

**State of Board of Health  
Agenda  
September 5, 2019 – 9:00 a.m.  
Perimeter Center – Boardroom 2**

Note: There is limited seating within Boardroom 2, with seats available for 100 members of the public. The meeting will also be viewable in Boardroom 1. There is limited seating within Boardroom 1, with seats available for 80 members of the public. Seating will be available on a first-come, first served basis. The maximum occupancy of Boardroom 2 and 1 is enforced by the Fire Marshal, and cannot be exceeded.

Sign-up sheets for individuals wishing to address the Board during the public comment period will be available in Boardroom 2 and Boardroom 1. Each individual will be allowed to put only one name on the sign-up sheet. Public Comment period 1 is reserved for comments concerning the Regulations for Licensure of Abortion Facilities and related topics. Public Comment Period 2 is reserved for comments for any other topics not previously identified in Public Comment Period 1.

|   |   |
|---|---|
| Call to Order and Welcome   | Faye Prichard, Chair  |
| Pledge of Allegiance  | Linda Hines   |
| Introductions   | Ms. Prichard  |
| Proclamation in Memoriam of Dr. Hughes Melton   | Ms. Prichard  |
| Review of Agenda  | Joseph Hilbert<br>Deputy Commissioner for Governmental<br>and Regulatory Affairs    |
| Approval of June 6, 2019 Minutes  | Ms. Prichard  |
| Commissioner’s Report   | M. Norman Oliver, MD, MA<br>State Health Commissioner                               |
| Regulatory Action Update  | Mr. Hilbert   |
| Break   |   |
| Public Comment Period 1 – Regulations for Licensure of Abortion Facilities and related topics |   |
| <u>Working Lunch/Regulatory Action Item</u>   |   |
| Regulations for the Licensure of Abortion Facilities<br>12VAC5-412<br>(Proposed Amendments)   | Rebekah Allen, JD<br>Senior Policy Analyst<br>Office of Licensure and Certification |
| Break   |   |

Public Comment Period 2 – Any other topics not previously identified in Public Comment Period 1.

Regulatory Action Items

State Medical Facilities Plan  
12 VAC5-230  
(Final Amendments)

Erik Bodin, Director  
Division of COPN, MCHIP and Cooperative  
Agreement  
Office of Licensure and Certification

Certificate of Quality Assurance of Managed  
Care Health Insurance Licensees  
12VAC5-408  
(Fast Track Amendments)

Ms. Allen

Regulations for Bedding and Upholstered Furniture  
Inspection Program  
12VAC5-125  
(Proposed Amendments)

Allen Knapp, Director  
Office of Environmental Health Services

2020 Board Meeting Schedule

Ms. Prichard

Member Reports

Other Business

Adjourn



# COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA  
STATE HEALTH COMMISSIONER

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

## MEMORANDUM

DATE: August 21, 2019

TO: Virginia State Board of Health

FROM: Rebekah E. Allen, JD  
Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Regulations for Licensure of Abortion Facilities – Amending Regulation after Assessment, Periodic Review, and Receipt of Public Comment

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Enclosed for your review are proposed amendments to the Regulations for Licensure of Abortion Facilities (12VAC5-412).

On February 21, 2019, an Order was entered in *Melendez v. Virginia State Board of Health* to suspend amendments promulgated by the Board in 2017 to 13 sections of 12VAC5-412. This regulatory action was initiated to (i) repropose the substance of the suspended 2017 rulemaking; (ii) conduct a periodic review of 12VAC5-412, as required by Executive Order 14 (amended July 16, 2018); and (iii) assess and consider changes to 12VAC5-412 beyond what VDH already contemplated in its 2017 rulemaking. VDH reviewed and analyzed 3,829 comments submitted during the 30-day public comment period following publication of the Notice of Intended Regulatory Action as well as the recommendations of VDH staff based on their experience conducting abortion facility inspections. Based on that information, VDH drafted the proposed amendments.

The proposed amendments to 12VAC5-412: add back several changes from the suspended 2017 rulemaking; consolidate relevant regulatory sections; distinguish between medication abortions and surgical abortions; exempt facilities performing only medication abortions from certain requirements; update the facility design and construction requirements; and make minor technical amendments. Forms and documents incorporated by reference were updated to reflect the proposed changes.

Sections 1.1, 1.3, and 1.4 of the *Guidelines for Design and Construction of Outpatient Facilities* referenced in the proposed amendments are included for the Board of Health to review. The inclusion of the *Guidelines* is required based on *Melendez*, but the referenced portions of the *Guidelines* have been changed to conform to *Whole Woman's Health v. Hellerstedt*.

The Board of Health is requested to approve the proposed amendments. Should the Board of Health approve them, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process. Following Executive Branch review and approval, the proposed amendments will be submitted to the Virginia Register of Regulations and the Virginia Regulatory

Town Hall website for publication with a 60-day comment period. Following the close of that public comment period, VDH will draft the final amendments.



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

## Proposed Regulation Agency Background Document

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|---|---|
| <b>Agency name</b>                                    | Virginia Board of Health  |
| <b>Virginia Administrative Code (VAC) citation(s)</b> | 12VAC5-412  |
| <b>Regulation title(s)</b>                            | Regulations for Licensure of Abortion Facilities                    |
| <b>Action title</b>                                   | Amend the Regulation after Assessment and Receipt of Public Comment |
| <b>Date this document prepared</b>                    | August 23, 2019   |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

This regulation governs the licensure of facilities that perform five or more first trimester abortions per month. This regulatory action seeks to amend the current regulation content. Regulatory language was reviewed and clarified if the content was unclear, inconsistent, or outdated, and was revised to conform to the *Form, Style and Procedure Manual for Publication of Virginia Regulations*. Language was also revised to more accurately reflect on whom the regulatory requirements were placed. Several changes from the 2017 rulemaking (which were remanded in *Melendez v. Virginia State Board of Health* (Case No. CL17-1164)) have been added back into the text.

The various types of policies and procedures required were consolidated into the section entitled "Policies and procedures." Other sections were also consolidated, such as equipment and supplies. Language was added to distinguish between medication abortions and surgical abortions, and to exempt facilities performing only medication abortions from some of the requirements that were inapplicable to medication abortions, such as anesthesia. Language was added to incorporate Sections 1.1, 1.3, and 1.4 of the

*Guidelines for Design and Construction of Outpatient Facilities*, 2018 Edition. Forms and documents incorporated by reference were updated to reflect the proposed changes.

## 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.*

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“Agency” means the Virginia Department of Health.

“APA” means the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia.

“Board” means Virginia Board of Health.

“OLC” means the Office of Licensure and Certification.

## Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, “mandate” has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”*

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Section 32.1-127 of the Code of Virginia requires the Board to adopt regulations that include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities. For purposes of this requirement, facilities in which five or more first trimester abortions per month are performed shall be classified as a category of "hospital". (§ 32.1-127(B)(1)). On February 21, 2019, by order entered in *Melendez v. Virginia State Board of Health* (Case No. CL17-1164), the Circuit Court of Henrico County remanded several sections of the regulation to the Board. On April 22, 2019, the Board, after considering the order of the Henrico County Circuit Court, decided to assess all regulation content and approved the issuance of this Notice.

The periodic review of this regulation is mandated by Executive Order 14 (as amended July 16, 2018).

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity’s overall regulatory authority.*

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Section 32.1-12 of the Code of Virginia gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Section 32.1-127 of the Code of Virginia requires the Board to adopt regulations that include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities. For purposes of this requirement, facilities in which five or more first trimester abortions per month are performed shall be classified as a category of "hospital" (§ 32.1-127(B)(1) of the Code of Virginia).

## Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.*

The rationale or justification for this regulatory change is that regulations should be clearly written, up to date, conform to the law, and should be the least burdensome means of protecting the health, safety, and welfare of citizens. The regulatory change is essential to protect the health, safety, and welfare of citizens because unclear regulations hamper licensees' ability to comply, out of date regulations may make reference to standards and practices that are not current, and reducing regulatory burden on medical care facilities allows the facilities to redirect resources to patient care. The goals of this regulatory change are to bring the regulatory text into alignment with the *Form, Style and Procedure Manual for Publication of Virginia Regulations*, statutes, legal decisions; update references to current medical guidelines; and reduce regulatory requirements or exempt eligible facilities from some requirements.

## Substance

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

No new regulatory sections are being proposed.

### Section 10 Definitions

Added definitions for applicant, board, drug, first trimester, governing body, inspector, medication abortions, OLC, surgical abortions, and working day. Revised definitions for abortion, administrator, informed written consent, licensee, and minor.

### Section 20 General

Revised to reflect the commissioner issues licenses and that licenses will denote what type of abortions are being performed at a facility. Added language about transfer or assignment of a license.

### Section 40 Separate license

Revised to clarify that that licenses are issued by the Commissioner.

### Section 50 Request for issuance

Renamed "Request for initial license." Revised to address an applicant's responsibilities during the initial license issuance process, including the requirement to disclose ownership of the abortion facility. Added

language regarding what happens after the initial licensure inspection. Repealed language about transfer or assignment of a license; this has been moved to section 20.

Section 60 License expiration and renewal

Revised to state OLC would not accept renewal applications after license expiration. Added language to include what a licensee can do if the license is not eligible for renewal or is expired.

Section 70 Return and/or reissuance of license

Renamed "Surrender of license; reissuance of license." Removed change of administrator or operator from reportable changes. Revised to clarify when the old license must be surrendered, when a new application for licensure is required, and when a closing abortion facility has to notify patients and the OLC of the location of patient records.

Section 80 Allowable variances

Reinstated some language from the 2017 rulemaking.

Section 90 Right of entry

Revised to align more closely with statutory language.

Section 100 On-site inspection

Added the right to redact personnel information from records prior to turning records over to an inspector. Added language regarding the inspector's obligation to inform the licensee of its right to redact records. Added language regarding what happens after the inspection.

Section 110 Plan of correction

Revised the time to correct to 45 working days. Added language about the OLC being able to verify a plan of correction.

Section 120 OLC complaint investigations

Renamed "Complaint investigations." Added language about determining if an on-site inspection is warranted for a complaint.

Section 130 Violation of this chapter or applicable law; denial, revocation, or suspension of license

Revised to align more closely with statutory language.

Section 140 Management and administration

Repealed subsections C and D as duplicative.

Section 150 Governing body

Repealed subsection B as that is already covered by the initial license application and change of ownership notifications.

Section 160 Policies and procedures

Exempted facilities only providing medication abortions from some policies and procedures requirements. Consolidated policies and procedures requirements from sections 180, 200, 330, and 340.

Section 170 Administrator

Revised to clarify that designation of administrators and alternates must be in writing. Revised to grant abortion facilities five working days to notify the OLC of a change in administrator.

Section 180 Personnel

Repealed subsections D and G; requirements regarding policies and procedures consolidated in section 160.

Section 190 Clinical staff



Revised to clarify who defines clinical privileges. Repealed subsection B; requirements about policies and procedures consolidated in section 160. Exempted facilities only providing medication abortions from some policies and procedures requirements. Revised to permit nurse practitioners and physician assistants to perform some tasks originally restricted to physicians. Consolidated subsection D of section 230.

Section 200 Patients' rights

Removed reference to out of date document incorporated by reference. Revised to clarify when the complaint documentation retention period starts.

Section 210 Quality management

Revised to permit an independent healthcare practitioner to serve in place of a physician on a quality improvement committee. Revised to clarify who the quality improvement committee reports to and who is responsible for implementing corrective action.

Section 220 Infection prevention

Repealed subdivisions 1, 2, and 3 of subsection A; requirements consolidated in section 160. Repealed subsections B, C, and E; requirements consolidated in section 160.

Section 230 Patient services; patient counseling

Exempted facilities only providing medication abortions from discharge planning. Revised to avoid any scope of practice conflicts with other agencies' regulations. Revised to clarify from whom informed consent is required. Repealed subsection D; requirements regarding a staff member trained in cardiopulmonary resuscitation consolidated in section 190.

Section 240 Medical testing and laboratory services

Exempted facilities only providing medication abortions from requirements involving tissues removed during an abortion. Clarifies what proper disposal of expired laboratory supplies entails.

Section 250 Anesthesia service

Exempted facilities only providing medication abortions from anesthesia-related requirements. Removes duplicative text lifted from 18VAC85-20-360.

Section 260 Administration, storage and dispensing of drugs

Repealed as duplicative of other agencies' requirements.

Section 270 Equipment and supplies

Renamed "Equipment and supplies; emergencies." Consolidated sections 270, 280, and 290. Exempted facilities only providing medication abortions from some equipment and supplies requirements. Updated industry guidelines document reference.

Section 280 Emergency equipment and supplies

Repealed; requirements regarding emergency equipment and supplies consolidated in section 270.

Section 290 Emergency services

Repealed; requirements regarding emergency services consolidated in section 270.

Section 300 Health information records

Renamed "Medical records." Reinstate changes from the 2017 rulemaking. Consolidates sections 300 and 310.

Section 310 Records storage

Repealed; requirements regarding records storage consolidated in section 300.

Section 320 Required reporting

Revised to add more specificity about what is a reportable event and to include oversight of mandate reporters of suspected abuse, neglect, or exploitation of adults.

