

State Board of Health – Executive Committee

Agenda

April 12, 2013 – 8:30 a.m.

Perimeter Center – Boardroom 2

9960 Mayland Drive

Richmond, Virginia 23233

Welcome and Introductions	Bruce Edwards, Chair
Discussion	Executive Committee Members
Adjourn	

State of Board of Health

Agenda

April 12, 2013 – 9:00 a.m.

Perimeter Center – Boardroom 2

9960 Mayland Drive

Richmond, Virginia 23233

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Mr. Edwards
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of December 14, 2012 Minutes	Mr. Edwards
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification

Public Comment

Note concerning Public Comment: A sign-up sheet for individuals wishing to address the Board during the public comment period will be available beginning at 7:45 a.m. Each individual will be allowed to put only one name on the sign-up sheet. There is limited seating within Boardroom 2, with seats available for 100 members of the public. Seating will be available on a first-come, first served basis. The maximum occupancy of Boardroom 2 is enforced by the Fire Marshal and cannot be exceeded.

Break

Regulatory Action Item

Regulations for Licensure of Abortion Facilities Mr. Bodin
12VAC5-412
(Final Regulations)

Lunch

Commissioner's Report Cynthia C. Romero, MD, FAAFP
State Health Commissioner

Regulatory Action Update Mr. Hilbert

Regulatory Action Item

Regulations for the Virginia Immunization David Trump, MD, MPH, MPA, Director
Information System Office of Epidemiology
12VAC5-115
(Final Regulations)

Appointment of Nominating Committee Mr. Edwards

Member Reports

Other Business

Adjourn

Note: The proceedings of the meeting will also be viewable via videoconference in Boardroom1. There is limited seating within Boardroom 1, with seats available for 80 members of the public. Seating will be available on a first-come, first served basis. The maximum occupancy of Boardroom 1 is enforced by the Fire Marshal and cannot be exceeded.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: April 2, 2013

TO: Virginia State Board of Health

FROM: Erik Bodin
Director - Office of Licensure and Certification

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

Enclosed for your review are final Regulations for Licensure of Abortion Facilities (12VAC5-412). The final regulations will replace the emergency Regulations for Licensure of Abortion Facilities that are currently in effect. Under state law, emergency regulations are only temporary in nature.

As mandated by Chapter 670 of the 2011 Acts of Assembly, the final regulations establish minimum standards for construction and maintenance; operation, staffing and equipping; staff qualifications and training; as well as requirements for policies related to infection prevention, disaster preparedness, and facility security.

The proposed regulations pertaining to the currently submitted final regulations were published in the Virginia Register of Regulations on January 28, 2013. A 60-day public comment period on the proposed regulations ended on March 29, 2013. A large volume of comments were received during the public comment period. A summary of those comments is contained in the attached Agency Background Document.

The Board of Health is requested to approve the final regulations. Should the Board of Health approve the final regulations, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the final regulations will be published in the Virginia Register of Regulations, and on the Virginia Regulatory Town Hall website, and a 30 day final adoption period will begin.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-412 12VAC5-410 (amendments)
Regulation title	Regulations for Licensure of Abortion Facilities
Action title	Establishes standards for facilities performing five or more first trimester abortions per month (12VAC5-412); deletes references to abortion facilities in the hospital regulations (12VAC5-410).
Date this document prepared	April 2, 2013

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

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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

Statement of final agency action

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

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

Legal basis

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

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

Purpose

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

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

Substance

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

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

Definitions

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

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

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

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

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

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

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

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

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

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

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

Procedures for Licensure or License Renewal

A license is valid for one year.

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

The Department may deny, suspend or revoke a license.

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

The Commissioner may rescind or modify a temporary variance.

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

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

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

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

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

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

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

Organization and Management

Each facility shall have a governing body.

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

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

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

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

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

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

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

Each facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care.

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

Quality Management and Infection Prevention

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

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

Patient Care

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

The facility shall offer each patient in a language or manner they understand appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.

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

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

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

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

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

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

Elective general anesthesia shall not be used.

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

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

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

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

A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the emergency department staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider

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

Health Information Records and Reports

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

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

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

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

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

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

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

Functional Safety and Maintenance

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

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

The abortion facility's structure, its component parts and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition.

