disease. Promotion of patient health and safety.

	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. C. Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following: 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 cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 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; 8. Procedures for appropriate disposal of non-reusable equipment; 9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations; 10. Procedures for cleaning of environmental surfaces with appropriate cleaning products; 11. An effective pest control program, managed in accordance with local health and environmental regulations; and 12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department. D. The abortion facility shall have an employee		

	health program that includes: 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. E. The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities: 1. A procedure for surveillance, documentation and tracking of reported infections; and 2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.		
12VAC5-412-230. Patient services; patient counseling.	A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician. B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion. C. A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant to the provisions of § 18.2-76 of the Code of Virginia. D. When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care. E. The abortion facility shall offer each patient seeking an abortion, in a language or manner 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. F. There shall be an organized discharge planning	§ 16.1-241 of the Code of Virginia- Jurisdiction; consent for abortion. § 18.2-76 of the Code of Virginia - Informed written consent required; civil penalty.	Intent: Specify the required restrictions on abortions performed and requirements regarding patient counseling and discharge. Likely impact: Clarity of restrictions on abortion procedures as well as the requirements regarding patient counseling and discharge.

	process that includes an evaluation of the patient's capacity for self-care and discharge instructions for patients to include instructions to call or return if signs of infection develop.		
12VAC5-412-240. Medical testing and laboratory services.	A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to § 18.2-76, shall be completed for each patient. 1. Use of any additional medical testing shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented. 2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test. 4. A written report of each laboratory test and examination shall be a part of the patient's record. B. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). 1. Facilities for collecting specimens shall be available on site. 2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards. 3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly. C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately. D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).	§ 18.2-76 of the Code of Virginia - Informed written consent required; civil penalty. Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). Regulated Medical Waste Management Regulations (9VAC20-120).	Intent: Specify the medical testing to be performed prior to an abortion procedure and the policies and procedures a facility must implement regarding medical testing and laboratory services. Likely impact: Clarity of requirements, policies and procedures facilities must implement and observe regarding medical testing and laboratory services. Promotion of patient health and safety.
12VAC5-412-250. Anesthesia service.	A. The anesthesia service shall comply with the Office-Based Anesthesia provisions of the Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).	Office-Based Anesthesia provisions of the Regulations	Intent: Specify policies, procedures and equipment facilities must

	B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia. C. When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration. D. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 B: 1. Appropriate equipment to manage airways; 2. Drugs and equipment to treat shock and anaphylactic reactions; 3. Precordial stethoscope; 4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation; 5. Continuous electrocardiograph; 6. Devices for measuring blood pressure, heart rate and respiratory rate; 7. Defibrillator; and 8. Accepted method of identifying and preventing the interchangeability of gases. E. Elective general anesthesia shall not be used. F. If deep sedation, or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until the patient meets the discharge criteria. G. In addition to the requirements of subsection D of this section, an abortion facility administering, deep sedation or a major conductive block, or administering general anesthesia in an emergent situation shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 C: 1. Drugs to treat malignant hyperthermia, when triggering agents are used; 2. Peripheral nerve stimulator, if a muscle relaxant is used; and 3. If using an anesthesia machine, the following shall be included: a. End-tidal carbon dioxide monitor (capnograph); b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture; c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced; d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a	Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).	have and implement with regards to anesthesia. Likely impact: Clarity of required policies, procedures and equipment with regards to anesthesia. Promotion of patient health and safety.

	single anesthetic agent can be actualized on any anesthesia machine at one time; 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; f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered; g. Alarm systems for high (disconnect), low (subatmospheric) and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and h. A gas evacuation system. H. The abortion facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria.		
12VAC5-412-260. Administration storage and dispensing of drugs.	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). 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. C. Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures 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. 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.). 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 §	§ 54.1-3401 of the Drug Control Act of the Code of Virginia Chapter 33 of Title 54.1 of the Code of Virginia-Pharmacy Regulations Governing the Practice of Pharmacy 18VAC110-20 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances 18VAC110-30 Regulations Governing the Practice of Medicine, Osteopathic	Intent: Specify requirements abortion facilities must comply with regarding administration, storage and dispensing of controlled substances. Likely impact: Clarity of requirements abortion facilities must comply with regarding administration, storage and dispensing of controlled substances. Promotion of patient health and safety.