Section 330 Abortion facility security and safety

Repealed; requirements regarding abortion facility security and safety consolidated in section 160.

Section 340 Disaster preparedness

Subsection A repealed; requirements about disaster preparedness policies and procedures consolidated in section 160.

Section 350 Maintenance

Reinstated changes from the 2017 rulemaking. Clarified when an equipment preventative maintenance program is required.

Section 360 Firefighting equipment and systems

Repealed as duplicative of section 370.

Section 370 Local and state codes and standards

Reinstated some language from the 2017 rulemaking. Updated references to the *Guidelines for Design and Construction of Outpatient Facilities* and revised which sections of the guidelines apply to abortion facilities.

FORMS (12VAC5-412)

Updated to reflect the changes in the proposed text.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-412)

Updated to reflect the changes in the proposed text and to reference the most current edition of each relevant document.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The primary advantages to the public is removal of language that was unclear, inconsistent, or outdated and reduction of the regulatory burden for abortion facilities, particularly for facilities that only provide medication abortions, while still ensuring adequate protections for health and safety. There are no primary disadvantages to the public. There are no primary advantages to the agency or the Commonwealth. There are no primary disadvantages to the agency or the Commonwealth. There is no other pertinent matters of interest to the regulated community, government officials and the public.

## Requirements More Restrictive than Federal

*Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.*

There are no applicable federal requirements.

## Agencies, Localities, and Other Entities Particularly Affected

*Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

There are no other state agencies or localities particularly affected. The entities that are particularly effected are current licensees and prospective licensees.

## Economic Impact

*Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.*

### Impact on State Agencies

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| <i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:<br>a) fund source / fund detail;<br>b) delineation of one-time versus on-going expenditures; and<br>c) whether any costs or revenue loss can be absorbed within existing resources | There are no projected costs, savings, fees, or revenues resulting from the regulatory change.  |
| <i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.  | There are no projected costs, savings, fees, or revenues resulting from the regulatory change for other state agencies.                   |
| <i>For all agencies:</i> Benefits the regulatory change is designed to produce.  | This regulatory action is designed to promote and assure the health and safety of patients who receive first trimester abortion services. |

### Impact on Localities

|  |   |
|--|---|
| Projected costs, savings, fees or revenues resulting from the regulatory change. | There are no projected costs, savings, fees or revenues resulting from the regulatory change for localities.                              |
| Benefits the regulatory change is designed to produce.                           | This regulatory action is designed to promote and assure the health and safety of patients who receive first trimester abortion services. |

### Impact on Other Entities

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be | The individuals, businesses, or other entities likely to be affect by the regulatory change include persons seeking services at abortion facilities; |
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| affected, include a specific statement to that effect.   | licensed abortion facilities; and persons or entities seeking licensure to operate an abortion facility.  |
| Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.  | Patients seeking abortions will be affected. While the Board does not have an annual average or median count of patients seeking abortions, the Division of Health Statistics reports that in 2017, 15,381 induced terminations were performed in the Commonwealth.<br><br>As of May 31, 2019, there are 14 licensed abortion facilities in Virginia, of which 6 are believed to be small businesses. |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:<br>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br>c) fees;<br>d) purchases of equipment or services; and<br>e) time required to comply with the requirements. | There are no projected costs for affected individuals, businesses, or other entities resulting from the regulatory change.  |
| Benefits the regulatory change is designed to produce.   | Reporting, recordkeeping, and other administrative costs as well as equipment costs for eligible facilities been reduced.   |

### Alternatives

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

No alternative was considered because the General Assembly required the Board to adopt regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed and amending the regulation is the least burdensome, less intrusive, and less costly method to accomplish the purpose of this action.

### Regulatory Flexibility Analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.*

No alternatives to the regulatory action were considered because the General Assembly required the Board to adopt regulations governing the licensure of facilities in which five or more first trimester abortions per month are performed. The regulatory action does not change any standards for small businesses or negatively affect small businesses.

### Periodic Review and Small Business Impact Review Report of Findings

*If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.*

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

This regulation is necessary for the protection of public health, safety, and welfare. This regulation also minimizes the economic impact on small businesses consistent with the stated objectives of applicable law. There is room for improvement on the clarity and understandability of the regulation.

There is a continued need for this regulation because the mandate to regulate facilities in which five or more first trimester abortions per month are performed still exists in the Code of Virginia. 3,829 public comments were received, with 69 being multiple comments from duplicate commenters. 40 comments recommended more restrictive abortion facility regulations, 458 recommended no change in the status of the regulations, and 3,268 recommended less restrictive abortion facility regulations. 14 comments offered specific recommendations for the regulations, 572 offered general recommendations, and 3,183 offered a mix of general and specific recommendations. 34 comments expressed general anti-abortion sentiment and did not address the regulations. 20 comments expressed general pro-choice sentiment and did not address the regulations. The complexity of the regulation is on par with the complexity of other medical care facility regulations that the Board has promulgated. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. It has been 2 years since the regulation has been evaluated.

### Public Comment

*Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.*

The following table summarizes comments received during the public comment period following the publication of the Notice of Intended Regulatory Action, for which commenters proposed specific amendments to the regulation. The table is organized in order of the regulatory sections:

| Commenter   | Comment   | Agency response  |
|---|---|--|
| <i>General Requests</i>   |   |  |
| (i) National Council of Jewish Women<br>(ii) Planned Parenthood South Atlantic<br>(iii) Ambika, Sabita Maitra, Regmi Sunita, National Council of Jewish Women<br>(iv) I. Ervolino<br>(v) I. Ervolino<br>(vi) Ann Svelan<br>(vii) Kris Kennedy<br>(viii) Kris Kennedy<br>(ix) Virginia Coalition to Protect Women’s Health, Planned Parenthood Advocates of Virginia, Virginia League of Planned Parenthood, Whole Woman’s Health Alliance | (i) Repeal in-person counseling requirement.<br>(ii) Do not inspect abortion facilities within 2 years unless it has inspected all other hospitals, pursuant to 2017 HB 2300.<br>(iii) Repeal 24-hour waiting period and ultrasound requirements.<br>(iv) Include referral to state mental health counselor and follow-up calls from state nurses as part of required care.<br>(v) Collect data on abortions and long-term outcomes.<br>(vi) Give women the opportunity to view what abortion does to the fetus prior to performing abortion.<br>(vii) Eliminate regulation requiring death certificate for medication abortions.<br>(viii) Allow dispensing of abortion medication in physicians’ offices.<br>(ix) Exempt facilities that only provide medication abortions from 12VAC5-412. | (i) The Board notes this comment; however, Va. Code § 18.2-76(D) already permits counseling to be performed by telephone.<br>(ii) The Board notes this comment; however, OLC practice is to inspect hospitals in order by license type.<br>(iii) The Board notes this comment; however, this requirement is established in the Va. Code § 18.2-76 and the Board does not have the authority to amend statutes.<br>(iv) The Board notes this comment; however, the agency does not have the resources to provide counseling and follow-up calls.<br>(v) The Board notes this comment; however, data on fetal death is already being collected by the agency’s Division of Vital Records.<br>(vi) The Board notes this comment; however, patients already have the option to view ultrasounds and abortion facilities are required to discuss the procedure prior to performing an abortion.<br>(vii) The Board notes this comment; however, fetal death certificates are outside the scope of this rulemaking.<br>(viii) The Board notes this comment; however, there is no Board prohibition on physicians’ offices dispensing medication for abortions. If a physician’s office intends to provide pregnancy-terminating medication to more than four patients in a month, it will have to be licensed as an abortion facility per Va. Code § 32.1-127.<br>(ix) The Board notes the comment. No abortion facility can be exempted from all regulations. 12 VAC 5-412 is written to comply with Va. Code § 32.1-127. |
| <i>12VAC5-412-10. Definitions</i>   |   |  |
| (i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance<br>(ii) Virginia Coalition to Protect Women’s Health,   | (i) Amend definition of administrator to include language allowing the duties of the administrator to be performed by multiple people.<br>(ii) Exempt facilities performing only  | (i) The Board has incorporated this suggestion into the proposed text.<br>(ii) 12VAC5-412 is written to comply with Va. Code § 32.1-127, which requires the regulation of abortion facilities.   |

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| Whole Woman's Health Alliance  | medication abortions from the regulations.   |  |
| <i>12VAC5-412-20. General.</i>   |  |  |
| (i) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance  | (i) Include new subsection that reads: "Va. Code 2.2-3705.2, related to disclosure of information to the public which would jeopardize the safety of any person, shall take precedence over any requirement in this Chapter."  | (i) Provisions of Va. Code § 2.2-3705.2 apply irrespective of regulatory provisions and to the extent there is a conflict between statute and regulation, statutory provisions would prevail. The Board does not have the authority to prohibit disclosure of information/records that are not already protected by another law.   |
| <i>12VAC5-412-50. Request for issuance.</i>  |  |  |
| (i) Planned Parenthood Advocates of Virginia<br>(ii) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance, Planned Parenthood Advocates of Virginia             | (i) Exempt facilities that provide only medication abortions from subsection C.<br>(ii) Amend subsection F to allow for assignment or transfer of license.   | (i) The Board notes the suggestion; however, this requirement is standard across medical facility regulations.<br>(ii) The Board notes the suggestion; however, Va. Code § 32.1-125 states that licenses cannot be assigned or transferred.  |
| <i>12VAC5-412-60. License renewal and expiration.</i>  |  |  |
| (i) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance<br>(ii) Whole Woman's Health Alliance  | (i) Prohibit inspection within 12 months of last inspection to determine eligibility for license renewal.<br>(ii) Amend (C) so if an abortion facility does not submit a plan of correction, they can become eligible for license renewal when they do submit it.          | (i) The Board notes the suggestion; however, the proposed prohibition would prevent the Board from conducting complaint investigations.<br>(ii) The Board notes the suggestion; however, this would allow an indefinite amount of time for an abortion facility to submit a plan of correction.  |
| <i>12VAC5-412-70. Return and/or reissuance of license.</i>   |  |  |
| (i) Whole Woman's Health Alliance, Planned Parenthood Metro Washington<br>(ii) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance<br>(iii) Planned Parenthood | (i) Repeal subdivision 5 of subsection B.<br>(ii) Repeal subdivision 6 of subsection B.<br>(iii) Do not require 30 days' advance notice for voluntary closure or change in administrator.<br>(iv) Do not require return and reissuance of license for change of ownership. | (i) The Board has incorporated this suggestion into the proposed text.<br>(ii) The Board has incorporated this suggestion into the proposed text.<br>(iii) The Board has incorporated the suggestion regarding change of administrator into the proposed text. The Board notes the suggestion regarding voluntary closure; however, 30 days' notice is standard across medical facility regulations for voluntary closure.<br>(iv) The Board notes the suggestion; however, Va. Code § 32.1-125 states |

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| <p>(iv) Metro Washington Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, Planned Parenthood Advocates of Virginia</p>  |  | <p>that licenses cannot be assigned or transferred.</p>   |
| <p><i>12VAC5-412-80. Allowable variances.</i></p>   |  |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</p>  | <p>(i) Amend to 2017 language.</p>   | <p>(i) The Board notes this comment and has incorporated part of the suggestion into the proposed text.</p>   |
| <p><i>12VAC5-412-90. Right of entry.</i></p>  |  |   |
| <p>(i) National Abortion Federation<br/>                 (ii) Whole Woman’s Health Alliance, National Abortion Federation<br/>                 (iii) Virginia Coalition to Protect Women’s Health<br/>                 (iv) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance<br/>                 (v) Planned Parenthood South Atlantic<br/>                 (vi) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance<br/>                 (vii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> | <p>(i) Require agency employees to present state ID and allow facility time to verify their identity before they are allowed entry.<br/>                 (ii) Delete reference to Va. Code § 32.1-25, which is confusing and duplicative.<br/>                 (iii) Allow inspection only when abortion facility is open for serving patients.<br/>                 (iv) Announce all inspections.<br/>                 (v) Announce all inspections expect complaint inspections.<br/>                 (vi) Prohibit inspections from interfering with patient services.<br/>                 (vii) Amend so that denying entry to an inspector does not constitute sufficient cause for “immediate” license revocation or suspension.</p> | <p>(i) The Board notes this comment; this is already provided for in subsection B and has been clarified in the draft language.<br/>                 (ii) The Board notes this comment; the statutory reference has been clarified.<br/>                 (iii) The Board notes this comment; however, the Board does not require abortion facilities to disclose the days they serve patients, so agency has no way of knowing when abortion facilities are open for serving patients. Additionally, portions of the inspection can be done without patients present.<br/>                 (iv) The Board notes this comment; however, unannounced inspections are standard across all OLC medical facility license types. If the timing of inspections is known and anticipated by abortion facilities, quality of care and patient safety could decrease during the time between inspections because facilities know that OLC will not be inspecting them during those times.<br/>                 (v) The Board notes this comment; however, unannounced inspections are standard across all OLC medical facility license types. If the timing of inspections is known and anticipated by abortion facilities, quality of care and patient safety could decrease during the time between inspections because facilities know that OLC will not be inspecting them during those times.<br/>                 (vi) The Board notes this comment; to the extent possible, OLC inspectors</p> |