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

Design and Construction

Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001.

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

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

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

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

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

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

relocations might be passed on to the facilities' patients, or potentially, result in some facilities electing to cease operations at some point in the future. VDH does not foresee any additional disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of public health and safety. There are no disadvantages associated with the proposed regulations in relation to the agency or the Commonwealth.

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

“All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation.”

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

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

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

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

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

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

Changes made since the proposed stage

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

None

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

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

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

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

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

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

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

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

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

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

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

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

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

<p>144 persons commented via email stating general opposition to the proposed regulations which seek "to impose unnecessary hurdles for women in Virginia seeking reproductive health care including not only abortion but also birth control, cancer screens, and routine reproductive health exams by forcing clinics to close." These commenters urge the Board of Health to "reject these unnecessary and harmful restrictions."</p>	<p>VDH notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>3,379 persons commented via form letter opposing the regulation stating the regulations should be based on health care needs, not politics, and that the proposed regulations will limit access to safe and legal abortion.</p>	<p>VDH notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>5 persons submitted form letters in support of the regulations stating the proposed regulations are reasonable, common sense measures to ensure that life-saving equipment is on hand, infections are prevented, and that clear written policies and building guidelines are in place.</p>	<p>VDH notes the support for the regulation.</p>
<p>1,120 persons commented via Townhall supporting the regulation, but did not cite specific sections for comment.</p>	<p>VDH notes the support for the regulation.</p>
<p>1,273 persons commented via Townhall opposing the regulation, but did not cite specific sections for comment.</p>	<p>VDH notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations.</p>
<p>377 comments did not express support or opposition to the regulation. Some of these comments encouraged a complete ban on abortion, some were incomprehensible, and some were the result of difficulty using the comment page of the TH (i.e., title but no comment).</p>	<p>VDH believes that no response is necessary for these comments as they do not speak to the regulation itself. The difficulty completing the comment was reported to the TH program management.</p>

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

None

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale

DEPARTMENT OF HEALTH
Regulations for Licensure of Abortion Facilities

Part I
Definitions and General Information and Procedures

Article 1
Definitions

12VAC5-410-10. Definitions.

As used in this chapter, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

"Board" means the State Board of Health.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Commissioner" means the State Health Commissioner.

"Consultant" means one who provides services or advice upon request.

"Department" means an organized section of the hospital.

"Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.

"Facilities" means building(s), equipment, and supplies necessary for implementation of services by personnel.

"Full-time" means a 37-1/2 to 40 hour work week.

"General hospital" means institutions as defined by § 32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

"Home health care department/service/program" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12VAC5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Medical" means pertaining to or dealing with the healing art and the science of medicine.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing home" means an institution or any identifiable component of any institution as defined by § 32.1-123 of the Code of Virginia with permanent facilities that include inpatient beds and whose primary function is the provision, on a continuing basis, of nursing and health related services for the treatment of patients who may require various types of long term care, such as skilled care and intermediate care.

"Nursing services" means patient care services pertaining to the curative, palliative, restorative, or preventive aspects of nursing that are prepared or supervised by a registered nurse.

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Organized" means administratively and functionally structured.

"Organized medical staff" means a formal organization of physicians and dentists with the delegated responsibility and authority to maintain proper standards of medical care and to plan for continued betterment of that care.

"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. ~~Outpatient abortion clinics are deemed a category of outpatient hospitals.~~

"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns or controls the physical facilities and/or manages or operates a hospital.

"Rural hospital" means any general hospital in a county classified by the federal Office of Management and Budget (OMB) as rural, any hospital designated as a critical access hospital, any general hospital that is eligible to receive funds under the federal Small Rural Hospital Improvement Grant Program, or any general hospital that notifies the commissioner of its desire to retain its rural status when that hospital is in a county reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

"Service" means a functional division of the hospital. Also used to indicate the delivery of care.

"Special hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g., tuberculosis, orthopedic, pediatric, maternity).

"Special care unit" means an appropriately equipped area of the hospital where there is a concentration of physicians, nurses, and others who have special skills and experience to provide optimal medical care for patients assigned to the unit.

"Staff privileges" means authority to render medical care in the granting institution within well-defined limits, based on the individual's professional license and the individual's experience, competence, ability, and judgment.

