

**State of Board of Health**  
**Agenda**  
**September 15, 2011 – 9:00 a.m.**  
**Wyndham Richmond Airport Hotel**  
**4700 S. Laburnum Avenue**  
**Richmond, Virginia 23231**

Welcome and Introductions	Bruce Edwards, Chair
Review of Agenda	Joseph Hilbert, Director of Governmental and Regulatory Affairs
Approval of June 2011 Minutes	Bruce Edwards
Commissioner's Report	Karen Remley, MD, MBA, FAAP State Health Commissioner
Public Comment	
Break	
<u>Regulatory Action Items</u>	
Regulations for Disease Reporting and Control 12VAC5-90 (Re-Proposed Amendments – pertaining to healthcare associated infections)	Keri Hall, MD, Director Office of Epidemiology
Regulations for Repacking of Crabmeat for Human Consumption 12VAC5-165 (Proposed Amendments)	Robert Hicks, Director Office of Environmental Health Services
Lunch	
Regulations for Licensure of Abortion Facilities 12VAC5-412 (Emergency Regulations)	Joseph Hilbert
Member Reports	
Other Business	
Adjourn	



# COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP  
State Health Commissioner

Department of Health  
P O BOX 2448  
RICHMOND, VA 23218

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

August 10, 2011

## Memorandum

To: State Board of Health

From: Keri Hall, M.D., M.S. *KH*  
Director, Office of Epidemiology

Subject: Re-Proposed Amendment to the *Regulations for Disease Reporting and Control*

Enclosed is a re-proposed amendment to the *Regulations for Disease Reporting and Control* for your review and discussion at the September 15, 2011 meeting of the Board of Health. The amendment would provide the Virginia Department of Health (VDH) with access to additional data on healthcare-associated infections (HAI). The agency originally proposed another amendment to these regulations, which was published in the *Virginia Register* on January 31, 2011 and included a comment period that ended on April 1, 2011. That proposed amendment required hospitals to report central line-associated bloodstream infections in two wards outside intensive care, *Clostridium difficile* infections, and Surgical Care Improvement Project measures pertaining to hip and knee replacement and coronary artery bypass graft surgeries. Comments submitted during the comment period indicated that this proposal was not well received by the hospital community.

The primary issue raised by hospitals was that the proposed Virginia regulations were duplicative of other recently mandated reporting requirements from federal agencies, specifically the Centers for Medicare and Medicaid Services (CMS). Beginning in January 2011, CMS required hospitals to report HAI data on additional measures, including Central Line Associated Blood Stream Infections (CLABSI). In 2012, hospitals will be required to begin reporting on Catheter-Associated Urinary Tract Infections (CAUTI) and Surgical Site Infections (SSI) as well. CMS is also proposing additional reporting requirements for both acute care and long-term care facilities, to be rolled out over the next several years, as illustrated in the attached table. We are asking you to consider a re-proposal of an amendment to these regulations that simply states that those data that are reported for federal purposes to CMS shall be shared with VDH.

The current proposed amendment has been reviewed and approved by Robin Kurz of the Office of the Attorney General. If the Board approves these regulations, the proposed regulation will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the *Virginia Register*. The proposed amendment will be open for a sixty day comment period after publication. I look forward to discussing this regulatory action with you at the upcoming meeting.

# Healthcare Facility HAI Reporting to CMS via NHSN – Current and Proposed Requirements (8/1/2011)

HAI Event	Facility Type	Start Date
CLABSI	Acute Care Hospitals Adult, Pediatric, and Neonatal ICUs	January 2011
CAUTI	Acute Care Hospitals Adult and Pediatric ICUs	January 2012
SSI	Acute Care Hospitals Colon and abdominal hysterectomy procedures	January 2012
I.V. antimicrobial start ( <i>proposed</i> )	Dialysis Facilities	January 2012
Positive blood culture ( <i>proposed</i> )	Dialysis Facilities	January 2012
Signs of vascular access infection ( <i>proposed</i> )	Dialysis Facilities	January 2012
CAUTI	Inpatient Rehabilitation Facilities	October 2012
CLABSI ( <i>proposed</i> )	Long Term Care Hospitals	October 2012
CAUTI ( <i>proposed</i> )	Long Term Care Hospitals	October 2012
MRSA Bacteremia	Acute Care Hospitals Facility-wide	January 2013
<i>C. difficile</i> LabID Event	Acute Care Hospitals Facility-wide	January 2013
HCW Influenza Vaccination	Acute Care Hospitals, OP Surgery, ASCs	January 2013
SSI ( <i>proposed</i> )	Outpatient Surgery/ASCs	January 2014



Virginia  
Regulatory  
Town Hall

[townhall.virginia.gov](http://townhall.virginia.gov)

## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health (State Board of)
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5 -90
<b>Regulation title</b>	Disease Reporting and Control
<b>Action title</b>	Expanded Requirements for Reporting Healthcare-Associated Infections
<b>Date this document prepared</b>	August 10, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

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

The Agency is proposing that data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.

### 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.*

CDC – Centers for Disease Control and Prevention  
CMS – Centers for Medicare and Medicaid Services  
HAI – healthcare-associated infection  
NHSN – National Healthcare Safety Network

## Legal basis

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

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The *Code of Virginia*, § 32.1-35.1, requires acute care hospitals to report infection information to the CDC's National Healthcare Safety Network (NHSN) and for the State Board of Health to define infections to be reported and the patient populations to be included.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

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The proposed regulatory action provides the Virginia Department of Health (VDH) with additional measures related to healthcare-associated infections from acute care hospitals without increasing the burden on the hospitals to provide the information. Data entered into the Centers for Disease Control and Prevention's (CDC) HAI reporting system for hospital quality monitoring by CMS would be made available to authorized staff members of VDH. This will allow VDH to have a means of measuring patient safety in hospitals, with the goal of helping to reduce the occurrence of healthcare-associated infections, without adding new reporting requirements for Virginia hospitals.

## Substance

*Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)*

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The Agency proposes to amend 12 VAC 5-90-370, pertaining to the Reporting of Healthcare-associated Infections. This is a re-proposal of an amendment based on comments received on a proposal that was published in the Virginia Register on January 31, 2011. That proposed amendment required additional reporting of HAIs to VDH by hospitals, and the comments received were not supportive of that action. The Agency has responded by submitting the current re-proposal, which simply states that, "Data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department."