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|  |  | <p>already limit their presence during inspections. Patient observation (with patient consent) is part of the inspection.</p> <p>(vii) The Board has incorporated the suggestion into the proposed text. The Board notes the Commissioner may still revoke or suspend licenses under Va. Code § 32.1-135.</p>   |
| <i>12VAC5-412-100. On-site inspection.</i>   |  |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Planned Parenthood South Atlantic</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(iii) Whole Woman’s Health Alliance</p> <p>(iv) Virginia Coalition to Protect Women’s Health</p> <p>(v) Virginia Coalition to Protect Women’s Health</p> <p>(vi) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(vii) Virginia Coalition to Protect Women’s Health, National Abortion Federation</p> <p>(viii) Virginia Coalition to Protect Women’s Health, National Abortion Federation</p> <p>(ix) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</p> <p>(x) Virginia Coalition to Protect Women’s Health</p> <p>(xi) Whole Woman’s Health Alliance,</p> | <p>(i) Amend subsection A to reference Va. Code §§ 32.1-111.7, 32.1-125.1, 32.1-126, 32.1-162.4, 32.1-162.10, and 35.1-22.</p> <p>(ii) Amend subsection A to say “scheduled on-site inspections.”</p> <p>(iii) Repeal subsection B.</p> <p>(iv) Require that the OLC representative give the facility sufficient additional time to redact the requested records, no more than one day.</p> <p>(v) Allow 2 hours for a person authorized to retrieve records to arrive on the premises.</p> <p>(vi) Require announcement of all inspections.</p> <p>(vii) Require redaction of records before they are made public to OLC representative.</p> <p>(viii) Prohibit removal of patient records, even if redacted, from the premises.</p> <p>(ix) Include penalty for improper disclosure of any information by inspector.</p> <p>(x) Allow inspections only during times the facility is open to serve patients.</p> <p>(xi) Repeal subsection C as in 2017 rulemaking.</p> | <p>(i) The Board notes this comment; most listed statutes are inapplicable. OLC practice is to inspect hospitals in order by license type, not less than biennially.</p> <p>(ii) The Board notes this comment; unannounced inspections are standard across all OLC medical facility license types. If the timing of inspections is known and anticipated by abortion facilities, quality of care and patient safety could decrease during the time between inspections because the facilities know that OLC will not be inspecting them during those times.</p> <p>(iii) The Board notes the comment; cited deficiencies need to be supported by evidence, which cannot be done if OLC is not allowed to take copies of records as evidence. No originals are removed from the premises.</p> <p>(iv) The Board notes the comment; this would increase inspection times and costs to the state. OLC rarely takes more than three pages of records per patient as evidence as part of an inspection, so 24 hours to redact is excessive.</p> <p>(v) The Board notes the comment; the proposed change would increase inspection times and costs to the agency.</p> <p>(vi) The Board notes this comment; unannounced inspections are standard across all OLC medical facility license types. If the timing of inspections is known and anticipated by abortion facilities, quality of care and patient safety could decrease during the time between inspections because the facilities know that OLC will not be inspecting them during those times.</p> <p>(vii) The Board notes the comment; abortion facilities already have the option to redact records.</p> |

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| <p>National Abortion Federation</p>  |   | <p>(viii) The Board notes the comment; cited deficiencies need to be supported by evidence, which cannot be done if OLC is not allowed to take copies of records as evidence. No originals are removed from the premises.</p> <p>(ix) The Board notes the comment; these regulations are for the licensure of abortion facilities.</p> <p>(x) The Board notes this comment; however, the Board does not require abortion facilities to disclose the days they serve patients, so agency has no way of knowing when abortion facilities are open for serving patients. Additionally, portions of the inspection can be done without patients present.</p> <p>(xi) The Board notes this comment; a time limit is needed for the arrival of a person who has access to the records and to provide OLC inspectors with records because the lack of access could extend an inspection for an indefinite amount of time, increasing costs to the agency. With a time limit present, if a person who has patient records access does not appear or does not furnish records to the inspector, it can be cited as a deficiency and the inspection can proceed on to subsequent steps.</p> |
| <p><i>12VAC5-412-110. Plan of correction.</i></p>  |   |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> | <p>(i) In subdivision 2 of subsection B, change “30 working days” to “90 calendar days.”</p> <p>(ii) In subsection B, change “15 working days” to “30 working days”</p> | <p>(i) The Board notes this comment; this deadline has been extended to 45 working days, which is standard across all OLC medical facility license types.</p> <p>(ii) The Board notes this comment; 15 working days is standard across all OLC medical facility license types.</p>  |
| <p><i>12VAC5-412-120. OLC complaint investigations.</i></p>  |   |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p>   | <p>(i) Amend to eliminate investigation of frivolous complaints.</p>  | <p>(i) The Board notes this comment. While the OLC cannot determine complaint is frivolous without investigation, factors have been added in determining whether to conduct an on-site inspection.</p>  |
| <p><i>12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.</i></p>   |   |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, National Abortion Federation</p>  | <p>(i) Do not revoke or suspend license for infractions unrelated to patient care and safety.</p>   | <p>(i) The Board notes this comment; the Commissioner has the right to revoke a license whenever a regulation is violated. This is standard across all OLC medical facility license types.</p>  |

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| <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(iii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</p>                                  | <p>(ii) In subsection A, repeal “of any applicable regulation.”</p> <p>(iii) Amend subsections B and C to say the Commissioner “shall” restore or reissue license.</p>  | <p>(ii) The Board notes this comment; existing regulatory language reflects Va. Code § 32.1-135.</p> <p>(iii) The Board notes this comment; existing regulatory language reflects Va. Code § 32.1-135.</p>  |
| <p><i>12VAC5-412-140. Management and administration</i></p>   |   |   |
| <p>(i) Virginia Coalition to Protect Women’s Health</p> <p>(ii) Whole Woman’s Health Alliance</p> <p>(iii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(iv) Planned Parenthood Advocates of Virginia</p> | <p>(i) Remove requirement to give notice of change of operator.</p> <p>(ii) Clarify the definition of operator.</p> <p>(iii) Include penalty for disclosure of patient information by inspectors.</p> <p>(iv) Exempt facilities that provide only medication abortions from subsection D.</p> | <p>(i) The Board notes this comment; though the Board is proposing to move the reportable change list to section 70, change of operator has been removed from the proposed text.</p> <p>(ii) The Board notes this comment; because operator is no longer referenced in the proposed text, a definition is no longer needed.</p> <p>(iii) The Board notes this comment; these regulations are for the licensure of abortion facilities. Additionally, abortion facilities have the option to redact patient records prior to providing copies to the OLC. OLC staff are bound by HIPAA.</p> <p>(iv) The Board notes this comment; it is standard for all medical facility license types, irrespective of service provided, need to provide the OLC with identifying information so that OLC can regulate them.</p> |
| <p><i>12VAC5-412-150. Governing body.</i></p>   |   |   |
| <p>(i) National Abortion Federation</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p>   | <p>(i) Clarify language to ensure the confidentiality of facility information that is reported to OLC, including facility ownership information.</p> <p>(ii) Repeal this section.</p>   | <p>(i) The Board notes this comment; the Board does not have the authority to deem information/records confidential by regulation.</p> <p>(ii) The Board notes this comment; a governing body to oversee management of the facility, appoint an administrator, and draft policies and procedures is standard across all OLC medical facility license types.</p>   |
| <p><i>12VAC5-412-160. Policies and procedures.</i></p>  |   |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</p> <p>(ii) Virginia Coalition to Protect</p>  | <p>(i) Ensure confidentiality of clinic fire, disaster, and other security policies.</p> <p>(ii) Repeal subdivision 4 of subsection A.</p> <p>(iii) Include penalty for disclosure of clinic policies and procedures by inspectors.</p>   | <p>(i) The Board notes this comment; the Virginia Freedom of Information Act already exempts disaster preparedness/recovery and building security plans, policies, and procedures from release to the public.</p> <p>(ii) The Board notes this comment; facilities that provide only medication abortions are exempt from this</p>  |

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| <p>(iii) Women’s Health, Whole Woman’s Health Alliance<br/>Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(iv) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, Planned Parenthood Advocates of Virginia</p>  | <p>(iv) Exempt facilities performing only medication abortions from this section.</p>  | <p>provision, which is now located in subdivisions of 6 and 7 of subsection C. This provision has been clarified.</p> <p>(iii) The Board notes this comment; these regulations are for the licensure of abortion facilities.</p> <p>(iv) The Board notes this comment; written policies and procedures to address critical functional areas is standard across all OLC medical facility license types.</p>  |
| <p><i>12VAC5-412-170. Administrator.</i></p>  |  |   |
| <p>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, Planned Parenthood Advocates of Virginia</p>  | <p>(i) Allow for multiple administrators.</p> <p>(ii) Exempt facilities performing only medication abortions from this section.</p>  | <p>(i) The Board has incorporated this suggestion into the proposed text.</p> <p>(ii) The Board notes this comment; an administrator is standard across all OLC medical facility license types.</p>   |
| <p><i>12VAC5-412-180. Personnel.</i></p>  |  |   |
| <p>(i) National Abortion Federation</p> <p>(ii) Virginia Coalition to Protect Women’s Health</p> <p>(iii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</p> <p>(iv) Planned Parenthood Advocates of Virginia</p> <p>(v) National Abortion Federation</p> <p>(vi) Whole Woman’s Health Alliance</p> <p>(vii) Virginia Coalition to Protect Women’s Health,</p> | <p>(i) In subsection H, add 2017 language requiring redaction of records removed from premises.</p> <p>(ii) Amend subsection H to maintain employee health information separately within personnel file.</p> <p>(iii) Repeal subsection B, C, E, F, and G.</p> <p>(iv) Exempt facilities that provide only medication abortions from subsection C.</p> <p>(v) Repeal subsection D.</p> <p>(vi) Ensure protections for the safety and privacy of individuals employed or associated with abortion care.</p> | <p>(i) The Board has incorporated this suggestion into the proposed text, which is now located in section 100.</p> <p>(ii) The Board has incorporated this suggestion into the proposed text.</p> <p>(iii) The Board notes this comment; written job applications, job descriptions, and personnel files is standard across all OLC medical facility license types, as are policies and procedures regarding staffing. Additionally, a criminal history check is required by Va. Code § 32.1-126.02.</p> <p>(iv) The Board notes this comment; a criminal history check is required by Va. Code § 32.1-126.02.</p> <p>(v) The Board notes this comment; policies and procedures related to staff training is standard across all OLC medical facility license types.</p> <p>(vi) The Board notes this comment; the Board does not have the authority to</p> |

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| <p>(viii) Whole Woman's Health Alliance<br/>Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance</p>   | <p>(vii) Prohibit removal of personnel files from the premises.<br/>(viii) Include penalty for disclosure of facility personnel information by inspector.</p>          | <p>deem information/records confidential by regulation.<br/>(vii) The Board notes this comment; cited deficiencies need to be supported by evidence, which cannot be done if OLC inspectors are not allowed to take copies of records as evidence. No originals are removed from the premises.<br/>(viii) The Board notes this comment; these regulations are for the licensure of abortion facilities.</p>   |
| <p><i>12VAC5-412-190. Clinical staff.</i></p>   |  |   |
| <p>(i) Whole Woman's Health Alliance, National Abortion Federation<br/>(ii) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance<br/>(iii) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance</p> | <p>(i) Amend to 2017 language.<br/>(ii) Repeal first sentence of subsection C.<br/>(iii) Exempt facilities performing only medication abortions from this section.</p> | <p>(i) The Board notes this comment; the language in this section has been amended to include nurse practitioners and physician assistants, and will only apply to when the patient has been given anesthesia.<br/>(ii) The Board notes this comment; the language in this subsection has been amended to include nurse practitioners and physician assistants. In addition, the physician, nurse practitioner, or physician assistant has fewer responsibilities in the revised regulations.<br/>(iii) The Board notes this comment; facilities that provide only medication abortions are exempt from subsection B and C, which specifies who shall remain on the premises.</p> |
| <p><i>12VAC5-412-200. Patients' rights.</i></p>   |  |   |
| <p>(i) Virginia Coalition to Protect Women's Health, National Abortion Federation<br/>(ii) Whole Woman's Health Alliance</p>  | <p>(i) Amend to 2017 language.<br/>(ii) Change "she/her" to "they/their."</p>  | <p>(i) The Board has incorporated this suggestion into the proposed text.<br/>(ii) The Board notes this comment; the Virginia Register of Regulations style guide does not allow for the use of "they/their" in the singular. The proposed regulatory text has been amended to say "the patient."</p>   |
| <p><i>12VAC5-412-210. Quality improvement.</i></p>  |  |   |
| <p>(i) Virginia Coalition to Protect Women's Health, Whole Woman's Health Alliance, Planned Parenthood Metro Washington</p>   | <p>(i) Repeal subsection C.</p>  | <p>(i) The Board notes this comment; a quality improvement committee is standard across all OLC medical facility license types.</p>   |
| <p><i>12VAC5-412-220. Infection prevention.</i></p>   |  |   |
| <p>(i) Virginia Coalition to Protect Women's Health,</p>  | <p>(i) Amend to 2017 language.</p>   | <p>(i) The Board notes this comment; CDC recommendations are still mentioned in the proposed text, but the specific</p>   |