"Unit" means a functional division or facility of the hospital.

12VAC5-410-60. Separate license.

A. A separate license shall be required by hospitals maintained on separate premises even though they are operated under the same management. Separate license is not required for separate buildings on the same grounds or within the same complex of buildings.

B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, and outpatient surgery, outpatient abortions) surgery).

CHAPTER 412
REGULATIONS FOR LICENSURE OF ABORTION FACILITIES

Part I
Definitions and Requirements for Licensure

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 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 12 weeks from conception based on an appropriate clinical estimate by a licensed physician.

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

"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 (i) when the abortion facility is in compliance with all applicable federal, state, and local statutes and regulations and the provisions of this chapter and (ii) 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.

12VAC5-412-30. Classification.

Abortion facilities shall be classified as a category of hospital.

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 this chapter.

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 are 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.

12VAC5-412-60. License expiration and renewal.

A. Licenses shall expire at midnight April 30 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 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.

12VAC5-412-70. Return and/or reissuance of license.

A. It is the responsibility of the abortion 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 five calendar days of the abortion facility closing. The abortion facility's patients and the OLC shall be notified where all patient records will be located.

D. The OLC shall determine if any changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the abortion facility during the process of evaluating a change.

E. The abortion facility will be notified in writing by the OLC whether a license can be reissued or a new application is needed.

12VAC5-412-80. Allowable variances.

A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.

B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.

C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.

D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.

12VAC5-412-90. 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 as an inspector designated by OLC; the abortion facility may verify the identity of the inspector prior to his 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.

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, noncompliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-110.

B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction, or supervision. If copies of records are removed from the premises, patient names and addresses contained in such records shall be redacted by the abortion facility before removal.

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

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 § 32.1-27 of the Code of Virginia 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.

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 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.

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 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia.

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

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

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

Part II
Organization and Management

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 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.

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;

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 of the Code of Virginia 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.

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.

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 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.

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 nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined.

B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience.

C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order, and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility.

D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.

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 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. 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.

Part III

Quality Management and Infection Prevention

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 nonphysician 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, 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 and Health Administration;

6. Use of personal protective equipment;

7. Use of safe injection practices;

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

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

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

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 nonreusable 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; and
5. Compliance with requirements of the U.S. Occupational Safety and 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.

Part IV
Patient Care Management

12VAC5-412-230. Patient services; patient counseling.

A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy 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 she understands, appropriate counseling and instruction in the abortion procedure and shall develop, implement, and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.

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

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

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

1. Use of any additional medical testing shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.

2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

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

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

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

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

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

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

C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic 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).

12VAC5-412-250. Anesthesia service.

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

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

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

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

B:

1. Appropriate equipment to manage airways;

2. Drugs and equipment to treat shock and anaphylactic reactions;

3. Precordial stethoscope;

4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;

5. Continuous electrocardiograph;

6. Devices for measuring blood pressure, heart rate, and respiratory rate;

7. Defibrillator; and

8. Accepted method of identifying and preventing the interchangeability of gases.

E. Elective general anesthesia shall not be used.

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

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

1. Drugs to treat malignant hyperthermia, when triggering agents are used;

2. Peripheral nerve stimulator, if a muscle relaxant is used; and

3. If using an anesthesia machine, the following shall be included:

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

H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria.

12VAC5-412-260. Administration, storage and dispensing of drugs.

A. Controlled substances, as defined in § 54.1-3401 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 [(§54.1-3300 et seq.)] 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 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 § 54.1-3404 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.

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.

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 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.

Part V
Support Services - Health Information Records and Reports

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. Physicians' and nurses' progress notes;
 - h. Condition at time of discharge;
 - i. Patient instructions (preoperative and postoperative); and
 - j. Names of referral physicians or agencies; and
6. Any other information required by law to be maintained in the health information record.

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.).

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 USC § 301 et seq. - Pub. L. No. 101-629).

C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the:

1. Abortion facility name;
2. Type and circumstance of the event being reported;

3. Date of the event; and

4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies.

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

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

Part VI

Functional Safety and Maintenance

12VAC5-412-330. Abortion facility security and safety.