**Issues**

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

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

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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Hospitals are increasingly accountable to multiple organizations to demonstrate their performance relative to patient safety, including healthcare-associated infections. Hospital staff responsible for monitoring these infections are feeling the burden of increasing demands for data. In 2011, CMS began requiring them to use the CDC’s NHSN to report all central line-associated bloodstream infections in intensive care units in order to maximize their reimbursement for Medicare and Medicaid services. In 2012, CMS will expand that to include the reporting of data on certain surgical site infections. The list of reporting requirements from the federal government is expected to grow in coming years. Rather than add more requirements, potentially not aligned with the federal government, and increase the reporting burden on hospitals in Virginia, VDH proposes that Virginia hospitals will share data with the Agency. This will provide VDH with additional data on the performance of Virginia hospitals by gaining access to the data hospitals enter into the CDC system for the CMS hospital quality program, thus achieving the goal of measuring progress toward preventing infections without adding reporting burdens to an already stressed system.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal, which are 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.*

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This re-proposal clearly aligns state reporting with federal reporting requirements.

**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.*

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No locality would be particularly affected.

**Public participation**

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

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

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, [www.townhall.virginia.gov](http://www.townhall.virginia.gov), or by mail, email or fax to Diane Woolard, PhD, MPH, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Suite 516E, Richmond, VA 23218; telephone (804) 864-8141; fax (804) 864-8139; email [diane.woolard@vdh.virginia.gov](mailto:diane.woolard@vdh.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

**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.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</b></p>	<p>The Agency has federal funds to support this effort through July 2012. After that, the requirement could place a financial hardship on the Agency. Any available opportunities for funding to support the necessary staff resources will be pursued. If none are available, existing staff will be forced to absorb the responsibilities.</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>No cost to localities is anticipated.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>Hospitals will be minimally impacted by the change to the existing regulation.</p>
<p><b>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.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Approximately 90 acute care hospitals will be impacted. Half of those have fewer than 200 beds.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting,</b></p>	<p>Hospital staff resources, particularly infection preventionists, will be needed to complete the required tasks.</p>

<p><b>recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b></p>	
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>Increased information for healthcare consumers on hospital infections and quality performance.</p>

**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.*

The Agency is not aware of any viable alternatives to the proposed amendment. The regulations are mandated per the *Code of Virginia*. The health department believes the regulations provide the best solution in response to the law. Regulated constituents were involved in the development of the proposed amendment.

**Regulatory flexibility analysis**

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

Multiple meetings and discussions have been held involving the Agency, hospitals of differing bedsizes, and other health-oriented organizations to develop the contents of this regulatory amendment. An existing reporting system that hospitals already use will provide the necessary information. Hospitals merely have to confer rights to the data to VDH, which is a function that can be performed through the CDC system. The amendment will allow the Agency to track the same performance measures that are being reported to the federal government.

**Public comment**

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

Commenter	Comment	Agency response
	No comments were received.	

**Family impact**

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

The amendment is not expected to have any impact on the family.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.*

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

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
12VAC5-90-370.B.	12VAC5-90-370.A.	Hospitals must report central line-associated bloodstream infections (CLABSI) in adult intensive care units	Data reported into the Centers for Disease Control and Prevention’s National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.

Part XIII

Report of Healthcare-Associated Infections

**12VAC5-90-370. Reporting of healthcare-associated infections.**

A. Reportable infections and method and timing of reporting.

~~1. Acute care hospitals shall collect data on the following healthcare associated infection in the specified patient population: central line associated bloodstream infections in adult intensive care units, including the number of central line days in each population at risk, expressed per 1,000 catheter days.~~

~~2. All acute care hospitals with adult intensive care units shall (i) participate in CDC's National Healthcare Safety Network by July 1, 2008, (ii) submit data on the above named infection to the NHSN according to CDC protocols and ensure that all data from July 1, 2008, to December 31, 2008, are entered into the NHSN by January 31, 2009, and (iii) ensure accurate and complete data are available quarterly thereafter according to a schedule established by the department.~~

~~3. All acute care hospitals reporting the information noted above shall authorize the department to have access to hospital specific data contained in the NHSN database.~~

Data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.

B. Liability protection and data release. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. Infection rate data may be released to the public by the department upon request. Data shall be aggregated to ensure that no individual patient may be identified.



# COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

KAREN REMLEY, MD, MBA, FAAP  
STATE HEALTH COMMISSIONER

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

## MEMORANDUM

DATE: August 10, 2011

TO: Virginia State Board of Health

FROM: Robert W. Hicks, Director  
Office of Environmental Health Services

SUBJECT: Regulations for the Repacking of Crab Meat, 12VAC5-165 (Proposed)

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Prior to the adoption of the Regulations for the Repacking of Crab Meat for Human Consumptions (12VAC5-165), the Division of Shellfish Sanitation (DSS) disallowed the repacking of domestic and imported crabmeat. As the industry needs changed, certain establishments that had been issued a Certificate of Inspection by DSS were exempted from the ban provided they agreed to meet certain requirements. As the number of exemptions issued increased, these certain requirements became the basis for the adoption of regulations, which eliminated the need to issue exemptions. For over the past decade the regulations have been in place and we have gained additional knowledge about the safety of the process of transferring both domestic and foreign crab meat from the container of one establishment into the container of an establishment certified by DSS to repack crab meat. Therefore, we are proposing amendments to these regulations based on the current industry practices, federal requirements, and our ten-year implementation experience with the regulations.

DSS has attempted to address changes in the way foreign crab meat is being repacked since the initial adoption of the regulation, as well as industry concerns and requests in amending the regulations. The Repacking Crab Meat Regulation amendments were developed through a stakeholder process, which included comments from the general public. Following a 30-day comment period on the regulations and working with industry representatives, the agency revised the regulations and is offering proposed regulations.

The 30-day comment period for the Notice of Intended Regulatory Action (NOIRA) ended March 30, 2011. Since then, the agency has contacted all industry stakeholders on the regulations, meeting with some stakeholders individually, and discussed the regulations with the Virginia Tech Seafood Extension Agency. If the Board approves these amendments then the agency will move forward with submitting them for Executive Branch review.



