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# Proposed Regulation
# Agency Background Document

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| **Agency name** | Virginia Department of Health |
| **Virginia Administrative Code (VAC) citation(s)** | 12VAC5-412 |
| **Regulation title(s)** | Regulations for Licensure of Abortion Facilities |
| **Action title** | Amend the regulations following periodic review |
| **Date this document prepared** | August 26, 2015 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.*

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. This regulatory action will 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 regarding emergency services more specifically with medical best practices, update the requirements for facility design and construction, and make minor technical amendments.

## Acronyms and Definitions

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

There are no technical terms or acronyms utilized in this document.

## 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)).

## Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.*

As stated within the Summary section, 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. This regulatory action will 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 regarding emergency services more specifically with medical best practices, update the requirements for facility design and construction and make minor technical amendments.

The regulations are mandated by § 32.1-127 of the Code of Virginia. The regulations ensure health and safety standards are maintained throughout licensed facilities within the Commonwealth. The review of the regulations was mandated by Executive Directive. Upon review, the Department of Health found areas of the regulations which could be improved, therefore protecting the health and safety of patients of these facilities to a higher degree.

Section 32.1-127.001 of the Code of Virginia requires the State Board of Health to adopt minimum standards for design and construction that are consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities, now the Guidelines for Design and Construction of Hospitals and Outpatient Facilities.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.*

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

Definitions
Technical change. Addition of the terms medication induced abortion and surgical abortion in order to tailor the facility design and construction guidelines more precisely to the requirements of each facility.

Classification
Repeal the section. Unnecessary due to Code requirements.

Violation of this chapter or applicable law; denial, revocation, or suspension of license
Amend this section to include guidance issued by the Virginia Department of Health Office of Licensure and Certification.

Patient services; patient counseling
Remove an unnecessary restriction not required by the Code. Clarify the requirements of parental consent. Ensure all requirements of parental consent are within the regulations. Make additional technical changes which are in line with medical best practices.

Medical testing and laboratory services
Remove an unnecessary documentation requirement. Reformatting. 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.

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.

Documents Incorporated by Reference
Update those documents incorporated by reference to reflect the most current publications.

## 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 regulatory action to the public are increased health and safety protections at abortion facilities. The primary disadvantage to the public associated with the regulatory action is some abortion facilities may need to change some of their current operating policies and procedures. This may cause a financial impact on these facilities. That financial impact might be passed on to the facilities' patients. 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 regulatory action in relation to the agency or the Commonwealth.

## Requirements more restrictive than federal

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

There are no applicable federal requirements associated with these regulations.

## Localities particularly affected

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

The Department does not anticipate any locality will be particularly affected by the proposed regulation.

## Public participation

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

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

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to **Susan Puglisi, Policy Analyst, 9960 Mayland Drive, Richmond, VA 23233, phone number: 804-367-2157, fax number: 804-527-4502, and susan.puglisi@vdh.virginia.gov.** Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage 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 (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

## Economic impact

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

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| **Projected cost to the state to implement and enforce the proposed regulation, including:**<br>**a) fund source / fund detail; and**<br>**b) a delineation of one-time versus on-going expenditures** | The proposed amendments to the regulatory chapter will not increase the costs to the state to implement and enforce the regulations. |
| **Projected cost of the new regulations or changes to existing regulations on localities.** | The proposed amendments to the regulatory chapter will not increase the costs on localities. |
| **Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.** | There are 18 licensed abortion facilities in operation in the Commonwealth. |
| **Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.** Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | All 18 licensed abortion facilities in operation in the Commonwealth will be affected by these amendments. 8 of these facilities qualify as small businesses. |
| **All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:**<br>**a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and**<br>**b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.** | VDH believes the projected costs associated with the proposed regulatory changes will be minimal. The projected changes will require minimal additional recordkeeping and other administrative costs. There will be no costs related to these regulatory changes related to the development of real estate. |
| **Beneficial impact the regulation is designed to produce.** | This regulatory action is designed to promote and assure the health and safety of patients who receive first trimester abortion services. |

## Alternatives

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

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

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.