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| <p>Whole Woman’s Health Alliance, National Abortion Federation</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, Planned Parenthood Advocates of Virginia</p>   | <p>(ii) Exempt facilities performing only medication abortions from this section.</p>  | <p>document that was stricken from the 2017 regulations is not. The material in question can now be found in the proposed subsection E of 12VAC5-412-160.</p> <p>(ii) The Board notes this comment; infection prevention is standard across all OLC medical facility license types. Because all abortion facilities are required to use a method approved by the FDA to confirm pregnancy, which could include blood and/or urine, and handle medication, infection prevention regulations are necessary.</p> |
| <p><i>12VAC5-412-230. Patient services; patient counseling.</i></p>  |  |   |
| <p>(i) Whole Woman’s Health Alliance</p> <p>(ii) Whole Woman’s Health Alliance</p> <p>(iii) Virginia Coalition to Protect Women’s Health, Virginia League of Planned Parenthood</p> <p>(iv) Virginia League of Planned Parenthood</p>                              | <p>(i) In subsection E, amend to say ...”policies and procedures for the provision of or referral for family planning services...”</p> <p>(ii) Define first trimester as 13 weeks and 6 days after last menstrual period.</p> <p>(iii) Amend this provision to clarify that licensed abortion facilities can provide second trimester abortions.</p> <p>(iv) Repeal this section</p> | <p>(i) The Board has incorporated this suggestion into the proposed text, which is now located in section 160.</p> <p>(ii) The Board has incorporated this suggestion into the proposed text, which is now located in section 10.</p> <p>(iii) The Board notes this comment. The Board has proposed removing the first trimester limitation.</p> <p>(iv) The Board notes this comment; requirements regarding counseling and informed written consent comes from Va. Code § 18.2-76.</p>                      |
| <p><i>12VAC5-412-240. Medical testing and laboratory services.</i></p>   |  |   |
| <p>(i) National Abortion Federation</p> <p>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> <p>(iii) Planned Parenthood Advocates of Virginia, Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> | <p>(i) Amend subdivision 3 of subsection A to remove reference to the current CDC guidelines.</p> <p>(ii) Repeal subsection 3 of subsection A.</p> <p>(iii) Exempt facilities providing only medication abortions.</p>   | <p>(i) The Board has incorporated this suggestion into the proposed text.</p> <p>(ii) The Board has incorporated this suggestion into the proposed text</p> <p>(iii) The Board notes this comment; provisions regarding tissues removed resulting from an abortion will not apply to medication abortion only facilities in the proposed text. However, laboratory services are still relevant because of the potential use of blood and/or urine tests for pregnancy confirmation.</p>                       |
| <p><i>12VAC5-412-250. Anesthesia service.</i></p>  |  |   |
| <p>(i) Virginia Coalition to Protect Women’s Health</p> <p>(ii) National Abortion Federation</p> <p>(iii) National Abortion Federation</p>   | <p>(i) Repeal subdivisions 3 and 5 of subsection D.</p> <p>(ii) Amend subsection E to permit general anesthesia.</p>   | <p>(i) The Board notes this comment. Because abortion facilities are required to comply with office-based anesthesia provisions, this equipment is still required by 18VAC85-20-360(B) and the Board does not have the authority to alter other agencies’ regulations.</p>  |

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| <p>(iv) Virginia Coalition to Protect Women’s Health</p>  | <p>(iii) Exempt facilities providing only medication abortions.<br/><br/>(iv) Amend to read “The anesthesia service shall be directed by and under the supervision of a qualified medical professional acting within their scope of practice and licensed in Virginia.”</p>      | <p>The equipment previously listed in these subdivisions is no longer specifically listed in the proposed text.<br/><br/>(ii) The Board notes this comment; abortion facilities are already permitted to use general anesthesia, so long as it is not elective.<br/><br/>(iii) The Board has incorporated this suggestion into the proposed text.<br/><br/>(iv) The Board notes this comment; anesthesia service has to be directed and supervised by physicians, per the office-based anesthesia regulations (18VAC85-20-320).</p>  |
| <p><i>12VAC5-412-260. Drugs.</i></p>  |  |  |
| <p>(i) Virginia Coalition to Protect Women’s Health, Kris Kennedy</p>   | <p>(i) Amend to allow non-physicians to prescribe, dispense, order, and administer drugs to terminate pregnancy.</p>   | <p>(i) The Board notes this comment; this section has been repealed in the proposed text.</p>  |
| <p><i>12VAC5-412-270. Medical testing and laboratory services.</i></p>  |  |  |
| <p>(ii) Virginia Coalition to Protect Women’s Health<br/><br/>(iii) Planned Parenthood Advocates of Virginia</p>  | <p>(i) Amend to read: “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.”<br/><br/>(ii) Exempt facilities providing only medication abortions.</p> | <p>(i) The Board notes this comment. Deficiencies cited indicate continued need for these requirements.<br/><br/>(ii) The Board notes this comment. Abortion facilities that provide only medication abortions are exempt from subdivisions 2, 3, 6, and 7 of subsection A in the proposed text.</p>   |
| <p><i>12VAC5-412-280. Emergency equipment and supplies.</i></p>   |  |  |
| <p>(i) Whole Woman’s Health Alliance<br/><br/>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation<br/><br/>(iii) Planned Parenthood Advocates of Virginia, Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</p> | <p>(i) Amend to 2017 language.<br/><br/>(ii) Remove reference to current edition of AHA’s ACLS guidelines.<br/><br/>(iii) Exempt facilities providing only medication abortions.</p>   | <p>(iv) The Board has incorporated this suggestion into the proposed text, which is now located in section 270.<br/><br/>(v) The Board notes this comment; these guidelines are not referenced in the existing section 280, thus no change is needed.<br/><br/>(vi) The Board notes this comment. Section 280 has been moved into section 270; the proposed text no longer list the conditions abortion facilities must provide equipment to treat. Medication abortion only facilities are exempted from subdivisions 2, 3, 6, and 7 in the subsection A of section 270 in the proposed text.</p> |
| <p><i>12VAC5-412-290. Emergency services.</i></p>   |  |  |

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| <ul style="list-style-type: none"> <li>(i) National Abortion Federation</li> <li>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, Planned Parenthood Advocates of Virginia</li> <li>(iii) National Abortion Federation</li> </ul> | <ul style="list-style-type: none"> <li>(i) In subsection B, remove reference to AHA’s guidelines.</li> <li>(ii) Exempt facilities providing only medication abortions.</li> <li>(iii) Repeal subsection C.</li> </ul>   | <ul style="list-style-type: none"> <li>(i) The Board notes this comment. These guidelines provide an objective baseline from which OLC can determine the appropriateness and adequacy of equipment, supplies, and drugs maintained in the abortion facilities for emergencies.</li> <li>(ii) The Board note this comment. The requirement to be prepared to handle patient emergencies and have appropriate resources to transfer patients to a higher level of care is standard across all OLC medical facility license types.</li> <li>(iii) The Board notes this comment. This subsection has been repealed in the proposed text, but the requirement has been moved to section 270. Providing the receiving facility with necessary patient information improves response time and patient outcomes.</li> </ul> |
| <p><i>12VAC5-412-300. Health information records.</i></p>  |   |   |
| <ul style="list-style-type: none"> <li>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</li> <li>(ii) Virginia Coalition to Protect Women’s Health, National Abortion Federation</li> </ul>           | <ul style="list-style-type: none"> <li>(i) Amend to 2017 language.</li> <li>(ii) Amend subdivision 5 of subdivision B to read “Laboratory tests, pathologist’s report of tissue (if performed), and radiologists report of x-rays (if performed);”</li> </ul> | <ul style="list-style-type: none"> <li>(i) The Board has incorporated this suggestion into the proposed text.</li> <li>(ii) The Board notes this comment. The inclusion of “If medically indicated” in the proposed text implies that these results would only be included in the medical record if they were medically indicated and performed.</li> </ul>   |
| <p><i>12VAC5-412-320. Required reporting.</i></p>  |   |   |
| <ul style="list-style-type: none"> <li>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</li> <li>(ii) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation</li> </ul>          | <ul style="list-style-type: none"> <li>(i) Add language for confidentiality of records.</li> <li>(ii) Amend to 2017 language.</li> </ul>  | <ul style="list-style-type: none"> <li>(i) The Board notes this comment; confidentiality of patient records is already protected by HIPAA and exempted by the Virginia Freedom of Information Act from release to the public.</li> <li>(ii) The Board has incorporated this suggestion into the proposed text.</li> </ul>   |
| <p><i>12VAC5-412-330. Abortion facility security and safety.</i></p>   |   |   |
| <ul style="list-style-type: none"> <li>(i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance</li> <li>(ii) Whole Woman’s Health Alliance,</li> </ul>   | <ul style="list-style-type: none"> <li>(i) Add language for confidentiality of plans, policies, and procedures.</li> <li>(ii) Amend to 2017 language.</li> </ul>  | <ul style="list-style-type: none"> <li>(i) The Board notes this comment. These records are already exempted by the Virginia Freedom of Information Act from release to the public.</li> <li>(ii) The Board notes this comment. Given the controversy surrounding abortions and past terroristic attacks on abortion facilities or their employees, requiring</li> </ul>   |



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| National Abortion Federation  |  | safety and security plans is essential to patient and personnel safety. It is also standard across all OLC medical facility license type.   |
| <i>12VAC5-412-340. Disaster preparedness.</i>   |  |   |
| (i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance   | (i) Repeal this section.   | (i) The Board notes this comment. The requirement to have plans in place to ensure appropriate response to unexpected life-threatening events, like fire, hurricanes, and earthquakes, is standard across all OLC medical facility license types.                       |
| <i>12VAC5-412-350. Maintenance.</i>   |  |   |
| (i) Virginia Coalition to Protect Women’s Health, National Abortion Federation  | (i) Amend to 2017 language.  | (i) The Board has incorporated this suggestion into the proposed text.  |
| <i>12VAC5-412-360. Firefighting equipment and systems.</i>  |  |   |
| (i) Virginia Coalition to Protect Women’s Health, National Abortion Federation  | (i) Amend to 2017 language.  | (i) The Board has incorporated this suggestion into the proposed text.  |
| <i>12VAC5-412-370. Local and state codes and standards.</i>   |  |   |
| (i) Virginia Coalition to Protect Women’s Health, Whole Woman’s Health Alliance, National Abortion Federation<br><br>(ii) Planned Parenthood Advocates of Virginia, Whole Woman’s Health Alliance | (i) Amend to 2017 language.<br><br>(ii) Exempt facilities providing only medication abortions.                                 | (i) The Board notes this comment and has incorporated part of this suggestion into the proposed text.<br><br>(ii) The Board notes this comment. Abiding by local and state codes and standards is standard across all OLC medical facility license types.               |
| <i>12VAC5-412. Forms.</i>   |  |   |
| (i) National Abortion Federation<br><br>(ii) National Abortion Federation   | (i) Keep Application for Abortion Facility Licensure confidential.<br><br>(ii) Keep owner’s personal information confidential. | (i) The Board notes this comment; the Board does not have the authority to deem information/records confidential by regulation.<br><br>(ii) The Board notes this comment; the Board does not have the authority to deem information/records confidential by regulation. |

The following table summarizes comments received during the public comment period following the publication of the Notice of Intended Regulatory Action, for which commenters did not propose specific amendments to the regulation:

| Commenter                  | Comment  | Agency response  |
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| 3 individuals via Virginia | Abortion facilities cannot self-regulate and regulations should be strengthened. | The Board notes the comment and the request for additional regulation. |

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| Regulatory Town Hall  |   |  |
| 194 people via Virginia Regulatory Town Hall  | Regulations should be enforced and maintained because abortion facilities are not capable of self-regulating.   | The Board notes the support for the regulations.   |
| 8 individuals via Virginia Regulatory Town Hall   | TRAP regulations are medically unnecessary. A woman's healthcare decisions are between her and her provider.  | The Board notes the opposition to the regulations. The comments did not provide any suggested amendments to specific sections of the proposed regulations. |
| Lois Shepherd, Mary Faith Marshall, Julia Taylor, and Maria Cecilia Dieuzeide via email | The Board should review the current regulations and replace them with regulations that advance health and expand access to reproductive healthcare.   | The Board notes the request to repeal and replace the regulations.   |
| 5 individuals via Virginia Regulatory Town Hall   | Increase health and safety regulations for facilities in which five or more first trimester abortions per month are performed.  | The Board notes the comment and the request for additional regulation.   |
| 64 individuals via Virginia Regulatory Town Hall  | Keep strong health and safety regulations.  | The Board notes the support for the regulations.   |
| 15 individuals via Virginia Regulatory Town Hall  | Let science and medicine guide amendment of the TRAP regulations.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.  |
| 3 individuals via Virginia Regulatory Town Hall   | The Board should enforce and expand regulations for facilities in which five or more first trimester abortions per month are performed.   | The Board notes the comment and the request for additional regulation.   |
| 40 individuals via Virginia Regulatory Town Hall  | The Board should enforce and maintain current regulations facilities in which five or more first trimester abortions per month are performed.   | The Board notes the support for the regulations.   |
| 4 individuals via Virginia Regulatory Town Hall   | Facilities in which five or more first trimester abortions per month are performed should not get a free pass on regulations just because there is a pro-abortion governor. These facilities need more oversight. | The Board notes the comment and the request for additional regulation.   |
| 4 individuals via Virginia Regulatory Town Hall   | Facilities in which five or more first trimester abortions per month are performed should not get a free pass on regulations just because there is a pro-abortion governor. Keep the current regulations.         | The Board notes the support for the regulations.   |
| 3,152 individuals signed on to the statement from Progress Virginia via email           | Heed the expertise of doctors, medical professionals, and legal experts and amend the onerous, medically unnecessary, and unconstitutional TRAP regulations to be based on science and the standard of care.      | The Board notes the opposition to the regulations. The comments did not provide any suggested amendments to specific sections of the proposed regulations. |