The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to:

1. Abortion facility security;

2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and

3. Provisions for disseminating safety-related information to employees and users of the abortion facility.

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.

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 nonlead-based paint, lacquer, varnish, or shellac that will allow sanitization.

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

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. 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).

Part VII
Design and Construction

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

Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia.

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

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

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-412)

Application for Abortion Facility Licensure

Guidelines for Design and Construction of Health Care Facilities, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C., 2010 Edition.

American Heart Association (AHA) Guidelines for CPR and ECC Science

Centers for Disease Control (CDC) 2010 STD Treatment Guidelines

CDC Guide to Infection Prevention in Outpatient Settings

Joint Commission Standards for Ambulatory Care

OSHA Bloodborne Pathogens

OSHA Reporting Illnesses and Injuries



COMMONWEALTH of VIRGINIA

Department of Health

CYNTHIA C. ROMERO, MD, FAAFP
STATE HEALTH COMMISSIONER

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April 12, 2013

Memorandum

To: State Board of Health

From: David H. Trump, MD, MPH, MPA
Director, Office of Epidemiology

Subject: Final *Regulations for the Virginia Immunization Information System (VIIS)*

Enclosed you will find final *Regulations for the Virginia Immunization Information System (VIIS)* for your review and discussion at the April 12, 2013, meeting of the Board of Health. Their purpose is to establish a system that will contain birth to death immunization histories of participants. The Board is required by the Code of Virginia, §32.1-46.01 to promulgate regulations to implement VIIS.

The comment period for the proposed regulations ended on January 18, 2013. One comment was received but cannot be addressed in this regulatory action. The regulation has been reviewed and approved by both Robin Kurz, of the Office of the Attorney General, and Maureen Dempsey, MD, FAAP, former Deputy Commissioner for Public Health. I look forward to discussing this regulatory action with you at the upcoming meeting.

If the Board approves them, the final regulations will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the *Virginia Register*. The regulations become effective 30 days following publication.



Final Regulation Agency Background Document

Agency name	Department of Health/Office of Epidemiology/Division of Immunization
Virginia Administrative Code (VAC) citation	12VAC5-115
Regulation title	Virginia Immunization Information System
Action title	Regulations for the Virginia Immunization Information System (VIIS), the statewide registry for private and public healthcare systems
Date this document prepared	01/22/2013

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

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Section 32.1-46.01 of the Code of Virginia requires the State Board of Health to establish regulations for the Virginia Immunization Information System (VIIS). VIIS is a voluntary, statewide immunization registry that consolidates patient immunization histories from birth to death into a complete, accurate, and definitive record that is available to Virginia's participating health care providers. The VIIS regulations are designed to: (1) define who is allowed access to VIIS; (2) specify requirements for this access; (3) ensure compatibility with current state and federal guidelines in the areas of patient data confidentiality and system security; (4) discuss the security features of the application; (5) define the data to be collected; (6) state the mechanisms for populating and capturing data; (7) define the approved use of data, the authorized recipients, and the procedure for obtaining the data; and (8) discuss the use of VIIS in a public health emergency.

There have been no changes from the proposed regulations.

Statement of final agency action

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

The State Board of Health approved the final regulations for the Virginia Immunization Information System on April 12, 2013.

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.

Statutory authority to promulgate these regulations is granted to the State Board of Health by § 32.1-46.01 of the Code of Virginia.

Purpose

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

The purpose of this regulatory action is to comply with two bills dealing with VIIS passed by the 2005 General Assembly, SB 1132 and HB 2519. The identical bills were presented by Senator Janet D. Howell and Delegate John M. O'Bannon, III and called for the establishment of VIIS. The statewide immunization information system contains birth to death immunization histories of participating clients and merges this data from all healthcare providers for that patient into one record. This consolidated record, which is available to participating health care providers in Virginia, will help providers identify appropriate immunizations to give their patients. It will increase immunization rates and protect the public health of all residents of Virginia in the following ways: (1) ensure that children receive vaccines appropriately, as currently recommended by the Advisory Committee for Immunization Practices (ACIP); (2) prevent the under- and over-immunization of children; (3) generate parental reminders, recall notices and manufacturer recalls; (4) produce immunization coverage reports; (5) identify areas of under-immunized population for educational purposes and other immunization rate improvement activities; and (6) provide, in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins, or other preventive medications or emergency treatments.