## Regulatory flexibility analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

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 comment

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

The Department of Health received a total of 5,529 comments during the public comment period of the NOIRA. Of those 4,752 were unique comments, 777 were repeated comments.

| Comment | Agency response |
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| Victoria Cobb on behalf of the Family | VDH shall respond to each of these proposed |

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| Foundation commented that the existing regulations should be retained, or in the alternative amended to reflect the following:<br>• If a doctor violates parental consent upon discovery through inspections the violation shall be reported to the Board of Medicine for assessment of a $2,500 civil fine. Additionally if the child is 15 years of age or younger a report of possible suspected child abuse or neglect be filed with either local law enforcement or the Department of Social Services.<br>• Drugs shall be administered according to FDA guidelines.<br>• Facilities should include in their policy manuals, language reflected in the Code of Virginia that employees should not be required to dispense or administer medical treatment that conflict with their deeply-held moral or religious beliefs and that refusal to participate shall not form the basis for any claim of damages or for any disciplinary or recriminatory action against the employee.<br>• Violations of federal or state drug laws and the name and DEA license number of the offending person should be reported immediately upon discovery to local law enforcement, the Virginia Board of Pharmacy, the Virginia Board of Medicine and the DEA.<br>• In the case of medical emergency or transfer to a hospital, the time, date, and specific complication shall be reported to the Department of Vital Records. | amendments separately:<br>• As stated within the comment, the penalty for violation of parental consent is laid out within §18.2-76 of the Code of Virginia. Therefore it is unnecessary to reiterate that penalty within the regulations. It is against VDH policy to reiterate requirements and penalties laid out within the Code when unnecessary as relisting these requirements can cause the regulations to become lengthy and burdensome. VDH/OLC currently is in the practice of reporting all appropriate Code and regulatory violations to the Department of Health Professions and will continue to do so.<br>• Section 63.2-1509 of the Code of Virginia deals with the issue of "mandatory reporters" and requires that any person licensed to practice medicine or any of the healing arts report child abuse and neglect to the local Department of Social Services or the Department of Social Services toll free hotline. As this requirement is laid out in the Code it is unnecessary to reiterate that requirement within the regulations. It is against VDH policy to reiterate requirements and penalties laid out within the Code when unnecessary as relisting these requirements can cause the regulations to become lengthy and burdensome.<br>• 12VAC5-412-60 of the Regulations already requires that all controlled substances shall be stored, administered and dispensed in accordance with federal and state laws. Further guidance documents are intended to provide direction, however they are not intended to be regulatory requirements. Therefore integrating FDA guidelines into the regulations would be inappropriate.<br>• The Conscience Clause referenced in this comment exists in §18.2-75 of the Code of Virginia. Therefore it is unnecessary to reiterate that requirement here or require the facility to formalize the requirement within a policy and procedure. It is against VDH policy to reiterate requirements and penalties laid out within the Code when unnecessary as relisting these requirements can cause the regulations to become lengthy and burdensome.<br>• As stated previously, 12VAC5-412-60 of the Regulations already requires that all controlled substances shall be stored, administered and dispensed in accordance |

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| | with federal and state laws. Also, VDH/OLC currently is in the practice of reporting all appropriate Code and regulatory violations to the appropriate authorities and will continue to do so.<br>• The Division of Vital Records issues and is the custodian of vital records for the Commonwealth of Virginia. Vital records are birth, death, marriage, and divorce certificates. Therefore this suggested reporting would be inappropriate. |
| Cianti Stewart-Reid on behalf of Planned Parenthood Advocates of Virginia commented that the regulations should be amended in the following ways:<br>• 12VAC5-412-110 Plan of correction: The Board of Health should amend this section to allow providers to raise objections to items in inspection reports and remove inaccurate items from the reports before a plan of correction is submitted.<br>• 12VAC5-412-160 Policies and Procedures: Strike item 4 which requires the development and implementation of a policy for "admissions and discharges, including criteria for evaluating the patient before admission and before discharge." Licensed abortion providers do not admit or discharge patients in the normal course of practice and therefore the requirement for maintenance of this policy is medically unnecessary and inappropriate.<br>• 12VAC5-412-200 Patient's Rights: The final sentence of Part A and all other subparts should be struck from this section as they are inconsistent with the Joint Commission Standards of Ambulatory Care.<br>• Planned Parenthood Advocates of Virginia notes support for the comments submitted by the Virginia Coalition to Protect Women's Health. | VDH shall consider these suggestions for future regulatory actions; however as these suggested amendments are outside the scope of the NOIRA published January 12, 2015 they shall not be considered within this regulatory action. |
| Rose Codding on behalf of Falls Church Healthcare Center commented that the Regulations should be amended in the following ways:<br>• 12VAC5-412-30 Classification: Define the class of hospital as "Class 4- Office based Out-Patient Medical Practices and non ASC, non Hospital-Based Abortion Facilities"<br>• 12VAC5-412-50 (F) Request for | VDH has considered Ms. Codding's comment regarding 12VAC5-412-370 and have suggested edits to that section, which address this comment. In regards to Ms. Codding's other suggested edits, VDH shall consider these suggestions for future regulatory actions; however as these suggested amendments are outside the scope of the NOIRA published January 12, 2015 they shall not be considered within this regulatory action. |