	54.1-3404 of the Drug Control Act of the Code of Virginia.	Medicine, Podiatry, and Chiropractic 18VAC85-20-400 et seq. § 54.1-3404 of the Drug Control Act of the Code of Virginia.	
12VAC5-412-270. Equipment and supplies.	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: 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, 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.	N/A	Intent: Specify equipment and supplies abortion facilities are required to maintain. Likely Impact: Clarity of required equipment and supplies abortion facilities must maintain. Promotion of patient health and safety.
12VAC5-412-280. Emergency equipment and supplies.	An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for 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	Intent: Specify emergency equipment and supplies abortion facilities are required to maintain. Likely impact: Clarity of required emergency equipment and supplies abortion facilities must maintain. Promotion of patient health and safety.
12VAC5-412-290. Emergency services.	A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for resuscitation and control of hemorrhage and other complications. B. An abortion facility that performs abortions using	N/A	Intent: Specify requirements abortion facilities must comply with regarding

	intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support. C. A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.		emergency services. Likely impact: Clarity of requirements of abortion facilities regarding emergency services. Promotion of patient health and safety.
12VAC5-412-300. Health Information records.	An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. 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; and 6. Any other information required by law to be maintained in the health information record.	N/A	Intent: Specify requirements abortion facilities must comply with regards to Health Information records. Likely impact: Clarity of requirements of abortion facilities regarding Health Information records. Effective VDH oversight of abortion facilities.
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.).	Health Insurance Portability and Accountability Act (42 USC § 1320d et	Intent: Specify requirements abortion facilities must comply with regards to

		seq.)	records storage. Likely impact: Clarity of the requirements of abortion facilities with regards to records storage.
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. The abortion facility shall report the following events to OLC: 1. Any patient, staff or visitor death. 2. Any serious injury to a patient. 3. Medication errors that necessitate a clinical intervention other than monitoring; 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and 5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 U.S.C. § 301 et seq. - PL 101-629). C. Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies. E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC except as required or permitted by law. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.	Board of Health Regulations Governing Vital Records (12VAC5-550-120). Safe Medical Devices Act of 1990 (21 U.S.C. § 301 et seq.- PL 101-629) § 8.01-581.17 of the Code of Virginia. Privileged communications of certain committees and entities. § 63.2-1509 of the Code of Virginia. Physicians, nurses, teachers, etc., to report certain injuries to children; penalty for failure to report.	Intent: Specify requirements of abortion facilities in regards to reporting. Likely impact: Clarity of abortion facility requirements in regards to reporting. Effective VDH oversight of abortion facilities.
12VAC5-412-330. Abortion Facility Security and Safety.	A. The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to:	N/A	Intent: Specify required policies and procedures abortion

	1. Abortion facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and B. 3. Provisions for disseminating safety-related information to employees and users of the abortion facility.		facilities must implement in regards to facility security and safety. Likely impact: Clarity of the required policies and procedures abortion facilities must implement in regards to facility security and safety. Promotion of patient health and safety.
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. An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.	N/A	Intent: Specify required policies and procedures abortion facilities must implement with regards to disaster preparedness. Likely impact: Clarity of the required policies and procedures abortion facilities must implement with regards to disaster preparedness. Promotion of patient health and safety.
12VAC5-412-350. Maintenance.	A. The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization. B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with	N/A	Intent: Specify requirements abortion facilities must comply with in regards to facility maintenance. Likely impact: Clarity of requirements

	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.		abortion facilities must comply with in regards to facility maintenance. Promotion of patient health and safety.
12VAC5-412-360. Fire-fighting equipment and systems	A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. C. 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).	Statewide Fire Prevention Code § 27-94 et seq. of the Code of Virginia	Intent: Specify requirements abortion facilities must comply with in regards to fire-fighting equipment and systems. Likely impact: Clarity of requirements abortion facilities must comply with in regards to fire-fighting equipment and systems. Promotion of patient health and safety.
12VAC5-412-370. Local and state codes and standards.	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.	Uniform Statewide Building Code § 32.1-127.001 Fetal death or induced termination of pregnancy report items. 12VAC5-550-120	Intent: Specify that abortion facilities are required to comply with state, local codes and additional standards. Likely impact: Clarity regarding what standards besides the “Regulations for Licensure of Abortion Facilities” facilities must comply with.