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-165
<b>Regulation title</b>	Regulations for the Repacking of Crab Meat for Human Consumption
<b>Action title</b>	
<b>Date this document prepared</b>	8/10/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

The regulations under 12VAC5-165 et seq. pertain to the practice of transferring crab meat from one processor's container into the container of a different processor, primarily for marketing purposes. When these regulations were adopted in 2000, they were developed to address the sanitation, product traceability, and labeling concerns associated with the situation where one processor would purchase crab meat packed by another certified crab meat processor, whether of a domestic or foreign origin, and repack the meat into the new processor's container.

Currently, crab meat shipped into the United States from foreign companies originates from nearly thirty or more different processing facilities in the foreign country, even though it is shipped by one exporter to the US. Under this multi-source practice, the one-on-one relationship between the original processor and the Virginia crab meat processor can no longer exist. As such, several of the requirements that depended upon this relationship cannot be reliably met, and new processes for assuring the safety of this meat must be developed.

## Legal basis

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

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The legal authority to promulgate the regulations is §28.2-801 of the Code of Virginia. The promulgating entity is the State Board of Health.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

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Some of the provisions of 12VAC5-165 either cannot be met by certified Virginia repacking establishments because of changes in the way that crab meat is being imported from foreign countries and shipped into the U.S or are unnecessary and have no relevance to public health. The amended regulations provide requirements that Virginia processors can reasonably meet and will address the existing risks of the importation of crab meat from unapproved sources and the repacking of foreign crab meat and labeling it as domestic crab meat.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

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The Department proposes repealing 12VAC5-165-70 which states that the Division of Shellfish Sanitation (Division) should be contacted when any condition that may compromise the safety of the product exists. This provision is unnecessary and burdensome to both industry and the Division. The repacker must be able to decide the appropriate disposition of product they are processing without the approval or disapproval of the Division.

The Department proposes modifying 12VAC5-165-90 which addresses the verification of shipping temperatures of imported crab meat. The modification is to include all crab meat and to clarify the verification.

The Department proposes modifying 12VAC5-165-100.A which addresses sampling requirements for imported crab meat to be repacked. The current U. S. Food and Drug Administration import requirements in the Code of Federal Regulations: 21 CFR 123.12 'Special requirements for imported products' have specific requirements for fish and fishery products which preclude the end product sampling requirement currently in place.

The Department proposes modifying 12VAC5-165-100.B, which addresses organoleptic sensing. There is a lack of local capacity to train persons in organoleptic sensing to the level of being certified in seafood decomposition, which has made this regulation impractical. In its place, repacking establishments may organoleptically sense, to the best of the individual’s capability, each container when opened and keep records attesting to this practice. Unsatisfactory containers would be discarded and a record kept of this process.

The Department proposes modifying 12VAC5-165-220.B which requires that the lot number indicate the original source firm that picked the crab meat. Since a reliable indication of the establishment that picked the meat may be unrealistic, some other means of identifying lot numbers may be used by the repacker.

The Department proposes repealing 12VAC5-165-280 which requires that records must be kept separate from other production records. This requirement is unnecessary since the method and type of records being kept are dictated by the repacker’s Hazard Analysis Critical Control Point plan.

Other sections of this regulation may be addressed during this process.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

The proposed regulations will serve to protect the public's health by clarifying requirements for repacking crab meat. There are no disadvantages to the public or the Commonwealth.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which are 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.*

No applicable federal requirements.

**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.*

All localities will be affected equally.

**Public participation**

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

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

Anyone wishing to submit written comments may do so by mail, email or fax to Julie Henderson, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)382-3223 (phone), (804)864-7481 (fax), julie.ray@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website ([www.townhall.virginia.gov](http://www.townhall.virginia.gov)) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>	None.
<b>Projected cost of the regulation on localities</b>	None.
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	Crab meat processors.
<b>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.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	The Division of Shellfish Sanitation currently has 19 certified crab meat dealers.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	No additional costs to certified crab meat dealers.

**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.*

Regulations are mandated by Code of Virginia. No alternative exists.

**Regulatory flexibility analysis**

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

- 1) All crab meat industries certified by the Division of Shellfish Sanitation are small business. As such, all compliance and reporting requirements are at the minimum that are needed to protect public health.
- 2) The schedules for reporting cannot be less stringent than required and adequately protect public health.
- 3) Reporting requirements have been consolidated and simplified as much as possible.
- 4) There is not any design or operational standards that replace performance standards.
- 5) Small businesses cannot be exempted from these regulations and still adequately protect public health.

**Public comment**

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

No comments received.

Commenter	Comment	Agency response

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights*

*of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

- 1) The proposed modification of these regulations will neither strengthen nor erode the authority and rights of parents in the education, nurturing, and supervision of their children.
- 2) The proposed modification of these regulations will neither encourage nor discourage economic self-sufficiency, self-pride, nor the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents.
- 3) The proposed modification of these regulations will neither strengthen nor erode the marital commitment.
- 4) The proposed modification of these regulations will neither increase nor decrease disposable family income.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

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

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
12VAC 5-165-10	N/A	Importer not defined.	Importer means either the owner or consignee at the time of entry into the United States, or the agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.
12VAC 5-165-10	N/A	Processor is defined as a person who operates an establishment that cooks, picks, packs, repacks or pasteurizes crab meat.	Processor means any person engaged in commercial, custom, or institutional processing of crab meat, either in the United States or in a foreign country.
12VAC 5-165-70	N/A	Oversight of safety of product. Any condition that may compromise the safety of the final product shall be identified by the repacker and the Division shall be contacted for appropriate disposition of the product.	Repealed. The processor is responsible for the safety of the product and may decide the appropriate disposition independently from the Division in consult with VA Tech Seafood Extension or using the U. S. FDA Seafood Hazards Guide.