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| Issuance and 12VAC5-412-70 Return and/or Reissuance of License: Remove the requirement that a change in administrators or ownership triggers and automatic need for re-licensure as the current requirement interferes with best business practices and discourages investors who want to improve licensed facilities. Subsection E of 12VAC5-412-70 is too broad and needs to be clarified; specifically there is no definition of "operator"<br>• 12VAC5-412-90 Right of Entry and 12VAC5-412-100 On-site Inspections: The regulations should differentiate between complaint driven inspections and routine inspections. Routine inspections should be done on a scheduled basis as done with the CLIA system. The commenter also notes support for VDH's proposed "rating" system to categorize major, minor administrative etc deficiencies that may be cited during inspection.<br>• 12VAC5-412-170 Administrator: Health centers should have greater flexibility in assigning the tasks set out in Section 170 to appropriate staff in a way that assures compliance without requiring the hiring of a single administrator responsible for all such tasks.<br>• 12 VAC5-412-210 Quality Management: Amend the regulations to better reflect the realities of a small health center. The commenter states "It is overbearing and counterproductive to the effective operation of the smaller facility to require governing bodies, quality assurance committees of four or more staff members and administrators in smaller doctor's offices or medical practices."<br>• 12VAC5-412-320 Required Reporting: Add to this section a system of self reporting of adverse events and apply this to all health care facilities. Amend to clarify the events listed in B (2) and B(5).<br>• 12VAC5-412-370 Local and State Codes and Standards: Amend so the applicability of local building and fire codes have precedence. Reference to and applicability of the FGI Guidelines is unwarranted for doctor's office providing office-based, non-invasive | |

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| procedures.<br>• General Applicability:<br>  ○ Do not make broad citations to sections of related regulations without specifying what that regulation is supposed to ensure.<br>  ○ A licensed facility should be advised directly of changes to the regulations, similar to advisories that are given for CLIA changes.<br>  ○ Provision of Medication abortion should be regulated as any other general medical service provided in a doctor's office setting. Therefore the Board should delineate appropriate regulations for Medication Abortion and D & C abortions. Medication Abortion should be regulated as any other general medical service provided in a doctor's office setting. | |
| Katherine Greenier on behalf of the Virginia Coalition to Protect Women's Health commented that the Regulations should be amended in the following ways:<br>• 12VAC5-412-10 Definitions: The regulations should be revised to ensure that facilities that provide only medication abortion are subject only to medically appropriate requirements rather than being subjected to "one size fits all" regulations. Amendments should be made to the definition of "Abortion Facility and "Abortion" to clarify that these regulations were intended to apply only to facilities that provide surgical abortion care.<br>• 12VAC5-412-20 General: Creation of a new subsection which would state §2.2-3705.2 of the Code shall take precedence over any requirement in this chapter.<br>• 12VAC5-412-80 Allowable variances: This provision should be amended to reflect the standard for variances already in place for hospitals and outpatient surgical hospitals.<br>• 12VAC5-412-90 Right of entry: This provision should be amended to clarify that the inspection should only be conducted when the facility is open for | VDH has considered Ms. Greenier's comments regarding 12VAC-412-130, 12VAC5-412-290 and 12VAC5-412-370. VDH has suggested edits to these sections which address these comments. In regards to Ms. Greenier's other suggested edits, VDH shall consider these suggestions for future regulatory actions; however as these suggested amendments are outside the scope of the NOIRA published January 12, 2015 they shall not be considered within this regulatory action. |