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| 3 individuals via Virginia Regulatory Town Hall  | Heed the expertise of doctors, medical professionals, and legal experts and amend the onerous, medically unnecessary, and unconstitutional TRAP regulations to be based on science and the standard of care.      | The Board notes the opposition to the regulations. The comments did not provide any suggested amendments to specific sections of the proposed regulations.   |
| 15 individuals via Virginia Regulatory Town Hall | Repeal TRAP.  | The Board notes the comments, but repealing this chapter is outside the authority of the Board as the Code of Virginia requires the regulation.  |
| 4 individuals via Virginia Regulatory Town Hall  | TRAP is medically unnecessary and politically-motivated.  | The Board notes the opposition to the regulations. The comments did not provide any suggested amendments to specific sections of the proposed regulations.   |
| 7 individuals via Virginia Regulatory Town Hall  | Facilities in which five or more first trimester abortions per month are performed should have the same standards as other healthcare facilities. Regulations should be strengthened for higher health standards. | The Board notes the comment and the request for additional regulation.   |
| Mary Kay Stine via email                         | Abortion facilities should have the same standards as other medical facilities.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.  |
| 75 individuals via Virginia Regulatory Town Hall | Abortion facilities should have the same standards as other medical facilities.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.  |
| 2 individuals via Virginia Regulatory Town Hall  | Referencing the Virginia Health Group closure, abortion clinics are dirty and need more oversight, not less.  | The Board notes the comment and the request for additional regulation.   |
| 2 individuals via Virginia Regulatory Town Hall  | Referencing the Virginia Health Group closure, abortion clinics are dirty and regulations help keep them safe for women.  | The Board notes the support for the regulations.   |
| 34 individuals via Virginia Regulatory Town Hall | Generally anti-abortion without comment about this regulatory action.   | The Board believes that no response is necessary for these comments because they do not speak to the regulations.  |
| 20 individuals via Virginia Regulatory Town Hall | Generally pro-choice without comment about this regulatory action.  | The Board believes that no response is necessary for these comments because they do not speak to the regulations.  |
| 9 individuals via Virginia Regulatory Town Hall  | Did not express either support or opposition or request a specific amendment to the regulations.  | The Board believes that no response is necessary for these comments because they do not speak to the regulations.  |
| 23 individuals via Virginia Regulatory Town Hall | The current regulations are a way of keeping women from accessing abortion care. These commenters gave general recommendations to amend TRAP to protect abortion access.  | The Board notes the opposition to the regulations. The comments did not provide any suggested amendments to specific sections of the proposed regulations. 12 VAC 5-412 is written to comply with Va. Code § 32.1-127. |

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| Muriel Azria-Evans via Virginia Regulatory Town Hall                              | The current regulations are not related to safety. The Board should not add any additional restrictions.  | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Barbara Favola and Kaye Kory on behalf of the Women's Healthcare Caucus via email | Architectural and excessive administrative requirements place undue burdens on providers and yield no medical benefit. The Board should treat abortion facilities the same as other outpatient medical providers and take steps to ensure patient confidentiality and access to healthcare.   | The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the proposed regulations. 12VAC5-412 is written to comply with Va. Code § 32.1-127.   |
| Bruce Hill via Virginia Regulatory Town Hall                                      | The Board should resist unnecessary and politically motivated changes to the abortion facility regulations. Make decisions based on common sense.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Kelsea Jeter via Virginia Regulatory Town hall                                    | The current regulations, including those dictating hallway widths and parking spaces, are designed to limit access to abortion, which is already one of the most highly regulated procedures. The Board should trust patients and their doctors to make the best medical decisions for themselves and leave personal politics out of the exam room. | The building guidelines were modified to conform to <i>Whole Woman's Health v. Hellerstedt</i> , 136 S. Ct. 2292 (2016).  |
| Carla M. via Virginia Regulatory Town Hall  | The current regulations, especially the 24-hour waiting period, create an undue burden for women seeking an abortion. Abortion facilities are unfairly targeted by the regulations.   | The 24-hour waiting period requirement is established in the Va. Code § 18.2-76. The Board is not authorized to amend statute.  |
| LaChanda Mills via Virginia Regulatory Town Hall                                  | The current regulations do not confer any medical benefit, and some requirements actually harm patients, such as the waiting period, paperwork, and inspector observation.  | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Deborah Minden via Virginia Regulatory Town Hall                                  | The regulations are an attempt to regulate women's bodies. Hallway width has nothing to do with safe termination of a pregnancy. The Board should not support more regulations for abortion facilities.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Erin Parish-Gibson via Virginia Regulatory Town Hall                              | Making women wait or travel to receive an abortion will not change their minds about having one, it will only cause the undesired pregnancy to have more negative impact on their health and financial well-being. These regulations serve no health purpose.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Leslie Rubio via Virginia Regulatory Town Hall                                    | The 24-hour waiting period, medically unnecessary abdominal ultrasound, and requiring abortion facilities to adhere to hospital-standard building requirements creates additional hardship for women getting an abortion. The Board should remove the regulations.  | The Board notes the comments, but abolishing abortion facility regulations is beyond the scope and authority of the Board as the Code of Virginia requires the regulations. The 24-hour waiting period and the abdominal ultrasound requirements are set by |

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|   |   | the Va. Code § 18.2-76, which the Board is not authorized to amend. Facilities in which five or more first trimester abortions per month are performed are classified as hospitals under the Va. Code § 32.1-127. |
| Heather Shumaker on behalf of the National Women’s Law Center via email                       | Virginia’s TRAP regulations are unconstitutional and the Board should repeal them.  | The Board notes the comments, but abolishing abortion facility regulations is beyond the scope and authority of the Board as the Code of Virginia requires the regulations.                                       |
| Sara Imershein via Virginia Regulatory Town Hall  | Chapter 412 should be immediately eliminated. This chapter is unnecessary for the protection of public health, safety, and welfare; it maximizes negative economic impact on small businesses; and it is verbose, unwieldy, arbitrary, and impossible to justify for Virginians’ public health or individuals Virginians. | The Board notes the comments, but abolishing abortion facility regulations is beyond the scope and authority of the Board as the Code of Virginia requires the regulations.                                       |
| 8 individuals via Virginia Regulatory Town Hall   | The Board should keep and enforce the regulations.  | The Board notes the support for the regulations.  |
| Richard Cheliras via Virginia Regulatory Town Hall  | Make abortion facilities adhere to an appropriate level of cleanliness, sanitation, and accessibility for medical emergency response.   | 12 VAC 5-412 is written to comply with Va. Code § 32.1-127.   |
| Judith Gebelein and Kathryn Mullarkey via email   | The regulations do not take in to account women’s psychological health after an abortion.   | The Board does not have the authority to regulate physicians’ scope of practice. If a physician feels that a particular patient needs additional support, that is a judgment call for the physician, not OLC.     |
| Josh Hetzler on behalf of the Family Foundation of Virginia via Virginia Regulatory Town Hall | This NOIRA process is illegitimate because the NOIRA document does not state any proposed changes.  | The Board notes the comment.  |
| 73 individuals via Virginia Regulatory Town Hall  | Abortion facility regulations are essential to women’s health and safety.   | The Board notes the support for the regulations.  |
| Kathleen Hall via Virginia Regulatory Town Hall   | Keep the current requirements for sanitation, personnel, procedure safety, access to hospitals when needed, and requirements to help women in making the decision regarding her unborn baby.  | The Board notes the support for the regulations.  |
| Anna Swanson via Virginia Regulatory Town Hall  | Abortions are medical procedures and involve bodily fluids. They should be regulated for staffing, safety, and informed consent.  | The Board notes the support for the regulations.  |

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| Tiffany Wood via Virginia Regulatory Town Hall | Abortion clinics should provide the highest possible medical conditions and doctors should perform all procedures, not nurses or physician assistants. | Va. Code § 18.2-71 requires that a physician perform all abortions in Virginia. The Board notes the support for the regulations. |
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## Public Participation

*Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.*

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to **Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email: [regulatorycomment@vdh.virginia.gov](mailto:regulatorycomment@vdh.virginia.gov); fax: (804) 527-4502**. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<https://townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://commonwealthcalendar.virginia.gov/>). Both oral and written comments may be submitted at that time.

## Detail of Changes

*Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.*

*If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.*

*If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.*

| Current section number | New section number, if applicable | Current requirement | Change, intent, rationale, and likely impact of new requirements |
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| <p>10</p> | <p>N/A</p> | <p style="text-align: center;">CHAPTER 412<br/>REGULATIONS FOR LICENSURE<br/>OF ABORTION FACILITIES<br/>Part I<br/>Definitions and Requirements for<br/>Licensure</p> <p><b>12VAC5-412-10. Definitions.</b><br/>The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"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.</p> <p>"Abortion facility" means a facility in which five or more first trimester abortions per month are performed.</p> <p>"Administrator" means the person appointed by the governing body as having responsibility for the overall management of the abortion facility. Job titles may include director, executive director, office manager, or business manager.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Informed written consent" means the knowing and voluntary written consent to abortion by a pregnant woman of any age in accordance with § 18.2-76 of the Code of Virginia.</p> <p>"Licensee" means the person, partnership, corporation, association, organization, or professional entity that owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.</p> <p>"Minor" means a patient under the age of 18.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p style="text-align: center;">CHAPTER 412<br/>REGULATIONS FOR LICENSURE<br/>OF ABORTION FACILITIES<br/>Part I<br/>Definitions and Requirements for<br/>Licensure</p> <p><b>12VAC5-412-10. Definitions.</b><br/>The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Abortion" means <del>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</del> <u>dead fetus medication abortions and surgical abortions.</u> Spontaneous miscarriage is excluded from this definition.</p> <p>"Abortion facility" means a facility in which five or more first trimester abortions per month are performed.</p> <p>"Administrator" means the person <u>or persons appointed designated</u> by the governing body as having <u>the responsibility and necessary authority</u> for the <del>overall</del> <u>daily</u> management of the abortion facility. Job titles may include director, executive director, office manager, or business manager.</p> <p><u>"Applicant" means the person, partnership, corporation, association, organization, or professional entity that applies for initial issuance of a license to operate an abortion facility.</u></p> <p><u>"Board" means the State Board of Health.</u></p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Department" means the Virginia Department of Health.</p> <p><u>"Drug" means a drug as defined in § 54.1-3401 of the Code of Virginia.</u></p> |
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|  | <p>"Patient" means any person seeking or obtaining services at an abortion facility.</p> <p>"Physician" means a person licensed to practice medicine in Virginia.</p> <p>"Spontaneous miscarriage" means the expulsion or extraction of a product of human conception resulting in other than a live birth and which is not an abortion.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><u>"First trimester" means 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care practitioner.</u></p> <p><u>"Governing body" means the person or group of persons designated in writing by the licensee as having the responsibility and necessary authority for the overall management of the abortion facility.</u></p> <p><del>"Informed written consent" means the knowing and voluntary written consent to abortion by a pregnant woman of any age in accordance with informed written consent as defined by § 18.2-76 D of the Code of Virginia.</del></p> <p><u>"Inspector" means an employee of the department designated by the commissioner to conduct inspections or investigations on the commissioner's behalf.</u></p> <p>"Licensee" means the person, partnership, corporation, association, organization, or professional entity that owns <del>or</del> <u>and</u> on whom rests the ultimate responsibility and authority for the conduct of the abortion facility.</p> <p><u>"Medication abortion" means the use of a drug to terminate the pregnancy of a woman.</u></p> <p><del>"Minor" means a patient person under the age of 18 years of age.</del></p> <p>"Patient" means any person seeking or obtaining services at an abortion facility.</p> <p>"Physician" means a person licensed to practice medicine in Virginia.</p> <p><u>"OLC" means the Office of Licensure and Certification of the department.</u></p> <p>"Spontaneous miscarriage" means the expulsion or extraction of a product of human conception resulting in other than a live birth and which is not an abortion.</p> |
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|  |  |  | <p><u>“Surgical abortion” means the use of an instrument, or the combined use of an instrument and drug, to terminate the pregnancy of a woman.</u></p> <p><u>“Working day” means any day other than a Saturday, Sunday, or federal or state holiday.</u></p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) clarify the difference between medication abortions and surgical abortions;</li> <li>(ii) clarify the difference in authority and responsibility between the administrator and the governing body;</li> <li>(iii) clarify what constitutes a working day;</li> <li>(iv) add definitions such as “inspector” so that subsequent regulatory sections are less complex and verbose; and</li> <li>(v) ensure terms derived from statute cross-reference the appropriate statutory provision.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) by distinguishing between medication abortions and surgical abortions, the Board can specify which subsequent regulatory sections are required based on services provided;</li> <li>(ii) eliminate confusion about which parts of a facility’s operations are under the purview of the administrator and which are under the purview of the governing body;</li> <li>(iii) eliminate confusion about what constitutes a working day since facilities do not always see patients daily;</li> <li>(iv) increase readability of later sections by defining terms rather than trying to define complex subjects within a regulatory requirement; and</li> </ul> |
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|    |     |   | <p>(v) eliminate any conflicts between terms defined in statute and terms defined in this chapter.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is clarity about the meaning of terms and improved readability of later regulatory sections.</p>  |
| 20 | N/A | <p><b>12VAC5-412-20. General.</b><br/> A license to establish or operate an abortion facility shall be issued only (i) when the abortion facility is in compliance with all applicable federal, state, and local statutes and regulations and the provisions of this chapter and (ii) when the application fee has been received by the department.</p> <p>No person or entity shall establish, conduct, maintain, or operate in this state, any abortion facility without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.</p> <p>Statutory Authority<br/> §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-20. General.</b><br/> <u>A. The commissioner may issue A a license to establish or operate an abortion facility shall be issued only if:</u><br/> <del>(i) when the 1. The applicant and the applicant's proposed abortion facility is are in compliance with all applicable federal, state, and local statutes and regulations and the provisions of this chapter;</del><br/> and<br/> <del>(ii) when the 2. The application fee has been received by the department</del><br/> <u>OLC.</u><br/> <u>The commissioner shall indicate on each license whether an abortion facility may perform medication abortions, surgical abortions, or both.</u><br/> <u>B. No person or entity shall establish, conduct, maintain, or operate in this state, Commonwealth any abortion facility without having obtained a license. Any person establishing, conducting, maintaining, or operating an abortion facility without a license shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.</u><br/> <u>C. An abortion facility shall not assign or transfer any license issued by the commissioner pursuant to this chapter.</u></p> <p>Statutory Authority<br/> §§ 32.1-12, <del>32.1-125</del>, and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:<br/> (i) rewrite the section in the active voice and break paragraphs with</p> |