Summary of changes made to the regulatory language from the emergency to the proposed stage:

VDH has made a few revisions to the regulations from the emergency/NOIRA stage to the proposed stage. These revisions are mostly of a relatively minor nature. First VDH made amendments to make these regulations more consistent with other VDH health care facility regulations. This consisted of some minor additions including a definition but mostly consisted of moving language in order for the formatting to be more consistent. Also, VDH amended the regulations to incorporate some interpretative guidance previously issued by VDH, thereby creating more thorough, comprehensive and transparent regulations. In addition, minor changes were made in order for these regulations to be consistent with recent amendments to Virginia Code § 18.2-76. Finally, VDH added language to specify that abortion facility employees who are mandated reporters under Virginia Code § 63.2-1509 are required to report suspected child abuse. These changes are described in more detail below.

VDH has added the term and definition of the term "Administrator" in order to remain consistent with other VDH Health Care Facility Regulations.
VDH removed the term "Ownership/person" as it was duplicative of the definition of "Licensee"
VDH has added the term and definition of the term "Spontaneous miscarriage."
VDH has amended 12VAC-412-50 (C) to reflect an amendment approved by the Board of Health at its June 15th, 2012 meeting.
VDH has amended 12VAC5-412-70 in order to be consistent with other VDH health care facility regulations.
VDH 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.
VDH has amended 12VAC5-412-80. Allowable variances 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.
VDH 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.
VDH has added 12VAC5-412-120. OLC complaint investigations in order to be consistent with other VDH health care facility regulations.
VDH has added 12VAC5-412-140. Management and administration in order to be consistent with other VDH health care facility regulations.
VDH 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 VDH made some amendments in order to be consistent with the amendment to Virginia Code § 18.2-76. Finally VDH made amendments in order to be consistent with other VDH health care facility regulations.
VDH made several changes to 12VAC5-412-170. Administrator in order to be consistent with other VDH health care facility regulations.
VDH has moved the Consent of the Patient and Minors sections to the Patient Care Management section beginning at 12VAC5-412-230.
VDH 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.

Section 230 Patient services; patient counseling the beginning of Part IV Patient Care Management has several additions taken from elsewhere in the regulations. These amendments were made in order to be consistent with other VDH health care facility regulations.
VDH made a few minor changes to section 240 Medical testing and laboratory services due to the amendment to the Informed Consent statute.
VDH has amended 12VAC5-412-290 to reflect an amendment approved by the Board of Health at its June 15th, 2012 meeting.
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.
VDH made several changes to Section 320 Required Reporting in order to be consistent with other VDH health care facility regulations. VDH also added provision F in this section which requires 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.

VDH has 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

Summary of changes made to the regulatory language by amendment at the June 15, 2012 Board of Health Meeting:

The Board of Health voted to amend 12VAC5-412-50 (C). The amendment allows an abortion facility to apply for licensure with either a copy of the abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.

The Board of Health voted to amend 12VAC5-412-80 (A). The amendment specifies that in no event shall a temporary variance exceed the term of the license.

The Board of Health voted to amend 12VAC5-412-290. The amendment requires 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. The amendment further requires that all patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.

The Board of Health voted to amend 12 VAC5-412-370. The amendment required all construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities to 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. 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. [Note: on July 16, 2012, the Office of the Attorney General cited a conflict between this regulatory provision and §32.1-127.001 in stating that it could not certify the proposed regulations.]

Summary of changes made to the regulatory language by amendment at the September 14, 2012 Board of Health meeting:

The Board of Health voted to amend 12 VAC5-412-370. The amendment requires abortion facilities tocomply 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.