12VAC 5-165-80	N/A	Crab meat for repacking from a foreign government shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by a foreign government public health authority and shall operate under a HACCP plan approved by a foreign government public health authority.	Added the FDA imports requirement that imported crab meat shall meet the requirements of the Code of Federal Regulations: 21 CFR 123.12 "Special requirements for imported products."
12VAC 5-165-90	N/A	Imported crab meat must be received with transport temperature conditions. The measuring device must be approved by the Division.	The regulation will be amended to include transport temperature receiving conditions for all crab meat whether domestic or foreign in line with the FDA requirements for pasteurized crab meat. The Division does not need to approve the temperature measuring device. The device used must meet the requirements of the FDA Seafood Hazards Guide for its intended use.
12VAC 5-165-100	N/A	Sampling and analysis of imported crab meat is currently required prior to repacking.	All imported crab meat must meet the FDA Code of Federal Regulations: 21 CFR 123.12 in order to be imported into the United States. The import requirements help to ensure that the crab meat is processed in a facility that is comparable to a U.S regulated facility, follows good manufacturing practices and Seafood Hazard Analysis and Critical Control Points (HACCP). The regulation is amended to allow for sampling prior to repacking and gives action levels for both aerobic plate counts and fecal coliform.
12VAC 5-165-120	N/A	Verification of container integrity for imported, pasteurized crab meat.	Amended regulation for all pasteurized crab meat to have a container integrity check and the records be kept on file for a minimum of one year.
12VAC 5-165-150	N/A	Containers of pasteurized crab meat destined for repacking shall be stored at a temperature of 36°F or less. Transportation is included.	Amended regulation to require all pasteurized crab meat to be stored at 36°F or less. Transportation requirement removed since it is the responsibility of the receiving company to ensure temperature requirements.
12VAC 5-165-180	N/A	Cooling of crab meat after repacking.	Remove "or both", requirement is unnecessary.
12VAC 5-165-200	N/A	Imported crab meat to be pasteurized is currently required to meet the National Blue Crab Industry Pasteurization and Alternative Thermal	Amended regulation to remove requirement. The FDA Seafood Hazards Guide and in plant validation studies conducted by VA Tech Seafood Extension serves to control hazards in pasteurization.

		Processing Standards.	
12VAC 5-165- 220	N/A	Lot number requirements on containers referred to the source firm.	Amended regulation to change source firm to original processor for consistency.
12VAC 5-165- 230	N/A	Imported crab meat is required to be packed into containers which bear a declaration of the country of origin.	Stickers are often placed onto containers with the country of origin. These stickers are easily removed from the container so that consumer believes the crab meat is domestic, which demands a higher price. The regulation is amended to require a pre-printed container with country of origin on the principal display panel.
12VAC 5-165- 260	N/A	The individual crab meat shall be easily traceable.	The current regulation does not define the scope of what must be traceable. The regulation is amended to require lots of crab meat to be traceable.
12VAC 5-165- 270	N/A	The minimum records to be kept are listed.	The regulation is amended to better clarify and be consistent with the type of records and length of time they must be kept.
12VAC 5-165- 290	N/A	Decertification of certified facilities.	The regulation is repealed since the penalty for not labeling the repacked crab meat with the country of origin is a Class 1 misdemeanor.
12VAC 5-165- 310	N/A	Persons guilty of a Class 1 misdemeanor if found to be packing or repacking foreign crab meat into a container without the country of origin indicated on the principal display panel.	Persons are clarified. The owner of a facility and the supervisory employees of that facility may be guilty of a Class 1 misdemeanor. It is not the intent of the Division to charge the hourly employee who is found repacking foreign crab meat as domestic crab meat. The person making the decisions; the owner or supervisor would be charged by the Division.

**Project 2705 - NOIRA**

**DEPARTMENT OF HEALTH**

**Modify regulations for repacking of crabmeat as result of periodic review**

CHAPTER 165  
REGULATIONS FOR THE REPACKING OF CRAB MEAT

Part I  
General Provisions

**12VAC5-165-10. Definitions.**

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

"Action level" means the limit established for a deleterious substance present in a product or the environment, above which level prescribed actions by the division may be required to protect public health.

"Agency" means the Virginia Department of Health.

"Certificate of Inspection" means a numbered certificate issued by the division to a shipper after an inspection confirms compliance with applicable regulations and standards.

"Certification number" means a unique number assigned to each shipper upon issuance of a Certificate of Inspection.

"Certified laboratory" means a laboratory certified by the U.S. Food and Drug Administration for analysis of food products.

"Critical Control Point (CCP)" means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can, as a result, be prevented, eliminated or reduced to acceptable numbers.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

~~"Decertification" means the revocation of a Certificate of Inspection.~~

"Department" means the Virginia Department of Health.

"Division" means the Division of Shellfish Sanitation.

"Establishment" means any vehicle, vessel, property, or premises where crustacea, finfish or shellfish are transported, held, stored, processed, packed, repacked or pasteurized in preparation for marketing.

"HACCP plan" means a written document that delineates the formal procedures that a dealer follows to implement a Hazard Analysis Critical Control Point methodology to assure food safety.

"Hazard analysis" means a process used to determine whether there are food safety hazards that are reasonably likely to occur while repacking crab meat and to identify the preventive measures that the repacker can apply to control those hazards.

"Importer" means either the owner or consignee at the time of entry of the crab meat into the United States, or the agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.

"Lot" means repacked crab meat that bears the same repack date and source code.

"Preventive measure" means actions taken to prevent or control a food safety hazard.

"Processing" means cooking, picking, packing, repacking or pasteurizing crab meat.

~~"Processor" means a person who operates an establishment that cooks, picks, packs, repacks or pasteurizes crab meat.~~ "Processor means any person engaged in commercial, custom, or institutional processing of crab meat, either in the United States or in a foreign country."

"Repacker" means a person who operates an establishment that transfers crab meat from a container originally packed by another establishment to another container.

"Repacking operation" means a process of transferring crab meat from the original shipper's packing container to a different packing container, including all steps beginning with the removal of the original containers of meat from the repacker's refrigeration and ending with the repacked crab meat in properly identified containers placed into refrigeration.

"Shipper" means a person who operates an establishment for the cooking, picking, repacking or pasteurizing of crab meat.

"Source code" means a code designated by the repacker which represents the crab processing facility where crab meat was obtained.

