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Regulatory  
Town Hall

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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-412
<b>Regulation title</b>	Regulations for Licensure of Abortion Facilities
<b>Action title</b>	Amend the regulations following periodic review
<b>Date this document prepared</b>	November 3, 2014

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*.

### 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.*

On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412. "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations to: clarify the requirements for parental consent, insert additional best practices regarding medical testing and laboratory services, insert additional best practices regarding anesthesia service, align the requirements for administration, storage and dispensing of drugs more precisely with the Code of Virginia, align the requirements regarding emergency services more specifically with medical best practices and update the requirements for facility design and construction.

### Legal basis

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

The regulation is promulgated under the authority of § 32.1-127 of the Code of Virginia. Section 32.1-127 of the Code of Virginia requires the Board to promulgate regulations including minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees and the public, (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities, (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions, (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence, and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes and certified nursing facilities. Facilities in which five or more first trimester abortions are performed per month are classified as a category of hospital for the purposes of this requirement. (§ 32.1-127(B)(1))

### 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.*

The regulations are mandated by § 32.1-127 of the Code of Virginia. On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014) which directed the Board of Health to conduct a periodic review of 12VAC5-412 “Regulations for Licensure of Abortion Facilities.” As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. The Department of Health has determined that the proposed regulatory action is essential to protect the health, safety and welfare of citizens as the regulatory action intends to update the regulations, align the regulations more precisely with the Code of Virginia, insert additional medical best practices and clarify certain provisions of the regulations as specified in the next section.

### Substance

*Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

No new regulatory sections are being proposed. The following amendments will be proposed:

#### Parental Consent

Clarify the requirements of parental consent. Ensure all requirements of parental consent are within the regulations.

#### Medical testing and laboratory services

Incorporate additional best practice standards. Remove an unnecessary mandate, which will allow the patient and physician to work together to determine the best course of action. Insert a new requirement which will allow tracking of lab results.

#### Anesthesia Service

Incorporate additional best practice standards. Add a documentation requirement.

#### Administration, storage and dispensing of drugs

Align these provisions more precisely with the Code of Virginia. Remove an unnecessary restriction that is not required by the Code of Virginia.

Emergency Services

Align these provisions more precisely with medical best practices. Remove an unnecessary provision that is not required due to federal requirements.

Facility Design and Construction

Update the design and construction requirements.

## 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, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

Section 32.1-127 of the Code of Virginia mandates that the Board of Health regulate abortion facilities where five or more first trimester abortions per month are performed. Section 32.1-127 requires that the regulations include minimum standards for construction and maintenance, the operation, staffing and equipping of the facility, qualifications and training of staff, and policies related to infection prevention, disaster preparedness and facility security. On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. The regulations are mandated by law, the review of the regulations was mandated by Executive Directive, and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes as determined by the regulatory review.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including 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 hearing is to be held to receive comments on this notice.*

*Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is \_\_\_\_\_; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this 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 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to **Susan Horn, Policy Analyst, 9960 Mayland Drive, Richmond, VA 23233, phone number: 804-367-2157, fax number: 804-527-4502, and**

**susan.horn@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi>). Both oral and written comments may be submitted at that time.

**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.*

As the amendments being considered will clarify the requirements of parental consent, the regulatory action will strengthen the authority and rights of parents in the education, nurturing, and supervision of their children. The regulatory action shall have no other impact on the institution of the family and family stability.

**Periodic review and small business impact review report of findings**

*If this NOIRA is the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

*In addition, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.*

The Department of Health received a total of 14,279 comments during the public comment period of the periodic review.

Comment	Agency response
Jill Abbey on behalf of Richmond Medical Center for Women, Rosemary Codding on behalf of Falls Church Healthcare Center, Dr. David Peters on behalf of A Tidewater Women’s Health Clinic and Elisabeth Van Der Woude on behalf of Amethyst Health Center for Women, Inc. commented the regulations should be repealed, or in the alternative	The Regulations are required by § 32.1-127 and are required to include minimum standards for the construction and maintenance of abortion facilities.