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|    |     |  | <p>multiple requirements into subparts;</p> <ul style="list-style-type: none"> <li>(ii) clarify who issues the license;</li> <li>(iii) match regulatory language to statutory language;</li> <li>(iv) indicate how the public will be able to know what type of abortions are offered at a facility; and</li> <li>(v) consolidate general provisions that apply to all FTAF licenses.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) reducing conflicts between regulatory language to statutory language reduces confusion for readers;</li> <li>(iii) because the Board is proposing to exempt some facilities from certain requirements based on the type of abortions offered, indicating the type of abortions on the publically posted license will better inform the public of what a facility's regulatory requirements; and</li> <li>(iv) improve the organization of the overall chapter by grouping logically related subjects together.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, clarity regarding who grants the license, and a better informed public regarding the type of abortions available at a facility.</p> |
| 40 | N/A | <p><b>12VAC5-412-40. Separate license.</b><br/>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.</p> <p>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</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-40. Separate license.</b></p> <p>A. <u>An applicant intending to operate</u> <del>An an</del> abortion facility <del>operating</del> at more than one location shall <del>be required to</del> obtain separate licenses for each location <del>in at</del> which <del>abortion services</del> <u>abortions</u> are provided.</p> <p>B. <u>An Abortion</u> <del>abortion</del> facilities <del>facility which have that has</del> separate</p>  |

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|    |     | <p>additional applicable license required for that type or classification of service.</p> <p>Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of this chapter.</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>   | <p>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.</p> <p><u>C.</u> Facilities licensed as either a general hospital or an outpatient surgical hospital by the <del>department commissioner</del> are not subject to the provisions of this chapter.</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite the section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) match regulatory language to statutory language.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) reducing conflicts between regulatory language to statutory language reduces confusion for readers.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity regarding on whom issues a license.</p> |
| 50 | N/A | <p><b>12VAC5-412-50. Request for issuance.</b></p> <p>A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially to the department's Office of Licensure and Certification (OLC).</p> <p>B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-50. Request for <u>initial license issuance.</u></b></p> <p><del>A. Abortion facility licenses shall be issued by the commissioner. All applications for licensure shall be submitted initially.</del></p> <p><u>1. Submit an application for initial licensure to the department's Office of</u></p>   |

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|  | <p>of name shall be reported to the OLC within 30 days.</p> <p>C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.</p> <p>D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee are submitted.</p> <p>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.</p> <p>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.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><del>Licensure and Certification (OLC) OLC:</del></p> <p><u>2. Submit a copy of the proposed abortion facility's certificate of use and occupancy or a statement from the certified architect or engineer of the proposed abortion facility that the premises is substantially complete and eligible for a certificate of occupancy.</u></p> <p><u>3. Identify the services that it intends to perform at its proposed abortion facility; and</u></p> <p><u>4. Disclose to the OLC the ownership interest of the proposed abortion facility and in the case of corporations, identify by name and address all individuals or entities holding 5.0% or more of total ownership.</u></p> <p>B. Each <u>proposed</u> abortion facility shall <del>be designated by</del> <u>have</u> a distinct identifying name <del>which that</del> shall appear on the application for <u>initial</u> licensure. <del>Any change of name shall be reported to the OLC within 30 days.</del></p> <p><del>C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the abortion facility's certificate of use and occupancy or a statement from the facility's certified architect or engineer that the facility is substantially complete and eligible for a certificate of occupancy.</del></p> <p><del>D.C.</del> The OLC shall consider an application complete when all requested information and the <del>appropriate</del> nonrefundable application fee are <del>submitted</del> <u>received by the OLC.</u></p> <p><del>E.D.</del> An applicant shall provide <del>Written</del> <u>written</u> notification from the applicant to OLC that it is ready for the <del>on-site survey</del> <u>initial licensure inspection</u> must be received 30 days prior to OLC scheduling of the initial licensure survey. <del>The OLC shall notify Applicants for initial licensure the applicant shall be notified of the time and date of the initial licensure survey inspection, after the notice of</del></p> |
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|  |  | <p><u>readiness is received by the OLC. The OLC will conduct the initial licensure inspection no sooner than 30 days after the OLC receives the applicant's written notification.</u></p> <p><u>F.E. As part of the initial licensure inspection, an applicant shall:</u></p> <ol style="list-style-type: none"><li><u>1. Make available to an inspector any requested records;</u></li><li><u>2. Allow an inspector access to interview the agents, employees, contractors, and any person under the applicant's control, direction, or supervision; and</u></li><li><u>3. Permit an inspector to enter upon and into the property of any proposed abortion facility to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter.</u></li></ol> <p><u>F. The OLC shall provide a written inspection report to the applicant. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-412-110.</u></p> <p><del>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.</del></p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ol style="list-style-type: none"><li>(i) rewrite the section in the active voice and break paragraphs with multiple requirements into subparts;</li><li>(ii) clarify what responsibilities that an applicant has; and</li><li>(iii) match regulatory language to statutory language.</li></ol> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> |
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|    |     |  | <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) eliminate any confusion about what steps an applicant must take as part of the application;</p> <p>(iii) that applicants have the same responsibility as licensees to cooperate with inspectors and the inspection process; and</p> <p>(iv) reducing conflicts between regulatory language to statutory language reduces confusion for readers</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity regarding what the regulatory requirements are and on whom regulatory requirements are placed.</p>   |
| 60 | N/A | <p><b>12VAC5-412-60. License expiration and renewal.</b></p> <p>A. Licenses shall expire at midnight April 30 following the date of issue and shall be renewable annually, upon filing of a renewal application and payment of the appropriate nonrefundable renewal application fee. Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter.</p> <p>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.</p> <p>C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-60. License expiration and renewal.</b></p> <p>A. Licenses shall expire at midnight April 30 following the date of issue and <del>shall be renewable</del> <u>may be renewed</u> annually, upon filing of a renewal application and payment of the <del>appropriate</del> nonrefundable renewal application fee. <del>Renewal applications</del> <u>The commissioner shall renew a license shall only be granted after a determination by the OLC determines that the applicant abortion facility</u> is in substantial compliance with this chapter.</p> <p>B. <u>An abortion facility shall submit a</u> <del>The annual</del> license renewal application <del>shall be submitted</del> to the OLC <del>at least</del> <u>no less than</u> 60 days prior to the expiration date of the current license. <del>A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.</del> <u>The OLC may not accept any renewal application submitted after the expiration of the current license.</u></p> <p>C. <u>Any An</u> abortion facility <del>failing that fails</del> <u>to submit an acceptable a</u> plan of correction as required in</p> |

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|    |     |   | <p>12VAC5-412-110 <del>shall</del> <u>may</u> not be eligible for license renewal <u>renew its license.</u></p> <p><u>D. An abortion facility whose license has expired or is not eligible to renew its license pursuant to subsection C:</u></p> <ol style="list-style-type: none"> <li><u>1. May not perform more than four first trimester abortions per month; and</u></li> <li><u>2. Shall comply with 12VAC5-412-50 to receive a license.</u></li> </ol> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> <li>(i) rewrite the section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) clarify that a renewal application cannot be accepted by the OLC after a license expires; and</li> <li>(iii) clarify what services a licensee whose license expires may perform.</li> </ol> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ol style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) incentivize abortion facilities to timely file their renewal applications as the Board cannot assess late fees for filing applications after the license expires;</li> <li>(iii) that the lack of a license is not a complete bar to the performance of abortions.</li> </ol> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity regarding what the regulatory requirements are.</p> |
| 70 | N/A | <p><b>12VAC5-412-70. Return and/or reissuance of license.</b></p> <p>A. It is the responsibility of the abortion facility's governing body to</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p>   |



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|  | <p>maintain a current and accurate license at all times.</p> <p>B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</p> <ol style="list-style-type: none"> <li>1. Change of location.</li> <li>2. Change of ownership.</li> <li>3. Change of name.</li> <li>4. Voluntary closure.</li> <li>5. Change of administrator.</li> <li>6. Change of operator.</li> </ol> <p>Notices shall be sent to the attention of the director of the OLC.</p> <p>C. The license issued by the commissioner shall be returned to the OLC when any of the changes listed in subsection B of this section occur. In addition, if the abortion facility is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within five calendar days of the abortion facility closing. The abortion facility's patients and the OLC shall be notified where all patient records will be located.</p> <p>D. The OLC shall determine if any changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the abortion facility during the process of evaluating a change.</p> <p>E. The abortion facility will be notified in writing by the OLC whether a license can be reissued or a new application is needed.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>12VAC5-412-70. <del>Return and/or Surrender of license; reissuance of license.</del></b></p> <p><del>A. It is the responsibility of the abortion facility's governing body to maintain</del> <u>An abortion facility shall maintain</u> a current and accurate license at all times.</p> <p><del>B. An abortion facility shall give written notification</del> <u>notify the director of the OLC in writing no less than 30 calendar days in advance of implementing any of the following planned changes:</u></p> <ol style="list-style-type: none"> <li>1. Change of location-;</li> <li>2. Change of ownership-;</li> <li>3. Change of name-;</li> <li>4. <u>Introduction of surgical abortions; or</u></li> <li>5. <u>Voluntary closure.</u></li> <li>5. <del>Change of administrator.</del></li> <li>6. <del>Change of operator.</del></li> </ol> <p><del>Notices shall be sent to the attention of the director of the OLC.</del></p> <p><del>C. The</del> <u>An abortion facility shall surrender the</u> license issued by the commissioner <del>shall be returned to the OLC when any of the changes listed in subsection B of this section occur upon receipt of the reissued or new license.</del></p> <p><del>D. In addition, if</del> <u>If the an</u> abortion facility is no longer operational, <del>or the license has been suspended or revoked, the it shall:</del></p> <ol style="list-style-type: none"> <li>1. <u>Surrender its</u> license <del>shall be returned to the OLC within no more than five calendar days of</del> <u>after</u> the abortion facility <del>closing</del> <u>ceases operations-; and</u></li> <li>2. <del>The abortion facility's</del> <u>Notify</u> all patients and the OLC <del>shall be notified</del> where all patient records will be located <u>no more than five calendar days after the abortion facility ceases operations.</u></li> </ol> <p><del>D-E.</del> <u>The OLC shall determine if any changes listed in subsection B affect the terms of the license or the an abortion facility's continuing</u></p> |
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|  |  |  | <p>eligibility for a license. <del>A licensing representative</del> <u>An inspector</u> may inspect the abortion facility during the process of evaluating a change.</p> <p><del>E.F. The OLC shall notify in writing the abortion facility</del> <u>abortion facility will be notified in writing by the OLC whether if the commissioner will reissue a the license can be reissued or a new application is needed. An abortion facility shall submit a new application at least 30 days in advance of any change of ownership or location.</u></p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) clarify what responsibilities that a licensee has;</li> <li>(iii) require a licensee to notify the OLC of a change in the types of abortions performed; and</li> <li>(iv) remove the requirement to notify the OLC of a change of administrator or operator.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) as an abortion facility must have a current and accurate license posted, the license should only be returned after a new or reissued license has been received;</li> <li>(iii) because the Board is proposing to exempt some facilities from certain requirements based on the type of abortions offered, knowing the type of abortions will allow the OLC to apply the appropriate regulatory requirements; and</li> <li>(iv) removal of change of administrator and operator is</li> </ul> |
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|    |     |   | <p>consistent with the regulations for hospitals.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, clarity regarding on whom regulatory requirements are placed, and improved consistency with other types of hospitals.</p>   |
| 80 | N/A | <p><b>12VAC5-412-80. Allowable variances.</b></p> <p>A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.</p> <p>B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.</p> <p>C. Consideration of a temporary variance is initiated when a written request is submitted to the</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-80. Allowable variances.</b></p> <p><del>A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.</del></p> <p><del>B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.</del></p> |