#### **12VAC5-165-70. Oversight for safety of product. (Repealed.)**

~~Any condition that may compromise the safety of the final product shall be identified by the repacker and the division shall be contacted for appropriate disposition of the product.~~

#### Part II

#### Sources of Crab Meat for Repacking

#### **12VAC5-165-80. Source facility requirements.**

Crab meat for repacking shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by either a state public health authority or by a foreign government public health authority, and shall operate under a HACCP plan approved by the state or a foreign government public health authority, or the U.S. Food and Drug Administration. Imported crab meat shall meet the requirements for imported products set forth in 21 CFR 123.12 or successor.

#### **12VAC5-165-90. Verification of shipping temperatures for imported crab meat.**

~~When imported crab meat is used as a source for repacking, the~~ The repacker shall provide a record of ~~international~~ transport temperature receiving conditions for each shipment ~~of crab meat, or other information sufficient to verify that the product was not temperature abused.~~ Temperature recording may be by maximum temperature recording, continuous temperature recording, or by other device such as adequate amount of ice or adequate quantity of chemical cooling media. ~~approved by the Division of Shellfish Sanitation.~~ The processor-repacker shall include the transport receiving temperature conditions as a part of the receiving CCP in it's the HACCP plan.

#### **12VAC5-165-100. Sampling and analysis requirements for imported crab meat.**

~~A. When imported crab meat is used as a source for repacking, the repacker shall take a minimum of five samples from the first two shipments prior to any processing to be analyzed by a certified laboratory. If all samples from both initial shipments meet the specified action levels, then the sampling interval may be reduced to once every three months (quarterly) for each shipper. If any quarterly samples exceed the action levels, then sampling will be required on all successive shipments until all samples from two successive shipments meet the action levels as follows:~~ When imported crab meat is used as a source for repacking, the importer or repacker may take samples from each lot prior to processing to be analyzed by a certified laboratory and maintain on file a copy of the sampling results for a minimum of 1 year. The action levels for the crab meat sampled are as follows:

1. Pasteurized crab meat.
  - a. Aerobic plate count; action level of >3,000/g.
  - b. Fecal coliforms; action level of >20/100g.
2. All other crab meat.
  - a. Aerobic plate count; action level of >100,000/g.
  - b. Fecal coliforms; action level of >93/100g.

B. When imported crab meat is used as a source for repacking, the importer or repacker shall may take a minimum of five samples from every shipment to be tested for decomposition by organoleptic sensing technique and maintain a copy of the results on file for a minimum of 1 year. ~~These analyses shall be conducted only by a designated person trained in organoleptic sensing technique either by Virginia Polytechnic Institute and State University (Virginia Tech), the United States Food and Drug Administration (FDA), or by another source approved by the division. The repacker shall submit to the division a copy of the certificate of training or other documentation denoting successful completion of the training from the trainer for each individual conducting the analysis, and shall maintain a copy in his records.~~

C. If any sample is found to exceed an action level or guideline, or is found to show evidence of decomposition, the repacker shall stop processing the lot sampled and ~~contact the division before proceeding with processing to determine the disposition of that lot.~~

D. All records of sample analyses ~~shall be kept on file at the repacker and repacker's establishment shall be~~ made available for review by the division Division. These records shall be maintained for a period of one year from the date of processing for products packaged for fresh distribution, and two years for products packaged for frozen or pasteurized distribution.

**12VAC5-165-120. Verification of container integrity for imported, pasteurized crab meat.**

The repacker shall evaluate the container integrity of all imported, pasteurized crab meat products. These evaluations shall also be conducted after any pasteurization by the repacker. This evaluation shall at a minimum include visual inspection of all containers for evidence of leaks. A record of inspection shall be maintained on file by the repacker for a minimum of one year.

**12VAC5-165-150. Pasteurized crab meat storage temperature.**

Containers of pasteurized crab meat ~~destined for repacking shall be stored and transported~~ in a refrigerated room or vehicle at a temperature of 36°F or less.

**12VAC5-165-180. Cooling of crab meat after repacking.**

Immediately after repacking, the repacker shall place containers of repacked crab meat ~~shall be either placed into crushed or flaked ice or placed into refrigeration not to exceed 36°F, or both.~~

**12VAC5-165-200. Imported crab meat to be pasteurized. (Repealed.)**

~~Prior to or after repacking, the repacker shall pasteurize all imported crab meat which has not been pasteurized in the country of origin. Pasteurization shall meet the National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards, revised November 8, 1993, with records of pasteurization to be kept as required in Article 3 (12VAC5-165-240 et seq.) of this part. The heat penetration in the crab meat during the pasteurization process for all container sizes and types shall be confirmed in writing by Virginia Tech or other authority approved by the division as meeting the aforementioned minimum requirements.~~

**12VAC5-165-220. Lot numbers.**

- A. Containers of repacked crab meat shall be stamped or embossed with the lot number.

~~B. Lot numbers shall consist of a repack date and a code indicating the original source firm that picked the crab meat. All codes for lot numbers shall be logged in the processor records with an explanation of the code. Lot numbers shall consist of a repack date and a code indicating the original processor. Records shall be maintained by the repacker for a minimum of one year with an explanation of the code.~~

**12VAC5-165-230. Country of origin for imported crab meat.**

Imported crab meat shall be packed by the repacker into pre-printed containers which bear a declaration of the country of origin of the repacked crab meat on the principal display panel of the container.

Article 3

Records and Recordkeeping

**12VAC5-165-240. Accessibility of records.**

All required records shall be ~~(i) kept in logical order, (ii) maintained by the repacker, and (iii) readily accessible by~~ shall be made available to the Division of Shellfish Sanitation staff for inspection.

**12VAC5-165-260. Traceability of repacked crab meat.**

The individual lots of crab meat shall be easily traceable from their source through the repacking process to the buyer and from the buyer back through the repacker to the particular lot source.

**12VAC5-165-270. Minimum records to be kept.**

The repacker shall, ~~at a minimum,~~ maintain the following information on each lot of repacked crab meat for a minimum of one year ( i) the original processor information, (ii) verification records of shipping temperature conditions, (iii) records required by the repacker's HACCP plan, and (iv) repacked crab meat sales records. Additional clarifying records may be required by the Division to identify lot codes on containers. the source plant, quantity received from source, type of meat, date of repacking, buyers, and quantities of repacked lots sold. Additional clarifying records may be required if individual lots of product cannot easily be traced.