<p>amended so that the facility design and construction requirements are removed or amended so that the facility design and construction requirements are not applied to existing facilities.</p>	
<p>CeCe Heil on behalf of the American Center for Law and Justice commented that Governor McAuliffe’s Executive Directive 1 and the resulting review of the regulations was inappropriate, and the regulations are required by statute and are necessary for the protection of public health, safety and welfare.</p>	<p>On May 12, 2014 Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 “Regulations for Licensure of Abortion Facilities.” The Governor may at any time request a periodic review of any regulation promulgated by an agency (§ 2.2-4017 of the Code of Virginia).</p>
<p>Holly Puritz on behalf of the American Congress of Obstetricians and Gynecologists commented that: 1) the provision requiring that medications to induce a termination of a pregnancy be administered by a physician (12VAC5-412-260) be modified to indicate that such medications may be administered by a licensed independent practitioner, as under the Code of Virginia nurse practitioners can administer medication under the supervision of a physician and there is no medical reason for this medication to be regulated differently; 2) the provision requiring pathologic examination in the event of the absence of placental villi or fetal tissue within the uterine contents (12VAC5-412-240) be amended to allow the physician to notify the patient that pregnancy tissue was not identified, explain the possibility of ectopic pregnancy and offer a pathologic examination of the tissue including a disclosure of the cost, allowing the patient to be made aware of the potential and presented with all options but not be forced to undergo such procedures, 3) that the provision requiring a written emergency services agreement with a licensed general hospital (12VAC5-412-290) be amended as such an agreement is not necessary as EMTALA requires the emergency room of a licensed general hospital to provide a presenting patient with a medical screening exam and any necessary treatment. ACOG suggests the provision be amended to require the physician at the abortion facility provide direct communication to the emergency department staff regarding the status of the patient and the suspected complication; and 4) that the facility design and construction requirements are medically unnecessary and should be removed to be replaced with less restrictive requirements.</p>	<p>The Virginia Department of Health (VDH) is considering amendments to the regulations to address this comment. VDH is considering the following changes:</p> <ul style="list-style-type: none"> <li>• Aligning the requirements for administration, storage and dispensing of drugs more precisely with the Code of Virginia</li> <li>• Inserting additional best practices regarding medical testing and laboratory services</li> <li>• Aligning the requirements regarding emergency services more specifically with medical best practices</li> </ul> <p>§ 32.1-127 of the Code of Virginia requires the regulations to include minimum standards for the construction and maintenance of abortion facilities..</p>
<p>42 commenters requested non-specific amendment to the regulations. A majority of these comments requested that existing</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p>

<p>facilities be “grandfathered in” to the facility and construction guidelines.</p>	<ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The Office of Licensure and Certification (OLC)’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience conducting surveys of abortion facilities.</li> </ul>
<p>2,716 commenters expressed general support for the regulations and requested the regulations be retained</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p> <ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The OLC’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience conducting surveys of abortion facilities.</li> </ul>
<p>10,654 commenters expressed general opposition to the regulations and requested the regulations be repealed</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p> <ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The OLC’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience in abortion facilities conducting surveys.</li> </ul>
<p>867 of the comments did not express support or opposition or request a specific amendment to the regulations. These comments were ambiguous and did not speak to the regulations. Some of these comments expressed a desire for a complete ban on abortion or expressed that the writer was pro-choice.</p>	<p>VDH believes that no response is necessary for these comments, because they do not speak to the regulations.</p>

Executive Order 17 (2014) requires that regulatory activity should be undertaken with the least possible intrusion into the lives of the citizens of the Commonwealth. Executive Order 17 (2014) requires that agencies consider 1) The use of economic incentives to encourage the desired outcomes, 2) The use of information disclosure requirements, rather than regulatory mandates, so that the public can make more informed choices, 3) The use of performance standards in place of mandating specific techniques or behavior and 4) The consideration of reasonably available alternatives in lieu of regulation. Section 32.1-127 of the Code of Virginia mandates that the Board of Health regulate abortion facilities where five or more first trimester abortions per month are performed. Section 32.1-127 requires that the regulations include minimum standards for construction and maintenance, the operation, staffing and equipping of the facility, qualifications and training of staff, and policies related to infection prevention, disaster preparedness and facility security. The regulations are mandated by law; the alternatives proposed in

Executive Order 17 (2014) are not viable as VDH has been directed by the General Assembly to promulgate regulations. VDH is confident that the regulations are necessary for the protection of public health, safety, and welfare and will be clearly written and, with the intended amendments, easily understandable. The regulations are written simply and do not overlap, duplicate or conflict with federal or state law or regulation. They were drafted based upon the best reasonably available and reliable information.

There is a continued need for the regulation as the regulation is mandated by law, § 32.1-127 of the Code of Virginia.

The nature of complaints regarding the regulation from the public are predominantly related to the facility design and construction requirements. Specifically that the facility design and construction requirements are medically inappropriate, unnecessary, financially burdensome and not required by the Code of Virginia. Facilities requesting a variance to the regulations reported that the cost to renovate the facility to comply with the regulations would be between \$19,500 to \$1,500,000, which represented between 43% and 4,500% of the facilities' annual revenue. Section 32.1-127.001 of the Code of Virginia requires that the Board of Health promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health (now the Facility Guidelines Institute).

The Emergency Regulations for Licensure of Abortion Facilities became Effective on December 29, 2011. The Final Regulations for Licensure of Abortion Facilities became effective on June 20, 2013. The Periodic Review of the Regulations for Abortion Facilities was filed on May 15, 2014 and was completed October 1, 2014. The regulatory chapter has been reviewed frequently enough that technology, economic and other conditions have not changed in the area affected by the regulation.