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|  |  | <p>commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.</p> <p>D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.</del></p> <p><del>D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.</del></p> <p><u>Upon the finding that the enforcement of one or more of these regulations would be clearly impractical, the commissioner may waive, either temporarily or permanently, the enforcement of one or more of these regulations, provided safety and patient care and services are not adversely affected.</u></p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice; and</li> <li>(ii) reinstate changes from a 2017 rulemaking that were remanded pursuant to <i>Melendez</i> and which are consistent with the regulations for hospitals.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) facilities performing five or more first trimester abortions per month are a category of hospital.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved</p> |
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|           |            |   | <p>readability of this section and clarity regarding on what regulatory requirements are.</p>   |
| <p>90</p> | <p>N/A</p> | <p><b>12VAC5-412-90. Right of entry.</b><br/> Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any such employee shall properly identify himself as an inspector designated by OLC; the abortion facility may verify the identity of the inspector prior to his admission. Such entries and inspections shall be made with the permission of the owner or person in charge, unless an inspection warrant is obtained after denial of entry from an appropriate circuit court. If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate revocation or suspension of the license. If the entity is unlicensed, the owner or person in charge shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.</p> <p>Statutory Authority<br/> §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-90. Right of entry.</b><br/> <u>A. 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 An inspector may enter upon and into the premises property of any licensed abortion facility, or any entity the department OLC has reason to believe is operated or maintained as an abortion facility without a license, to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and applicable laws.</u><br/> <u>B. Any such employee An inspector shall properly identify himself as an inspector designated by OLC the commissioner through the presentation of appropriate credentials; the abortion facility The owner or custodian of the property may verify the identity of the inspector prior to his admission upon or into the property.</u><br/> <u>C. Such entries and inspections shall be made An inspector may enter upon and into the property with the permission of the owner or person in charge custodian;. If an inspector is denied entry upon and into the property, unless the commissioner or his designee may obtained an inspection warrant is obtained after denial of entry from an appropriate circuit court pursuant to § 32.1-25 of the Code of Virginia.</u><br/> <u>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.</u></p> <p>Statutory Authority</p> |

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|     |     |  | <p>§§ 32.1-12, <del>32.1-25</del>, 32.1-27, and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) match regulatory language to statutory language.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) reducing conflicts between regulatory language to statutory language reduces confusion for readers.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is The likely impact of these proposed changes is improved readability of this section and improved clarity regarding the right of entry.</p> |
| 100 | N/A | <p><b>12VAC5-412-100. On-site inspection.</b></p> <p>A. An OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than biennially. If the department finds, after inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-110.</p> <p>B. The abortion facility shall make available to the OLC's representative any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction, or supervision. If copies of records are removed from the premises, patient names and addresses contained in such records</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-100. On-site inspection.</b></p> <p>A. <del>An</del> <u>The</u> OLC representative shall make periodic unannounced on-site inspections of each abortion facility as necessary, but not less often than biennially. <del>If the department finds, after inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a written licensing report of such findings. The abortion facility shall submit a written plan of correction in accordance with provisions of 12VAC5-412-110.</del></p> <p>B. The abortion facility shall make available to the OLC's representative <u>inspector</u> any requested records and shall allow access to interview the agents, employees, contractors, and any person under the abortion facility's control, direction, or supervision. If copies of records are</p>   |

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|  | <p>shall be redacted by the abortion facility before removal.</p> <p>C. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records is not available on the premises, such person or the designated alternate shall be available on the premises within one hour of the surveyor's arrival. A list of patients receiving services on the day of the survey as well as a list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within two hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-130.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p>removed from the premises, <u>the abortion facility may redact patient names and addresses of patients or personnel contained in such records shall be redacted by the abortion facility before prior to removal. The inspector shall inform the abortion facility that it may redact names and addresses of patients or personnel prior to the inspector removing copies of records from the premises.</u></p> <p>C. If <del>the OLC's representative an</del> <u>inspector</u> arrives on the premises to conduct <del>a survey</del> <u>an inspection</u> and <del>the administrator, the nursing director, or</del> a person authorized to give access to patient records is not available on the premises, <del>such the</del> <u>the</u> person or the designated alternate shall be available on the premises <del>within no more than one hour of</del> <u>after the surveyor's inspector's arrival. Upon request of the inspector, the abortion facility shall provide no more than 2 hours after the inspector's arrival:</u></p> <ol style="list-style-type: none"> <li><u>1. A list of patients receiving scheduled to receive abortions and services related to the provision of an abortion on the day days of the survey inspection; and</u></li> <li><u>2. as well as a A list of all of the abortion facility's patients for the previous 12 months shall be provided to the surveyor within two hours of arrival if requested.</u></li> </ol> <p><del>Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in accordance with 12VAC5-412-130.</del></p> <p><u>D. The OLC shall provide a written inspection report to the administrator. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-412-110.</u></p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> |
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|     |     |  | <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) better inform abortion facilities of their right to redact records; and</li> <li>(iii) reorganize the section more chronologically.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) ensure the privacy of patients and personnel; and</li> <li>(iii) that since the section is about inspection and plans of correction do not occur without an inspection, moving the plan of correction language to the end of the section is more chronologically consistent.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and a greater likelihood that abortion facilities will exercise their right to redact records.</p> |
| 110 | N/A | <p><b>12VAC5-412-110. Plan of correction.</b></p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;</li> <li>2. The expected correction date, not to exceed 30</li> </ul> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-110. Plan of correction.</b></p> <p>A. Upon receipt of a written <u>licensing inspection</u> report, <del>each abortion facility</del> <u>the administrator or his designee</u> shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.</p> <p>B. The administrator shall submit, <del>within 15 working days of receipt of the inspection report, an acceptable to the OLC</del> <u>a written plan of correction as determined by the OLC no more than 15 working days after receipt of the inspection report.</u> The plan of correction shall contain for each <u>licensing violation</u> cited:</p>   |



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|  |  | <p>working days from the exit date of the survey;<br/>         3. A description of the measures implemented to prevent a recurrence of the violation; and<br/>         4. The signature of the person responsible for the validity of the report.</p> <p>C. The administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with § 32.1-27 of the Code of Virginia or in denial, revocation, or suspension of a license in accordance with 12VAC5-412-130.</p> <p>D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p>1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;<br/>         2. The expected correction date, not to exceed <del>30</del> <u>45</u> working days from the exit date of the <del>survey</del> <u>inspection</u>;<br/>         3. A description of the measures implemented to prevent a recurrence of the <u>licensing</u> violation; and<br/>         4. The signature <u>and title</u> of the person responsible for the validity of the <del>report</del> <u>plan of correction, and the date of the signature</u>.</p> <p><del>C. The administrator OLC shall be notified whenever if the OLC determines any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with § 32.1-27 of the Code of Virginia or in denial, revocation, or suspension of a license in accordance with 12VAC5-412-130.</del></p> <p>D. <u>Upon request of the OLC, an applicant or licensee shall produce evidence that all or part of a plan of correction has been implemented. The OLC may conduct an inspection to verify any portion of a plan of correction.</u></p> <p><del>E. The administrator shall be responsible for assuring</del> <u>ensure</u> the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) make the amount of time to implement a correction consistent with the regulations for hospitals.</li> </ul> |
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|     |     |   | <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) facilities in which five or more first trimester abortions are performed per month are a category of hospital.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of the section and improved consistency in regulating categories of hospitals.</p>  |
| 120 | N/A | <p><b>12VAC5-412-120. OLC complaint investigations.</b></p> <p>A. The OLC shall investigate any complaints regarding alleged violations of this chapter and applicable law. When the investigation is complete, the abortion facility and the complainant, if known, will be notified of the findings of the investigation.</p> <p>B. As required by the OLC, the administrator shall submit a plan of correction for any deficiencies found during a complaint investigation in accordance with 12VAC5-412-110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b><u>12VAC5-412-120. OLC Complaint investigations.</u></b></p> <p>A. The OLC shall investigate any complaints regarding alleged violations of this chapter <del>and applicable law.</del> <u>The OLC shall determine if an investigation requires an on-site inspection. In making this determination, the OLC shall consider several factors, to include:</u></p> <ol style="list-style-type: none"> <li><u>1. If the complainant has first-hand knowledge of the alleged incident;</u></li> <li><u>2. The abortion facility's regulatory history, including the number of substantiated prior complaints;</u></li> <li><u>3. If the OLC has recently inspected the abortion facility, and if the incident would have been observed during the prior inspection; and</u></li> <li><u>4. The nature of the complaint, including degree of potential serious harm to patients.</u></li> </ol> <p>When the investigation is complete, the OLC shall notify the abortion facility and the complainant, if known, <del>will be notified in writing</del> of the findings of the investigation.</p> <p>B. <del>As required by the OLC</del> <u>For any licensing violation cited during a complaint investigation, the</u></p> |

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|     |     |   | <p>administrator shall submit a plan of correction for any deficiencies found during a complaint investigation in accordance with 12VAC5-412-110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice; and</li> <li>(ii) give the OLC the flexibility to determine whether a complaint warrants an on-site inspection.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) encourage efficient and effective use of agency resources in responding to complaints.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of the section and a more adaptive and efficient complaint process.</p> |
| 130 | N/A | <p><b>12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.</b></p> <p>A. When the department determines that an abortion facility is (i) in violation of § 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code of Virginia or of any applicable regulation or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia.</p> <p>B. If a license or certification is revoked as herein provided, a new license or certification may be issued</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or suspension of license.</b></p> <p>A. <u>When the department determines The commissioner may deny, suspend, or revoke the license to operate an abortion facility in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) if the commissioner determines that an abortion facility an applicant or licensee is:</u></p> <p><del>(i) in 1.</del> In violation of § 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code of Virginia</p>  |

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|  | <p>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 §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.</p> <p>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.</p> <p>D. The abortion facility has the right to contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>or of any applicable regulation; or</del><br/> <del>(ii) is permitting</del> 2. Permitting, aiding, or abetting the commission of any illegal act in the abortion facility,<del>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.</del></p> <p><u>Suspension of a license shall be for an indefinite time in all cases.</u></p> <p><del>B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner. Upon receipt of a completed application and a nonrefundable application fee, the commissioner may issue a new license to an abortion facility that has had its license to operate an abortion facility revoked if the commissioner determines that:</del></p> <p><del>1. after satisfactory evidence is submitted to him that the</del><br/> <u>The</u> conditions upon which revocation was based have been corrected; and</p> <p><del>2. after proper inspection has been made and</del><br/> <u>The applicant is in compliance with §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained.</u></p> <p><u>The abortion facility shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.</u></p> <p><del>C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may partially or completely restore a suspended license to an abortion facility when he if the commissioner determines that:</del></p> <p><del>1. the</del><u>The</u> conditions upon which suspension was based have been corrected; and</p> |
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|     |     |   | <p><del>2. that the</del> The interests of the public will not be jeopardized by resumption of operation.</p> <p><u>The abortion facility shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.</u> No additional fee shall be required for restoring <del>such a</del> license <u>pursuant to this subsection.</u></p> <p><del>D. The abortion facility has the right to</del> <u>An applicant or licensee may</u> contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).</p> <p>Statutory Authority<br/> <u>§§ 32.1-12, 32.1-127, and 32.1-135</u> of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) match regulatory language to statutory language.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) reducing conflicts between regulatory language to statutory language reduces confusion for readers.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p> |
| 140 | N/A | <p>Part II<br/>                     Organization and Management<br/> <b>12VAC5-412-140. Management and administration.</b><br/>                     A. The abortion facility shall comply with:</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p>   |