**12VAC5-165-280. Records to be kept separate. (Repealed.)**

~~Records for repacked imported crab meat shall be kept separate from other production records.~~

Article 4

Penalties

**12VAC5-165-290. Decertification of certified facilities. (Repealed.)**

~~Any certified crab meat processor found to be packing or repacking foreign crab meat into a container without the country of origin on the principal display panel will be decertified for 30 days, effective immediately upon the finding by the Director of the Division of Shellfish Sanitation.~~

**12VAC5-165-310. Improper labeling of foreign crab meat. (Repealed.)**

~~Persons, even if operating in a facility with a valid Certificate of Inspection, shall be guilty of a Class 1 misdemeanor if found to be packing or repacking foreign crab meat into a container without the country of origin indicated on the principal display panel.~~

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-165)

~~National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards, National Blue Crab Industry Association Grades and Cooking Standards Committee, revised November 8, 1993. Code of Federal Regulations: 21 CFR 123.12 "Special requirements for imported products".~~



# COMMONWEALTH of VIRGINIA

Department of Health

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RICHMOND, VA 23218

KAREN REMLEY, MD, MBA, FAAP  
STATE HEALTH COMMISSIONER

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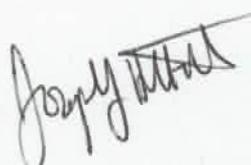
## MEMORANDUM

DATE: August 26, 2011

TO: Virginia State Board of Health

FROM: Joseph J. Hilbert, Director  
Governmental and Regulatory Affairs

SUBJECT: Emergency Regulations for Licensure of Abortion Facilities, 12VAC5-412



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Enclosed please find draft emergency regulations for the licensure of abortion facilities. The Board of Health is mandated by Senate Bill (SB) 924, enacted by the 2011 General Assembly, to promulgate regulations for facilities performing five or more first trimester abortions per month. The legislation requires the regulations to take effect within 280 days of enactment of SB924. In order to comply with that expedited timeframe, the Board is utilizing the emergency rulemaking process authorized by the Virginia Administrative Process Act.

SB924 requires the Board to promulgate regulations addressing minimum standards for:

- Construction and maintenance;
- Operation, staffing and equipping;
- Qualifications and training of staff; and
- Infection prevention, disaster preparedness and facility security.

The draft emergency regulations contain provisions pertaining to definitions, procedures for licensure or license renewal, organization and management, infection prevention, patient care, quality assurance, medical records and reports, functional safety and maintenance, and design and construction. You will note that this regulatory action also contains a few amendments to 12 VAC5-410 (Regulations for the Licensure of Hospitals in Virginia.)

This regulatory action also will serve as the Notice of Intended Regulatory Action (NOIRA) to initiate the process to promulgate permanent regulations that would replace these emergency regulations upon their expiration. Pursuant to state law, emergency regulations may remain effective for a maximum of 12 months, although the Governor can extend emergency regulations for up to an additional six months.

The draft emergency regulations have been reviewed by the Office of the Attorney General. If the Board approves these draft emergency regulations, the Virginia Department of Health will move forward with submitting them for the Executive Branch review pursuant to the provisions of the Virginia Administrative Process Act.

I look forward to discussing the draft emergency regulations with you at the September 15, 2011 Board meeting.



Virginia  
Regulatory  
Town Hall

townhall.virginia.gov

## Emergency Regulation and 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>	Establishes minimum standards for facilities performing five or more first trimester abortions per month.
<b>Date this document prepared</b>	August 26, 2011

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

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

### Preamble

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

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

Senate Bill 924, enacted by the 2011 General Assembly, mandates the Board of Health to promulgate regulations for facilities performing five or more first trimester abortions per month. SB924 specified that, for purposes of licensure, those facilities were to be classified as a category of hospital. SB924 further specified that the regulations have to be effective within 280 days of enactment. For that reason, the Board is utilizing the emergency rulemaking process authorized by the Administrative Process Act.

The regulations contain provisions pertaining to definitions, procedures for licensure or license renewal, organization and management, infection prevention, patient care, quality assurance, medical records and reports, disaster preparedness, facility security, functional safety and maintenance, and design and construction.

## Legal basis

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

---

Section 32.1-127, as amended by Chapter 670 of the 2011 General Assembly, mandates the State Board of Health to promulgate these emergency regulations, and provides the statutory authority for this emergency regulation.

## Purpose

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

---

The intent of this regulatory action is to promote and assure the safety of patients who receive first trimester abortion services. SB924 mandates that the regulatory action include minimum standards for facilities performing five or more first trimester abortions per month. The standards are required to include those for construction and maintenance; operation, staffing and equipping; qualifications and training of staff; and infection prevention, disaster preparedness and facility security.

## Need

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

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

Following approval of this Emergency Regulation and Notice of Intended Regulatory Action by the Governor, and its publication in the Virginia Register of Regulations, the subsequent public comment period may delineate specific issues that need to be addressed during the process of adopting the permanent, replacement regulations.

## Substance

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

---

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

### Definitions

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

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

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

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

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

“Minor” means a patient under the age of 18.

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

“Physician” means a person licensed to practice medicine in Virginia.

### Procedures for Licensure or License Renewal

License valid for one year.

Commissioner may suspend or revoke license.

VDH shall make periodic, unannounced annual onsite inspections.

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

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

Commissioner may allow a temporary variance to the regulatory provisions

### Organization and Management

Each facility shall have a governing body.

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

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

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

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

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

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

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

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

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

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

### Infection Prevention

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

### Patient Care

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

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

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

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

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

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

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

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

Elective general anesthesia shall not be used.

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

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

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

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

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

A written agreement shall be executed with a licensed general hospital to ensure that any patient of an abortion facility shall receive needed emergency treatment.

#### Quality Assurance

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

#### Medical Records and Reports

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

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

Provisions shall be made for the safe storage of medical records according to applicable provisions of state and federal law.