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| serving patients.<br>• 12VAC5-412-100 On-site inspection: This provision should be amended to protect the confidentiality of patients in the facility, patient records, and facility information. Further it is unreasonable that the regulations allow for license revocation if a staff member is not available to provide access to patient records within an hour of a inspector's arrival.<br>• 12VAC5-412-110 Plan of correction: In order to decrease unnecessary administrative burdens on abortion facilities and ensure patient health and safety the time frame for submitting a plan of correction should be increased to 30 working days and the correction date should be increased to 90 working days.<br>• 12VAC5-412-120 OLC complaint investigations: This provision should be amended so that OLC is only required to investigate credible patient health and safety complaints.<br>• 12VAC5-412-130 Violation of this chapter or applicable law; Denial, revocation or suspension of license: This provision should be amended to incorporate guidance issued by the Department.<br>• 12VAC5-412-140 Management and administration: This provision should be amended to ensure the confidentiality of information that is reported to the OLC.<br>• 12VAC-412-160 Policies and procedures: This provision should be amended to ensure the confidentiality of information that is reported to the OLC.<br>• 12VAC5-412-180 Personnel: This provision should be amended to ensure the confidentiality of information that is reported to the OLC.<br>• 12VAC5-412-190 Clinical staff: This provision should be amended to state that nothing in these regulations shall be interpreted to overlap or conflict with the rules of any supervisory agency with respect to clinical staff and the practice of medicine by physicians. Further this provision should be amended to state that no employee or agent of the OLC or department may disclose the names or other identifying information of any medical practitioners or other staff | |

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| employed by or providing services at an abortion facility. Violation of this provision should be grounds for disciplinary action including termination of employment.<br>• 12VAC5-412-290 Emergency services: This provision must be amended to remove the medically unnecessary transfer agreement requirement.<br>• 12VAC5-412-320 Required Reporting: This provision should be amended to ensure the confidentiality of information that is reported to the OLC.<br>• 12VAC5-412-340 Disaster preparedness: This provision should be amended to ensure the confidentiality of information that is reported to the OLC.<br>• 12VAC5-412-370 Local and state codes and standards: The FGI Guidelines should not be applied to health centers providing abortions. New regulations should be promulgated with the participation and input of all stakeholders including abortion providers, and should at a minimum ensure that the requirements of the Uniform Statewide Building Code and local zoning and building ordinances take precedence. Should the Department and the Board determine that the enabling statute requires it to apply the FGI Guidelines certain provisions from Chapter 3.8 Specific Requirements for Office-Based Procedure and Operating Rooms would be more appropriate than the provisions currently utilized. The provisions within Chapter 3.8 of the GFI Guidelines that are medically inappropriate should not be incorporated. The comment provided which sections are believed to be medically inappropriate. Facilities that only provide medication abortion should be entirely excluded from the regulations. Should the Department and the Board choose to apply the FGI Guidelines to health centers only providing medication abortion and not surgical abortion it should only apply those provisions in a way that is consistent with the intent of the Guidelines and with a level of flexibility that would reflect the non-surgical nature of the medication abortion procedure. | |

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| 1,660 commenters expressed general support for the NOIRA and requested non-specific amendments to the regulations. | These comments do not provide any suggested amendments to specific sections of the Regulations. VDH has proposed changes to the Regulations based on:<br>• Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;<br>• 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; and<br>• The parameters laid out in the NOIRA. |
| 1,489 commenters expressed support for non-specific amendments to the regulations which would "strengthen" the Regulations. | These comments do not provide any suggested amendments to specific sections of the Regulations. VDH has proposed changes to the Regulations based on:<br>• Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;<br>• 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; and<br>• The parameters laid out within the NOIRA |
| 1,091 commenters expressed general opposition to the NOIRA and requested the regulations be retained as they are currently written. | These comments do not provide any suggested amendments to specific sections of the Regulations. VDH has proposed changes to the Regulations based on:<br>• Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;<br>• 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; and<br>• The parameters laid out in the NOIRA. |
| 92 commenters expressed general opposition to the regulations and requested the regulations be repealed. | These comments do not provide any suggested amendments to specific sections of the Regulations. The Regulations are required by Section 32.1-127 of the Code of Virginia. |
| 416 of the commenters did not express support or opposition or request a specific amendment to the regulations. These comments were | VDH believes that no response is necessary for these comments, because they do not speak to the regulations. |

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| 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. | |

## Family impact

*Please assess the impact of this 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.

## Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

| Current section number | Proposed new section number, if applicable | Current requirement | Proposed change, intent, rationale, and likely impact of proposed requirements |
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| 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:<br>"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 | The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:<br>"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.<br>"Abortion facility" means a facility in which five or more first trimester |

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| | | birth or to remove a dead fetus. Spontaneous miscarriage is excluded from this definition.<br>"Abortion facility" means a facility in which five or more first trimester abortions per month are performed.<br>"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.<br>"Commissioner" means the State Health Commissioner.<br>"Department" means the Virginia Department of Health.<br>"First trimester" means the first 12 weeks from conception based on an appropriate clinical estimate by a licensed physician.<br>"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.<br>"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.<br>"Minor" means a patient under the age of 18.<br>"Patient" means any person seeking or obtaining services at an abortion facility.<br>"Physician" means a person licensed to practice medicine in Virginia. | abortions per month are performed.<br>"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.<br>"Commissioner" means the State Health Commissioner.<br>"Department" means the Virginia Department of Health.<br>"First trimester" means the first 12 weeks from conception ~~based on an appropriate clinical estimate by a licensed physician.~~ as determined in compliance with § 18.2-76 of the Code of Virginia.<br>"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.<br>"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.<br>"Medication induced abortion" means any abortion caused solely by the administration of any medication or medications given to a woman in the first trimester of pregnancy with the intent to produce abortion.<br>"Minor" means a patient under the age of 18.<br>"Patient" means any person seeking or obtaining services at an abortion facility.<br>"Physician" means a person licensed to practice medicine in Virginia.<br>"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.<br>"Surgical abortion" means any abortion caused by any means other than solely by the administration of any medication or medications given to a woman in the first trimester of |

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| | | "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.<br>"Trimester" means a 12-week period of pregnancy. | pregnancy with the intent to produce abortion.<br>~~"Trimester" means a 12-week period of pregnancy.~~<br><br>Rationale: Update the definition of first trimester to reflect the requirements of the Code of Virginia. Addition of the terms medication induced abortion and surgical abortion in order to tailor the facility design and construction guidelines more precisely to the requirements of each facility. Removal of the unnecessary term "trimester."<br><br>Likely impact: Consistency and clarity of the Regulations. Less burdensome regulations. |
| 12VAC5-412-30. Classification | | Abortion facilities shall be classified as a category of hospital. | ~~Abortion facilities shall be classified as a category of hospital.~~<br><br>Rationale: Repeal an unnecessary provision of the regulations. This requirement is set out in Code, therefore it is unnecessary to restate it within the regulations.<br><br>Likely impact: Less burdensome regulations. |

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| 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.<br>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.<br>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.<br>D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in | 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~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01 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.<br>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~~ §§ 32.1-125.01, 32.1-125.4, 32.1-132, 32.1-135.2 or 32.1-137.01 Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.<br>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.<br>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).<br><br>Rationale: Integrate Virginia Department of Health Office of Licensure and Certification guidance into the regulation. Technical amendment. |

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| | | accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). | Likely impact: Consistency and clarity of the Regulations. Less burdensome regulations. |
| 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.<br><br>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.<br><br>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.<br><br>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.<br><br>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, | 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.~~ as determined in compliance with § 18.2-76 of the Code of Virginia.<br><br>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. The informed written consent shall be notarized as required by § 16.1-241 of the Code of Virginia. 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.<br><br>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.<br><br>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.<br><br>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 or referral for family planning ~~and post-abortion counseling~~services to its patients.<br><br>F. There shall be an organized discharge planning process that includes ~~an evaluation of the patient's capacity for self-care and~~ an assessment of a patient's safety for discharge and discharge instructions for |