Substance

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

Regulations for VIIS will cover five main areas: 1) authorized participants of VIIS and their registration procedure, 2) data entry by participants either through user interface or data exchange, 3) requirements for patient confidentiality and system security, 4) approved and non-approved use of VIIS data, and 5) use of VIIS in a public health emergency.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

VIIS regulations will pose no disadvantage to the public or the Commonwealth. Many advantages will occur for both the general public and to the Commonwealth. An accurate patient immunization record allows health care providers to diagnose vaccine preventable diseases more effectively and to recommend immunizations that ensure patients receive all the age-appropriate vaccines recommended by ACIP. Accurate immunization information also decreases costs by preventing unnecessary duplicated immunizations, reminding clients of vaccines that are due or were recalled by the manufacturer, and identifying areas of need for increased education and other activities that may lead to improved immunization coverage rates.

There are also benefits to parents or guardians, which include the following:

- to remove the requirement to provide their child's immunization record to the healthcare provider(s);
- to consolidate the immunization histories from multiple providers into one record and therefore eliminate duplicate immunizations due to no known history of having received them
- to prevent additional visits to the child's provider(s) by identifying all age-appropriate immunizations that may be given during the current visit;
- to provide emergency room access to assess the child's immunization status at the time of an injury;
- to provide information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- to simplify the process for obtaining the child's immunization history for admission to schools, daycares, camps, college, etc.;
- to identify and recall the child who:
 - received a vaccine that was later recalled by the manufacturer, or
 - did not receive a recommended vaccine due to short supply;
- to guarantee lifetime access to the client's immunization history even if the health care provider's office is no longer in operation.

Changes made since the proposed stage

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

No changes made since the proposed stage.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Stephen	<p>Immunizations required for school attendance.</p> <p>There are substantial numbers of students attending schools that are at risk for contacting diseases for which there are immunizations available. These students have received the immunization treatments but remain unprotected. In light of the fact that there is no concern for these students attending school, why then is there so much effort placed on forcing a few students to get immunized whose parents do not want them immunized? If they were not immunized, they would be no more at risk than the many children that are not protected by the immunizations. "Requiring" immunizations and then quietly, through medical records privacy, allowing those that object to attend (based on religious or health issues or what ever) would seem reasonable. The purely fear tactics used over this issue to get a public out cry for forced immunizations, while there is no concern for exposure to those uneffected after receiving immunizations, is about government control rather than about health concerns.</p>	<p>School immunization requirements are addressed in Virginia Administrative Code 12VAC5-110. These regulations (12VAC5-115) refer to VIIS, the information system for the deposit for immunization data. This comment does not relate to VIIS and cannot be addressed in this regulatory process.</p>

Enter any other statement here

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	12VAC5-115-10	None	<p><u>Definitions.</u> Definitions of words and terms used in chapter 115 to ensure consistency in interpretation of VIIS regulations.</p>
	12VAC5-115-20	None	<p><u>Authorized participants.</u> Persons or organizations must first seek authorization before they are allowed to use VIIS. Authorized participants of VIIS must require immunization data to perform their job function and must be licensed or certified in Virginia to deliver or support health care services or public health. These participants include but are not limited to, any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist or any entity listed in § 8.01-581.1. Health care entities may only use VIIS for exchanging information on persons for whom they provide services. Other state or regional immunization registries may share data or have access to VIIS data after approval from VDH.</p>
	12VAC5-30	None	<p><u>Registration procedures.</u> Registration forms, agreements and security conditions are necessary to gain access to VIIS and participants have responsibilities which are listed in this section. Those persons electing to participate in VIIS must complete registration forms and assure compliance with necessary confidentiality and security access provisions. VDH will train and provide VIIS access after approval. Participants must designate an administrator who may allow VIIS access by other organization employees and in doing so shall assume responsibility for those users.</p>
	12VAC5-115-40	None	<p><u>Patient confidentiality.</u> This section assures parents/guardians and</p>