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

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

#### Functional Safety and Maintenance

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

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

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

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

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

Design and Construction

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

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC5-410-10		Definition of "Outpatient Hospital"	The following text is stricken from the definition: "Outpatient abortion clinics are deemed a category of outpatient hospitals." Rationale – Abortion clinics will be regulated pursuant to 12 VAC5-412, not 12 VAC5-410.
12 VAC5-5-410-60		Separate License	Deletes the term "outpatient abortions" from the provision authorizing VDH to require a hospital to have separate licenses for different types of services. Rationale - Abortion clinics will be regulated pursuant to 12 VAC5-412, not 12 VAC5-410.

**Alternatives**

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

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

**Public participation**

*Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated*

*in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.*

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

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

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

### Participatory approach

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

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

### Family impact

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

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

CHAPTER 410  
REGULATIONS FOR LICENSURE OF HOSPITALS IN VIRGINIA

Part I  
Definitions and General Information and Procedures

Article 1  
Definitions

**12VAC5-410-10. Definitions.**

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

"Board" means the State Board of Health.

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

"Commissioner" means the State Health Commissioner.

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

"Department" means an organized section of the hospital.

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

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

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

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

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

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

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

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

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

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

"Organized" means administratively and functionally structured.

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

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

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

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

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

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

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

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

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

**12VAC5-410-60. Separate license.**

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

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

CHAPTER 412  
REGULATIONS FOR LICENSURE OF ABORTION FACILITIES

Part I

Definitions and Requirements for Licensure

**12VAC5-412-10. Definitions.**

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

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

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

“Commissioner” means the State Health Commissioner.

“Department” means the Virginia Department of Health.

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

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

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

“Minor” means a patient under the age of 18.

“Ownership/person” means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns and/or manages or operates an abortion facility.

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

“Physician” means a person licensed to practice medicine in Virginia.

“Trimester” means a 12-week period of pregnancy.

**12VAC5-412-20. General.**

A license to establish or operate an abortion facility shall be issued only when the abortion facility is in compliance with all applicable federal, state and local statutes and regulations, the provisions of this chapter, and when the application fee has been received by the department.

No ownership/person, as defined in 12VAC5-412-10, shall establish, conduct, maintain, or operate in this State, any abortion facility as defined and included within provisions of this chapter without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.

**12VAC5-412-30. Classification.**

Abortion facilities shall be classified as a category of hospital.

**12VAC5-412-40. Separate license.**

An abortion facility operating at more than one location shall be required to obtain separate licenses for each location in which abortion services are provided.

Abortion facilities which have separate organized sections, units or buildings to provide services of a classification covered by provisions of other state statutes or regulations shall be

required to have any additional applicable license required for that type or classification of service.

Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of these regulations.

**12VAC5-412-50. Request for issuance.**

A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to Department's Office of Licensure and Certification (OLC).

B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days.

C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the facility's certificate of use and occupancy.

D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee is submitted.

E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC.

F. A license shall not be assigned or transferred. A new application for licensure shall be made at least 30 days in advance of a change of ownership or location.

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

A. Licenses shall expire at midnight April 30th following the date of issue, and shall be renewable annually, upon filing of a renewal application and payment of the appropriate non-refundable renewal application fee. Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter.

B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.

C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-120 shall not be eligible for license renewal.

**12VAC5-412-70. Posting of license.**

The abortion facility license issued by the commissioner shall at all times be posted in a place readily visible and accessible to the public.

**12VAC5-412-80. Return of license.**

A. It is the responsibility of the facility's governing body to maintain a current and accurate license.

B. The license issued by the commissioner shall be returned to the OLC when any of the following changes occur which may require reissuance of a license during the licensing year:

1. Revocation or suspension;
2. Change of location;
3. Change of ownership;
4. Change of name;
5. Voluntary closure.

C. The facility shall give written notification 30 working days in advance of any proposed changes that may require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC.

D. The OLC will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the facility during the process of evaluating a proposed change.

E. The facility will be notified in writing whether a new application is needed.

**12VAC5-412-90. Allowable variances.**

Upon finding that the enforcement of a specific regulation would be an impractical hardship unique to the abortion facility, the commissioner may grant a variance temporarily waiving the enforcement of the specific regulation, provided patient safety, patient care, and services are not adversely affected.

**12VAC5-412-100. Right of entry.**

Pursuant to §32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Such entries and inspections shall be made with the permission of the owner or person in charge, unless an inspection warrant is obtained after denial of entry from an appropriate circuit court. If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate revocation or suspension of the license. If the entity is unlicensed, the owner or person in charge shall be subject to penalties and other actions pursuant to §32.1-27 of the Code of Virginia.

**12VAC5-412-110. On-site inspection.**

A. An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than annually. If the department finds, after inspection, non-compliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-120.

B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the facility's control, direction or supervision.

C. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records, is not available on the premises, such person or the designated alternate, shall be available on the premises within 1 hour of the surveyor's arrival. A list of current patients shall be provided to the surveyor within 2 hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-127 and denial, suspension or revocation of the facility's license in accordance with 12 VAC5-412-130.

**12VAC5-412-120. Plan of correction.**

A. Upon receipt of a written licensing report each abortion facility shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.

B. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan of correction as determined by the OLC. The plan of correction shall contain for each violation cited:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;

2. The expected correction date, not to exceed 30 working days from the exit date of the survey;

3. A description of the measures implemented to prevent a recurrence of the violation; and

4. The signature of the person responsible for the validity of the report.

C. The administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with Virginia Code § 32.1-27 or in denial, revocation or suspension of a license in accordance with 12 VAC 5-412-130.

D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

**12VAC5-412-130. Denial, revocation or suspension of license.**

A. When the department determines that an abortion facility is (i) in violation of any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department, may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia.

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

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

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

Part II

Organization and Management

**12VAC5-412-140. Governing body.**

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility.

B. There shall be disclosure of facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.

C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.

D. The governing body shall have a formal organizational plan with written bylaws. These shall clearly set forth organization, duties and responsibilities, accountability, and relationships of professional staff and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.

E. The bylaws shall include at a minimum the following:

1. A statement of purpose;
2. Description of the functions and duties of the governing body, or other legal authority;
3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;
4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and
5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.