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| | | implement, and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.<br><br>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. | patients to include instructions to call or return if signs of infection develop.<br><br>Rationale: The amendment to part A removes a restriction more stringent than the Code of Virginia and aligns the Regulations more precisely with the Code of Virginia (§18.2-76 of the Code). The amendment also aligns part A with the definition of "First trimester" within 12VAC5-412-10. The amendment to part B inserts the requirements of parental consent within the Regulations, alerting providers of the necessity of notarization. The amendment to part E clarifies that the provider need not provide the family planning services but rather simply make referrals. The physician's regulatory advisory panel suggested the removal of "post-abortion counseling" as the panel stated such counseling is not medically necessary and it's unclear what sort of counseling this would entail. The amendment to part F was also suggested by the physician's regulatory advisory panel and is a technical amendment for clarity.<br><br>Likely impact: Bringing the regulations more in line with the Code of Virginia and medical best practices, greater clarity of the regulations, and greater transparency for providers. |
| 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.<br>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 | 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.<br>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.~~ Medical testing shall include a recognized method to confirm pregnancy and determination or |

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| | | documented.<br>2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.<br>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.<br>4. A written report of each laboratory test and examination shall be a part of the patient's record.<br>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).<br>1. Facilities for collecting specimens shall be available on site.<br>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.<br>3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.<br>C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts | documentation of Rh factor.<br>2. ~~Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.~~ Use of any additional medical testing shall be based on an assessment of patient risk.<br>~~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.~~<br>~~4.~~ 3. A written report of each laboratory test and examination shall be a part of the patient's record.<br>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).<br>1. Facilities for collecting specimens shall be available on site.<br>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.<br>3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.<br>C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present.; ~~if~~If villi or fetal parts cannot be identified with certainty, the patient shall be notified that pregnancy tissue was not identified and the possibility of ectopic pregnancy shall be explained to the patient. In such cases, |

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| | | 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.<br>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). | the patient shall be offered a pathologic examination of the tissue including a disclosure of the cost and should the patient desire, the tissue specimen shall be sent for further pathologic examination. ~~and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.~~ The facility shall track and log any specimens sent for further pathologic examination.<br>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).<br><br>Rationale: The requirements of subsection A 1 and A 2 were rearranged for greater clarity of the regulations. The physician's regulatory advisory panel suggested the elimination of subsection A 3, as this provision is unrelated to abortion procedures. The list was renumbered due to this suggested elimination. The amendment in subsection C removes mandatory additional testing and makes the testing permissive, allowing the physician and patient to discuss and determine the need for additional testing. A further amendment in subsection C requires the provider to track this additional testing should it be performed, so the facility can determine if follow up is necessary.<br><br>Likely impact: Greater clarity of the regulations, less burdensome regulations, strengthening of the doctor-patient relationship, and improved patient care. |
| 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.).<br>B. The anesthesia service shall be directed by and under the supervision of | 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.).<br>B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia.<br>C. When moderate sedation or conscious sedation is administered, the |

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| | | a physician licensed in Virginia.<br>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.<br>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:<br>1. Appropriate equipment to manage airways;<br>2. Drugs and equipment to treat shock and anaphylactic reactions;<br>3. Precordial stethoscope;<br>4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;<br>5. Continuous electrocardiograph;<br>6. Devices for measuring blood pressure, heart rate, and respiratory rate;<br>7. Defibrillator; and<br>8. Accepted method of identifying and preventing the interchangeability of gases.<br>E. Elective general anesthesia shall not be used.<br>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.<br>G. In addition to the requirements of subsection D | licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration. <u>The administration of sedation and monitoring of the patient shall be documented in the patient's medical record</u>.<br>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:<br>1. Appropriate equipment to manage airways;<br>2. Drugs and equipment to treat shock and anaphylactic reactions;<br>3. Precordial stethoscope;<br>4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;<br>5. Continuous electrocardiograph;<br>6. Devices for measuring blood pressure, heart rate, and respiratory rate;<br>7. Defibrillator; and<br>8. Accepted method of identifying and preventing the interchangeability of gases.<br>E. Elective general anesthesia shall not be used.<br>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.<br>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:<br>1. Drugs to treat malignant hyperthermia, when triggering agents are used;<br>2. Peripheral nerve stimulator, if a muscle relaxant is used; and<br>3. If using an anesthesia machine, the following shall be included: |