			<p>healthcare providers of persons enrolled in VIIS of the confidentiality of the data and, if they elect to do so, provides them with an opt-out procedure. Patients shall have the opportunity to opt-out of VIIS by contacting VDH or their healthcare provider. Confidentiality of VIIS patient data shall be assured by all users who must comply with VIIS regulations and state and federal laws. VIIS records shall be treated with the same confidentiality and privacy as any other patient records. Any inappropriate use shall result in immediate suspension of participant privileges and additional actions may be taken pursuant to Virginia Code § 32.1-27.</p>
	12VAC5-115-50	None	<p><u>Security.</u> This section assures the parents/guardians/providers of patients enrolled in VIIS of the security of the data. Each approved participant is assigned a security role level in VIIS and there is immediate suspension following any violation of security or misuse of data. Participants shall also have password-enabled screen savers, make every effort to protect VIIS screens from unauthorized view and log off whenever leaving the VIIS workstation. Data shall be encrypted and exchanged via a secure connection. The VIIS application, located on a secure website, includes additional security features, including an organizational code, user ID and password. It inactivates after a set period of time and disallows entry of participants if not used for a designated period of time.</p>
	12VAC5-115-60	None	<p><u>Population of VIIS.</u> This section discusses the sources of VIIS data, including the initial population of the application, the ongoing input of data and the inactivation of deceased patients. Birth certificate data are used to populate VIIS and death certificate data are used to make the VIIS record no longer viewable. Enrolled participants or organizations shall report data either by online data entry or by data exchange of files from other information systems. Both demographic and</p>

			<p>immunization data shall be reported by the participant. The social security number, if provided, is encrypted by the application, appears as asterisks, and does not print out on reports for that client. The application allows only exact matches when the social security number is used for search purposes. Participants shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for deduplication of clients. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy and enough information to correctly merge with existing clients.</p>
	<p>12VAC5-115-70</p>		<p><u>Release of VIIS data.</u> This section assures the public that VIIS data will be shared only with appropriate recipients after authorization by VDH and explains the mechanisms and requirements for requesting data, and the penalties for misuse of data. Specific patient data shall be released to that patient or his parents/guardian only after contacting VDH, who will verify the source and comply with federal and state regulations when releasing the information. Requests for patient-level data from health care entities providing health care services or processing health information for that patient must be in writing to VDH, who will authorize the request. The data shall be erased when no longer needed or when the computer is being terminated, due to replacement or the resignation, retirement or dismissal of the participant. Aggregate data from which personal identifying data have been removed or redacted may be released only after approval by VDH. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH.</p>
	<p>12VAC5-115-80</p>		<p><u>Data access in public health emergency.</u> This section defines the procedures for the State Health Commissioner to access VIIS or to designate others to view VIIS in a public health emergency. In the event of a public health emergency, the Commissioner may</p>

			<p>access VIIS by contacting the Division of Immunization. If additional persons are designated by the Commissioner to view VIIS information during the emergency, VDH shall contact these users, provide instruction and activate their account. The Commissioner, by notifying the Division of Immunization, may include public health emergency information on the main screen which may be viewed immediately by the VIIS participants.</p>
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Enter any other statement here

Project 1776 - Proposed

**DEPARTMENT OF HEALTH
Establishment of the Virginia Immunization Information System**

**CHAPTER 115
VIRGINIA IMMUNIZATION INFORMATION SYSTEM**

12VAC5-115-10. Definitions.

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

"Commissioner" means the State Health Commissioner or his designee.

"Data exchange" means electronically sending immunization information from an existing information system to VIIS and being able to retrieve information from VIIS.

"De-duplication" means the process in information systems that matches incoming data with existing client records and merges those identified as the same client.

"Health care entity" means any health care provider, health plan, or health care clearinghouse.

"Health care provider" means those entities listed in § 8.01-581.1 of the Code of Virginia, except that state-operated facilities shall also be considered health care providers for the purposes of this section. Health care provider shall also include all persons who are licensed, certified, registered, or permitted or who hold a multistate licensure privilege issued by any of the health regulatory boards within the Department of Health Professions, except persons regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Health plan" means an individual or group plan that provides or pays the cost of medical care and shall include any entity included in such definition as set out in 45 CFR 160.103.

"Participant" means a person or organization with a VIIS account.

"Patient" means the client who is receiving health services or his parent or guardian.