**12VAC5-412-150. Policy and procedures manual.**

Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering, at a minimum, the following topics:

1. Personnel;
2. Types of elective and emergency procedures that may be performed in the facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining written informed consent of the patient prior to the initiation of any procedures;
6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;
7. Infection prevention;
8. Risk and quality management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state, and local laws;
12. Facility security;
13. Disaster preparedness;
14. Patient rights;
15. Functional safety and facility maintenance; and
16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable.

These policies and procedures shall be based on recognized standards and guidelines.

A copy of the approved policies and procedures and revisions thereto shall be made available to the OLC upon request.

**12VAC5-412-160. Administrator.**

A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.

B. Any change in the position of the administrator shall be reported immediately by the licensee to the department in writing.

C. A qualified individual shall be appointed in writing to act in the absence of the administrator.

**12VAC5-412-170. Personnel.**

A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.

B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.

C. Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

D. When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.

E. The facility shall develop, implement and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

F. Job Descriptions.

1. Written job descriptions that adequately describe the duties of every position shall be maintained.

2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.

3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.

G. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.

H. Personnel policies and procedures shall include, but not be limited to:

1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;

2. Process for verifying current professional licensing or certification and training of employees or independent contractors;

3. Process for annually evaluating employee performance and competency;

4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and

5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

I. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.

**12VAC5-412-180. Clinical staff.**

A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and non-physician health care practitioners shall be clearly defined.

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

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

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

**12VAC5-412-190. Consent of the patient.**

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.

**12VAC5-412-200. Minors.**

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.

**12VAC5-412-210. Patients' rights.**

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

B. The facility shall establish and maintain complaint handling procedures which specify the:

1. System for logging receipt, investigation and resolution of complaints; and
2. Format of the written record of the findings of each complaint investigated.

C. The facility shall designate staff responsible for complaint resolution, including:

1. Complaint intake, including acknowledgment of complaints;
2. Investigation of the complaint;
3. Review of the investigation findings and resolution for the complaint; and
4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.

D. The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service.

E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:

1. Facility contact person; and
2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place.

F. The facility shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained for no less than three years.

Part III  
Infection Prevention

**12VAC5-412-220. Infection prevention.**

A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.
2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.
3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

B. Written infection prevention policies and procedures shall include, but not be limited to:

1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility;
2. Training of all personnel in proper infection prevention techniques;
3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;
4. Use of standard precautions;
5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration;
6. Use of personal protective equipment;
7. Use of safe injection practices;
8. Plans for annual retraining of all personnel in infection prevention methods;
9. Procedures for monitoring staff adherence to recommended infection prevention practices; and
10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection /sterilization to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

D. The facility shall have an employee health program that includes:

1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood borne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;
5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities:

1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop;
2. A procedure for surveillance, documentation and tracking of reported infections; and

3. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.

Part IV  
Patient Care

**12VAC5-412-230. Limitation of services offered by abortion facilities.**

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.

**12VAC5-412-240. Medical testing, patient counseling and laboratory services.**

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

1. Use of any additional medical testing, including but not limited to ultrasonography, shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.

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

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

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

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

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

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

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

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

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

E. 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 (9 VAC20-120).

**12VAC5-412-250. Anesthesia service.**

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

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

C. The 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.

D. 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.

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

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;
5. Continuous electrocardiograph;
6. Devices for measuring blood pressure, heart rate and respiratory rate;
7. Defibrillator; and
8. Accepted method of identifying and preventing the interchangeability of gases.

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

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

1. Drugs to treat malignant hyperthermia, when triggering agents are used;
2. Peripheral nerve stimulator, if a muscle relaxant is used; and
3. If using an anesthesia machine, the following shall be included:
  - a. End-tidal carbon dioxide monitor (capnograph);
  - b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;
  - c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
  - d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;

e. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;

f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered;

g. Alarm systems for high (disconnect), low (subatmospheric) and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and

h. A gas evacuation system.

H. 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.

I. Elective general anesthesia shall not be used.

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

A. Controlled substances, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).

B. Drugs, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed or administered by a physician.

C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.

D. The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.).

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Drug Control Act of the Code of Virginia.

**12VAC5-412-270. Equipment and supplies.**

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:

1. A bed or recliner suitable for recovery;
2. Oxygen with flow meters and masks or equivalent;
3. Mechanical suction;
4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways;
5. Emergency medications, intravenous fluids, and related supplies and equipment;
6. Sterile suturing equipment and supplies;
7. Adjustable examination light;
8. Containers for soiled linen and waste materials with covers; and

9. Refrigerator.

**12VAC5-412-280. Emergency equipment and supplies.**

An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support. Drugs shall include, at a minimum, those to treat the following conditions:

1. Cardiopulmonary arrest;
2. Seizure;
3. Respiratory distress;
4. Allergic reaction;
5. Narcotic toxicity;
6. Hypovolemic shock; and
7. Vasovagal shock.

**12VAC5-412-290. Emergency services.**

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

B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support.

C. A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.

**12VAC5-412-300. Quality assurance.**

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:

1. A physician
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff.

In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.

D. Measures shall be implemented to resolve problems or concerns that have been identified.

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

#### Part V

#### Medical Records And Reports

#### **12VAC5-412-310. Medical records.**

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
  - a. Physician orders;
  - b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
  - c. Anesthesia record;
  - d. Operative record;
  - e. Surgical medication and medical treatments;
  - f. Recovery room notes;
  - g. Physician and nurses' progress notes,
  - h. Condition at time of discharge,
  - i. Patient instructions, preoperative and postoperative; and
  - j. Names of referral physicians or agencies.

#### **12VAC5-412-320. Records storage.**

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored.

**12VAC5-412-330. Reports.**

A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC-5-550-120).

B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence.

Part VI

Functional Safety and Maintenance

**12VAC5-412-340. Policies and procedures.**

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

1. Facility security;

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

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

**12VAC5-412-350. Disaster preparedness.**

A. Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

**12VAC5-412-360. Maintenance.**

A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

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

**12VAC5-412-370. Fire-fighting equipment and systems.**

A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.

B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.

C. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).

Part VII  
Design and Construction

**12VAC5-412-380. Local and state codes and standards.**

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

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.