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| | | 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 18VAC85-20-360C:<br>1. Drugs to treat malignant hyperthermia, when triggering agents are used;<br>2. Peripheral nerve stimulator, if a muscle relaxant is used; and<br>3. If using an anesthesia machine, the following shall be included:<br>a. End-tidal carbon dioxide monitor (capnograph);<br>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;<br>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;<br>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;<br>e. Pressure- | a. End-tidal carbon dioxide monitor (capnograph);<br>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;<br>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;<br>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;<br>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;<br>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;<br>g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and<br>h. A gas evacuation system.<br>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 <u>and those criteria have been documented within the patient's medical record.</u><br><br>Rationale: An amendment to subsection C was suggested by a Board of Health member to stress the |

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| | | compensated anesthesia vaporizers, designed to administer a constant nonpulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;<br>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;<br>g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and<br>h. A gas evacuation system.<br>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. | importance of documentation of a patient's status. An amendment to subsection H restates a requirement located in 12VAC5-412-300 (5)(h). The restatement here stresses the importance of this documentation requirement.<br><br>Likely impact: Better patient care. |
| 12VAC5-290. Emergency services. | | A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, | 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 |

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| | | and related items for resuscitation and control of hemorrhage and other complications.<br>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.<br>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. | for resuscitation and control of hemorrhage and other complications.<br>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~~ Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.<br>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~~ appropriate receiving facility 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.<br><br>Rationale: The written agreement is not necessary due to the Emergency Medical Treatment and Labor Act (EMTALA). Some facilities may not be able to obtain such written agreements as the closest hospital may refuse to enter into such an agreement for a variety of reasons. The physician's regulatory advisory panel suggested the additional amendment stating that emergency department staff may not always be the appropriate staff for the |

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| | | | provider to be communicating with in the case of emergency transfer.<br><br>Likely impact: Less burdensome regulations. Greater accuracy of regulations. |
| 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.<br>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.<br>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. | ~~Abortion facilities~~ A. All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility shall ~~comply with~~ conform to state and local codes, zoning~~, and building~~ ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). ~~In addition, abortion facilities~~All construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility that perform only surgical abortions or a combination of surgical and medication induced abortions shall ~~comply~~ be designed and constructed consistent with Part 1 and ~~sections 3.1-1 through 3.1-8 and section 3.7~~ section 3.8 of Part 3 of the ~~2010~~ 2014 Guidelines for Design and Construction of ~~Health Care~~Hospitals and Outpatient 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. Abortion facilities that perform only medication induced abortions shall be designed and constructed consistent with Part 1 Section 1.1, 1.3 and 1.4 of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute.<br>Abortion procedures may take place in a procedure room, as detailed in Section 3.8-3.1, except that minimum square footage requirements for procedure rooms used for the provision of surgical abortion do not need to be greater than 120 square feet, with a minimum room dimension of 10 feet and a minimum clear dimension of 3 feet at each side and at the foot of the bed. Rooms designed in accordance with Section 3.8-3.2 are not required for abortion facilities. Section 3.7-3.6.13.1(2) shall not apply to facilities that do not have a room designed in |

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| | | | accordance with Section 3.8-3.2.<br>Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code and be consistent with the applicable sections of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute. The certification shall be forwarded to the OLC.<br>~~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.~~<br>B. In order to determine whether the abortion facility's design and construction is ~~in compliance~~consistent with ~~this provision~~the applicable sections of the 2014 Guidelines for Design and Construction of Hospitals and Outpatient Facilities of the Facilities Guidelines Institute, the commissioner may obtain additional information from the facility or its architect ~~concerning the design and construction of the facility~~.<br><br>Rationale: The proposed amendments are based upon the suggestions of the building regulatory advisory panel. The amendments bring the regulatory section more in line with other regulatory provisions governing building code compliance. The suggested amendments also consider an opinion by Attorney General Mark Herring issued to Commissioner Levine on May 4, 2015. The suggested amendments update the section to the latest edition |

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| | | | of the Facility Guidelines Institute Guidelines for Design and Construction of Health Care Facilities. Finally the suggested amendments tailor the facility design and construction guidelines more precisely to the requirements of each facility<br><br>Likely impact: Greater clarity and consistency of the regulations. |