"Public health emergency" means any (i) public health event caused by an act of bioterrorism or vaccine-preventable disease outbreak or (ii) other public health event resulting from natural or human cause.

"Security role" means the level of security assigned to a participant that determines what information the individual may access in the application and what system functions may be performed.

"VDH" or "Department of Health" means the Division of Immunization within the Virginia Department of Health.

"Virginia Immunization Information System" or "VIIS" means the statewide immunization registry.

"VITA" means the Virginia Information Technologies Agency.

12VAC5-115-20. Authorized participants.

A. Health care providers, including but not necessarily limited to any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist, or any entity listed in the definition of "health care provider" in § 8.01-581.1 of the Code of Virginia, are authorized to participate in VIIS.

B. Any health care entity may participate as long as it is licensed or certified in Virginia to deliver or support health care services or public health, requires immunization data to perform

the health service function, and uses VIIS only for exchanging information on persons for whom it provides services.

C. Other state or regional immunization registries may exchange data with VIIS. They may share data and have access to data by contacting the VIIS program manager and complying with the registration procedure discussed in 12VAC5-115-30.

D. VDH shall give access to VIIS under the condition that having access to immunization information is required to perform the job function of the participant. The VIIS program manager or designee shall assign the security role of the participant based on his needs and job responsibilities.

E. Access to VIIS requires only Internet access and is free to participants.

12VAC5-115-30. Registration procedures.

A. Participation in VIIS is voluntary.

B. Completed registration forms from authorized participants must be processed and approved by VDH before access to the system is allowed. Registration will require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS data are protected from unauthorized view and access. The participant shall update and submit the forms to VDH every year.

C. Once the participant is approved, VDH will provide training and activate the participant in the VIIS system.

D. Qualifying participant organizations shall designate an administrator for their organization. The administrator may then allow VIIS access by an employee in his organization and, in doing so, shall assume responsibility for registering that person, obtaining the most recent security forms that specify VITA or VDH security requirements, retaining all completed user forms, assigning the security role of the user, accepting legal responsibility for his proper use of VIIS, and terminating access to VIIS if the employee is noncompliant with VIIS requirements or no longer requires access.

E. An administrator may terminate his organization's participation at any time by notifying VDH in writing. All data entered by that organization shall remain in the system.

12VAC5-115-40. Patient confidentiality.

A. Access to VIIS information is authorized only under the condition that access to individual immunization information is required to perform the participant's job function.

B. Participants shall not conduct any activity that jeopardizes the proper function or security of VIIS. They shall use patient data only as authorized by law and this chapter and must immediately notify the patient and VDH of any breach of personal privacy or confidentiality.

C. Patients shall have the opportunity to opt-out of VIIS by doing one of the following:

1. Contacting their healthcare provider to allow the viewing of their immunizations only by that provider who administered them; or
2. Contacting VDH in writing requesting to be taken out of VIIS and have their record no longer viewable.

D. Patient immunization records shall not be copied except for authorized use. These copies shall not be left where they are visible by unauthorized personnel and shall be shredded before disposal.

E. VIIS records shall be treated with the same confidentiality and privacy as any other patient record. Any inappropriate use of VIIS records shall result in immediate suspension of participant privileges and an investigation conducted by VDH. Additional actions may be taken pursuant to § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges.

F. Nothing in this chapter alters the provision in 45 CFR Part 164 that permits covered healthcare entities to disclose protected health information to a public health authority without individual authorization.

12VAC5-115-50. Security.

A. After VDH gives access to a VIIS participant, a secure connection is established between his browser and VIIS. The system is password protected.

B. Participants must ensure that employees with authorized access do not disclose their user identification code or password to anyone, have physical security and password-enabled screen savers on computers accessing VIIS, make every effort to protect VIIS screens from unauthorized view, and log off the system whenever leaving the VIIS workstation.

C. The VIIS system, which is maintained on a secure website, automatically inactivates a user session after a predetermined period of inactivity. The inactivation period is determined by VITA security policy.

D. The VIIS system inactivates user accounts, denying access to the system when participants have not logged into the system after a predetermined period of time. This inactivation period is determined by VITA security policy. The administrator must reactivate the account.

E. There shall be a secure encrypted connection between VIIS and the participating organization sending or receiving data if data exchange is performed. The encryption process will be determined by VITA or VDH or both.

