Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-412
Regulation title	Regulations for Licensure of Abortion Facilities
Action title	Establishes minimum standards for facilities performing five or more first trimester abortions per month.
Date this document prepared	September 19, 2011

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

1) Please explain why this is an emergency situation as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

Senate Bill 924, enacted by the 2011 General Assembly, mandates the Board of Health to promulgate regulations for facilities performing five or more first trimester abortions per month. http://lis.virginia.gov/cgi-bin/legp604.exe?111+ful+CHAP0670+pdf SB924 specified that, for purposes of licensure, those facilities were to be classified as a category of hospital. SB924 further specified that the

regulations have to be effective within 280 days of enactment. For that reason, the Board is utilizing the emergency rulemaking process authorized by the Administrative Process Act.
The 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.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary. Please include a citation to the emergency language.

Section 32.1-127, as amended by Chapter 670 of the 2011 General Assembly, mandates the State Board of Health to promulgate these emergency regulations, and provides the statutory authority for this emergency regulation. http://lis.virginia.gov/cgi-bin/legp604.exe?111+ful+CHAP0670+pdf

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The intent of this regulatory action is to promote and assure the safety of patients who receive first trimester abortion services. SB924 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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Twenty-two other states currently regulate facilities performing abortions. The regulations of these other states address many of the same types of issues addressed in this regulatory action. The need for these regulations has been extensively and publicly articulated over the past several years during the annual sessions of the Virginia General Assembly. This regulatory action is mandated by SB924 enacted by the 2011 General Assembly.

Following approval of this Emergency Regulation and Notice of Intended Regulatory Action by the Governor, and its publication in the Virginia Register of Regulations, the subsequent public comment

period may delineate specific issues that need to be addressed during the process of adopting the permanent, replacement regulations.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

The vast majority of the provisions in this regulatory action are new:

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.

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

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

"Licensee" means the person, partnership, corporation, association, organization, or professional entity that owns or on whom rests the ultimate responsibility and authority for the operation 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.

Procedures for Licensure or License Renewal

License valid for one year.

Any license issued before April 30, 2012 shall not expire until April 30, 2013.

Commissioner may suspend or revoke license.

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

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

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

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.

Facility must submit plan of correction within 15 working days to address any deficiencies.

Commissioner may allow a temporary variance to the regulatory provisions

Organization and Management

Each facility shall have a governing body.

Each facility shall develop, implement and maintain a policies and procedures manual.

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.

A physician shall not perform an abortion without first obtaining the patient's informed written consent.

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

The facility shall conspicuously post information concerning how to submit an anonymous complaint to VDH.

Infection Prevention

The facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the current edition of "Guide to Infection

Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the CDC.

Patient Care

A facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided.

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

Use of additional medical testing, including ultrasonagraphy, shall be based on a patient risk assessment.

The facility shall offer each patient appropriate counseling and instruction in the termination procedure.

The facility shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling.

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

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

Anesthesia service shall be managed in accordance with the Office-Based Anesthesia provision of the Regulations Governing the Practice of Medicine, including provisions specifying the types of equipment, supplies and pharmacological agents that must be maintained. (18-VAC85-20-310 et seq.).

Elective general anesthesia shall not be used.

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

Controlled substances, as defined in the Virginia Drug Control Act, shall be stored, administered and dispensed in accordance with federal and state laws, including 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, administered or dispensed 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 equipment, supplies and drugs 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 that performs surgical procedures 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 an abortion facility shall receive needed emergency treatment.

Quality Assurance

The abortion facility shall implement an ongoing, comprehensive, integrated self-assessment program of the quality and appropriateness of care or services provided.

Medical 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 medical records according to applicable provisions of state and federal law.

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

The facility shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence.

Functional Safety and Maintenance

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

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

All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the provisions of the current edition of the Virginia Statewide Fire Protection Code.

The facility's structure, its component parts, and all equipment shall be kept in good repair and operating condition.

When patient monitoring equipment is utilized, a written preventive maintenance plan 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 12 VAC 5-550-120 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.

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC5-410-10		Definition of "Outpatient Hospital"	The following text is stricken from the definition: "Outpatient abortion clinics are deemed a category of outpatient hospitals." Rationale – Abortion clinics will be regulated pursuant to 12 VAC5-412, not 12 VAC5-410.
12 VAC5-5-410-60		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 clinics will be regulated pursuant to 12 VAC5-412, not 12 VAC5-410.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

SB924 enacted by the 2011 General Assembly mandates that the Board of Health promulgate these regulations, therefore there are no alternatives to this regulatory action.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so **via the Regulatory Town Hall website, www.townhall.virginia.gov or** by mail, email or fax to **Joseph Hilbert, Director of Governmental and Regulatory Affairs, 109 Governor Street, Richmond, VA 23219, 804-864-7006 (phone), 804-864-7022 (fax**), or email joe.hilbert@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, one or more public hearings will be held to receive comments on this notice.

Participatory approach

Please indicate the extent to which an ad hoc advisory group or regulatory advisory panel will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

VDH does not intend to appoint an ad hoc advisory group or a regulatory advisory panel in development of the proposed permanent replacement regulation. There has been, and will continue to be, ample opportunity for public participation. An extended public comment period will be held at the September 15, 2011 Board of Health meeting, prior to the Board considering the draft emergency regulations. In addition to a 30 day public comment period, one or more public hearings will be held following publication of the Notice of Intended Regulatory Action for the permanent replacement regulations. VDH will be responsible for reviewing and summarizing all of the public comment comments received concerning the NOIRA as part of its work to develop permanent replacement regulations.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage

economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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