12VAC5-115-60. Population of VIIS.

A. The VDH Divisions of Immunization and Vital Records have an agreement to populate demographic information in VIIS with birth certificate data. Death certificate data are used to make the VIIS record no longer viewable. Data exchange shall be performed on a periodic basis, but at least monthly.

B. Each participant shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for de-duplication of clients.

C. Data shall be reported in VIIS either by online data entry or by data exchange of files from other information systems. The health care provider or the designated health plan billed for the immunization shall report. Reporting shall occur within seven days of vaccine administration for online data entry participants. For data exchange participants, reporting shall occur within seven days of receipt of the information.

D. Both demographic and immunization data shall be reported by the participant.

1. Patient demographic information shall include, but is not limited to, patient's name, date of birth, gender, telephone number, home address, birth place, and mother's maiden name. The social security number, if provided, is encrypted by the application, appears as asterisks, and does not print out on reports for that client. The application allows only exact matches when the social security number is used for search purposes.

2. Patient immunization information shall include, but is not limited to, the type of immunization administered using industry standards such as vaccine groups, Health Level 7 codes, or Current Procedural Terminology codes; date the immunization was administered; identity of the health care provider who administered the vaccine; manufacturer; trade name; lot number; and, if present, any contraindications or religious or medical exemptions.

E. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy, and enough information to correctly merge with existing clients. Upon initial data delivery, and periodically thereafter, data shall be reviewed to

determine data quality. Any rejected records shall be resolved by the participant in a timely way. VDH may suspend system privileges and refer to § 32.1-27 of the Code of Virginia for additional action for any organization that submits inaccurate data.

F. If insufficient information is reported to allow de-duplication of clients, incoming data will be placed in a pending file and must be manually merged, if appropriate. All participants shall identify a contact to work with VDH on pending files.

G. VDH shall incorporate immunization data pursuant to subsection E of § 32.1-46 of the Code of Virginia into VIIS by data exchange from other immunization systems, patient care management billing systems, or information systems to the extent possible.

12VAC5-115-70. Release of VIIS data.

A. Specific patient data shall be disclosed to the extent required or permitted by state and federal law or regulations, after contacting VDH who will verify the source of the request.

B. Specific patient data may be disclosed to health care entities to the extent required or permitted by state and federal law or regulations. See § 32.1-127.1:03 of the Code of Virginia.

C. Patient data shall be erased when no longer needed or when the computer is being terminated due to the replacement of the computer or the resignation, retirement, or dismissal of the participant.

D. Aggregate data from which personal identifying data has been removed or redacted may be released for the purposes of statistical analysis, research, or reporting only after approval by VDH.

E. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH. Additional actions may be taken in accordance with § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges upon satisfactory completion of required remedial actions and guarantee of proper use of VIIS in the future.

12VAC5-115-80. Data access in public health emergency.

A. In the event of an epidemic or an outbreak of a vaccine-preventable disease or any disease of public health significance or threat, the commissioner may access VIIS in accordance with § 32.1-40 of the Code of Virginia by contacting the Division of Immunization. The commissioner may release VIIS data in accordance with § 32.1-41 of the Code of Virginia.

B. The commissioner may designate additional persons to view VIIS information during a public health emergency. VDH shall contact designated authorized users, provide instruction for those who are not current participants, and activate an account.

C. The commissioner, by notifying the Division of Immunization, may include public health emergency announcements and notices or guidelines on the main screen that may be viewed immediately by the VIIS participants.

FORMS (12VAC5-115)

[Administrator Information, VIISADM \(eff. 10/12\).](#)

[Electronic Data Exchange With VIIS \(eff. 10/12\).](#)

[Information Systems Security Access Agreement \(eff. 10/12\).](#)

[Organization Information, VIISORG \(eff. 10/12\).](#)

[VIIS Security Policy and User Confidentiality Agreement.](#)

[Memorandum of Agreement between Virginia Department of Health/Division of Immunization \(VDH/DOI\) and VIIS Organization Interested in Data Exchange \(8/11\).](#)

[Virginia Immunization Information System \(VIIS Opt Out-In form\).](#)

[VIIS User Acknowledgement Page.](#)

[VIIS User Signature Page.](#)