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|  | <p>1. This chapter (12VAC5-412);</p> <p>2. Other applicable federal, state, or local laws and regulations; and</p> <p>3. The abortion facility's policies and procedures.</p> <p>B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.</p> <p>C. The abortion facility shall permit OLC inspectors to conduct inspections to:</p> <ol style="list-style-type: none"> <li>1. Verify application information;</li> <li>2. Determine compliance with this chapter and applicable law;</li> <li>3. Review necessary records and documents; and</li> <li>4. Investigate complaints.</li> </ol> <p>D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</p> <ol style="list-style-type: none"> <li>1. Change of location.</li> <li>2. Change of ownership.</li> <li>3. Change of name.</li> <li>4. Voluntary closure.</li> <li>5. Change of administrator.</li> <li>6. Change of operator.</li> </ol> <p>Notices shall be sent to the attention of the director of the OLC.</p> <p>E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.</p> <p>F. Each abortion facility shall post notice of the existence of a human trafficking hotline to alert possible witnesses or victims of human trafficking to the availability of a means to gain assistance or report crimes. This notice shall be in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms. The notice shall meet the requirements of § 40.1-11.3 C of the Code of Virginia.</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p>Part II<br/>Organization and Management<br/><b>12VAC5-412-140. Management and administration.</b></p> <p>A. The abortion facility shall comply with:</p> <ol style="list-style-type: none"> <li>1. This chapter—(12VAC5-412);</li> <li>2. <del>Other applicable federal, state, or local laws and regulations</del> §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia; and</li> <li>3. The abortion facility's policies and procedures.</li> </ol> <p>B. The <del>abortion facility</del> <u>applicant or licensee</u> shall submit or make available <u>to the commissioner or his designee any reports and information necessary to establish compliance with this chapter and applicable law.</u></p> <p><del>C. The abortion facility shall permit OLC inspectors to conduct inspections to:</del></p> <ol style="list-style-type: none"> <li>1. <del>Verify</del> application information;</li> <li>2. <del>Determine compliance with this chapter and applicable law;</del></li> <li>3. <del>Review necessary records and documents; and</del></li> <li>4. <del>Investigate complaints.</del></li> </ol> <p><del>D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</del></p> <ol style="list-style-type: none"> <li>1. <del>Change of location.</del></li> <li>2. <del>Change of ownership.</del></li> <li>3. <del>Change of name.</del></li> <li>4. <del>Voluntary closure.</del></li> <li>5. <del>Change of administrator.</del></li> <li>6. <del>Change of operator.</del></li> </ol> <p><del>Notices shall be sent to the attention of the director of the OLC.</del></p> <p><del>E. The</del> <u>C. An abortion facility shall post its current license from the department commissioner shall be posted</u> at all times in a place readily visible and accessible to the public.</p> <p><del>F. D.</del> <u>Each abortion facility shall post notice that:</u></p> <ol style="list-style-type: none"> <li>1. <u>Alerts possible witnesses or victims of human trafficking of the existence of a human trafficking hotline to alert possible witnesses or victims</u></li> </ol> |
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|     |     |   | <p><del>of human trafficking to the availability of a as an available</del> means to gain assistance or report crimes; and</p> <p>2. This notice shall be <u>is</u> in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) remove duplicative requirements.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) duplicating requirements in multiple sections of regulation may be confusing and increases likelihood of sections being in conflict with one another.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p> |
| 150 | N/A | <p><b>12VAC5-412-150. Governing body.</b></p> <p>A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the abortion facility.</p> <p>B. There shall be disclosure of abortion facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.</p> <p>C. The governing body shall provide facilities, personnel, and other</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-150. Governing body.</b></p> <p>A. Each abortion facility shall <del>have</del> <u>designate in writing</u> a governing body responsible for the <u>overall</u> management and control of the operation of the abortion facility.</p> <p><del>B. There shall be disclosure of abortion facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The</del></p>   |

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|  |  | <p>resources necessary to meet patient and program needs.</p> <p>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.</p> <p>E. The bylaws shall include at a minimum the following:</p> <ol style="list-style-type: none"> <li>1. A statement of purpose;</li> <li>2. Description of the functions and duties of the governing body or other legal authority;</li> <li>3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;</li> <li>4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and</li> <li>5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.</li> </ol> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><del>OLC shall be notified of any changes in ownership.</del></p> <p><del>C.B.</del> The governing body shall provide <u>1. Provide facilities, personnel, and other resources necessary to meet patient and program needs;</u> and</p> <p><del>D.</del> <del>The governing body shall have</del> <u>2. Have a formal organizational plan with written bylaws. These shall that clearly set forth organization, duties and responsibilities, accountability, and relationships of professional management, clinical staff, and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.</u></p> <p><del>E.C.</del> The bylaws shall include at a minimum the following:</p> <ol style="list-style-type: none"> <li>1. A statement of purpose;</li> <li>2. Description of the functions and duties of the governing body or other legal authority;</li> <li>3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;</li> <li>4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and</li> <li>5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff; and</li> <li>6. <u>The identity of the person or organizational body responsible for formulating policies and procedures pursuant to 12VAC5-412-160.</u></li> </ol> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs</p> |
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|     |     |   | <p>with multiple requirements into subparts.</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p>  |
| 160 | N/A | <p><b>12VAC5-412-160. Policies and procedures.</b></p> <p>A. Each abortion facility shall develop, implement, and maintain documented policies and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but shall not be limited to the following topics:</p> <ol style="list-style-type: none"> <li>1. Personnel;</li> <li>2. Types of elective services performed in the abortion facility;</li> <li>3. Types of anesthesia that may be used;</li> <li>4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;</li> <li>5. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures;</li> <li>6. When to use sonography to assess patient risk;</li> <li>7. Infection prevention;</li> <li>8. Quality and risk management;</li> <li>9. Management and effective response to medical and/or surgical emergency;</li> <li>10. Management and effective response to fire;</li> <li>11. Ensuring compliance with all applicable federal, state, and local laws;</li> <li>12. Abortion facility security;</li> <li>13. Disaster preparedness;</li> <li>14. Patient rights;</li> </ol> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-160. Policies and procedures.</b></p> <p>A. <del>Each abortion facility</del> <u>A governing body shall:</u></p> <ol style="list-style-type: none"> <li><u>1. develop</u> <del>Approve,</del> <u>implement,</u> and maintain documented policies and procedures as specified in <u>this section that are based on recognized standards and guidelines,</u> which shall be readily available on the premises; <del>and shall be reviewed</del> <u>2. Review all policies and procedures at least annually with the administrator and appropriate clinical staff; and updated</u></li> <li><u>3. Update policies and procedures as deemed necessary by the governing body;</u> and</li> <li><u>4. Document in writing the annual review process and recommendations for changes or updates.</u></li> </ol> <p><u>A member of the clinical staff with training and expertise in infection prevention shall participate in the annual review of the infection prevention policies and procedures to ensure they comply with applicable regulations and standards.</u></p> <p><u>B. The personnel policies and procedures shall include</u> <del>but shall not be limited to the following topics:</del></p> <ol style="list-style-type: none"> <li><u>1. Personnel; Written job descriptions that meet the requirements of 12VAC5-412-180 B 4;</u></li> </ol> |

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|  |  | <p>15. Functional safety and abortion facility maintenance; and</p> <p>16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.</p> <p>B. These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><u>2. Verifying current professional licensing or certification and training of employees or independent contractors;</u></p> <p><u>3. Obtaining a criminal background check;</u></p> <p><u>4. Evaluating at least annually employee performance and competency;</u></p> <p><u>5. Verifying that independent contractors and their employees meet the personnel qualifications of the abortion facility;</u></p> <p><u>6. 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;</u></p> <p><u>7. Staff participation 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;</u></p> <p><u>8. Staff participation in annual fire safety and infection prevention in-service training and the process by which training is documented; and</u></p> <p><u>9. Appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided and the process by which staffing is documented.</u></p> <p><u>C. The patient and clinical services policies and procedures shall include:</u></p> <p><u>1. Ensuring and documenting that only health care practitioners who are permitted by law and are qualified by training and experience are performing abortions in the abortion facility;</u></p> <p><u>2. Types of elective services performed in the abortion facility;</u></p> <p><u>3. Types of anesthesia that may be used;</u></p> |
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|  |  |  | <p><u>4. Content and completion of medical records;</u></p> <p><u>5. Documentation in the patient's medical record of and criteria for evaluating a patient for discharge from anesthesia care, including:</u></p> <ul style="list-style-type: none"> <li><u>a. Stable vital signs;</u></li> <li><u>b. Responsiveness and orientation;</u></li> <li><u>c. Ability to move voluntarily;</u></li> <li><u>d. Controlled pain; and</u></li> <li><u>e. Minimal nausea and vomiting;</u></li> </ul> <p><u>6. Admissions Patient intake evaluation, to comply with subsection A of 12VAC5-412-240;</u></p> <p><u>7. and discharges Discharges, including criteria for evaluating the patient before admission and for medical stability before discharge;</u></p> <p><u>8. Ensuring that adequately trained health care practitioners remain with the patient until discharged from the abortion facility;</u></p> <p><u>5-9. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures an abortion;</u></p> <p><u>6-10. When to use sonography to assess patient risk;</u></p> <p><u>7. Infection prevention;</u></p> <p><u>8. Quality and risk management;</u></p> <p><u>9-11. Management and effective response to medical and/or or surgical emergency;</u></p> <p><u>12. The secure and temperature-controlled storage of drugs and the disposal of expired drugs;</u></p> <p><u>13. Patient rights;</u></p> <p><u>14. Provision of or referral for family planning services to the abortion facility's patients;</u></p> <p><u>15. Evaluation of all tissues removed during an abortion and for reevaluation of the</u></p> |
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|  |  |  | <p><u>patient if the evaluation of tissue is insufficient to confirm termination of the pregnancy; and</u></p> <p><u>16. Tracking and logging any tissue specimens sent for further pathologic examination.</u></p> <p><u>An abortion facility that provides only medication abortions shall be exempt from subdivisions 3, 5, 6, 7, 15, and 16 of this subsection.</u></p> <p><u>D. The safety and security policies and procedures shall include:</u></p> <ol style="list-style-type: none"><li><u>1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services;</u></li><li><u>2. Provisions for disseminating safety-related information to employees and users of the abortion facility;</u></li><li><u>10-3. Management and effective response to fire;</u></li><li><u>11. Ensuring compliance with all applicable federal, state, and local laws;</u></li><li><u>12-4. Abortion facility security; and</u></li><li><u>13-5. Disaster preparedness, to include provisions for evacuation of all occupants in the event of a disaster, exercise of the disaster preparedness plan not less than annually, and documentation of disaster preparedness exercises.</u></li></ol> <p><u>E. A member of the clinical staff with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures. The governing body shall document the process for development, implementation, and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based. The infection prevention policies and procedures shall include:</u></p> <ol style="list-style-type: none"><li><u>1. Screening incoming patients for acute infectious illnesses and applying appropriate measures to prevent transmission of</u></li></ol> |
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|  |  |  | <p><u>community-acquired infection within the abortion facility;</u></p> <p><u>2. Initial training, annual retraining, and use of standard precautions recommended by the U.S. Centers for Disease Control and Prevention by all employees and independent contractors, including:</u></p> <ul style="list-style-type: none"><li><u>a. Correct hand-washing technique, including indications for use of soap and water, and use of alcohol-based hand rubs;</u></li><li><u>b. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety and Health Administration; and</u></li><li><u>c. Use of personal protective equipment;</u></li></ul> <p><u>3. Use of safe injection practices recommended by the U.S. Centers for Disease Control and Prevention;</u></p> <p><u>4. Monitoring staff adherence to standard precautions;</u></p> <p><u>5. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);</u></p> <p><u>6. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal, storage, and transport of equipment and supplies;</u></p> <p><u>7. Storage for cleaning agents, such as locked cabinets or rooms for chemicals used for cleaning, in accordance with product-specific instructions;</u></p> <p><u>8. Use of cleaning agents, such as dilution, contact time, and management of accidental exposures, in accordance with product-specific instructions;</u></p> <p><u>9. Handling, storing, and transporting clean linens,</u></p> |
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|  |  |  | <p><u>clean or sterile supplies, and equipment;</u></p> <p><u>10. Handling, temporary storage, and transport of soiled linens;</u></p> <p><u>11. Handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;</u></p> <p><u>12. Processing of each type of reusable medical equipment between uses on different patients, with reference to the manufacturer's recommendations and any applicable state or national infection control guidelines, and addressing:</u></p> <ul style="list-style-type: none"><li><u>a. The level of cleaning, disinfecting, or sterilizing to be used for each type of equipment;</u></li><li><u>b. The process by which cleanliness, disinfection, or sterilization is achieved; and</u></li><li><u>c. The method for verifying that the recommended level of cleanliness, disinfection, or sterilization has been achieved;</u></li></ul> <p><u>13. Maintenance, repair, and disposal of equipment and supplies in accordance with manufacturer recommendations;</u></p> <p><u>14. Cleaning of environmental surfaces with appropriate cleaning products;</u></p> <p><u>15. An effective pest control program, managed in accordance with local health and environmental regulations;</u></p> <p><u>16. Other infection prevention procedures necessary to prevent or control transmission of an infectious agent in the abortion facility as recommended or required by the department;</u></p> <p><u>17. Surveillance, documentation, and tracking of reported infections; and</u></p> |
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|  |  |  | <p><u>18. Reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.</u></p> <p><u>F. The management and administration policies and procedures shall include:</u></p> <p><u>14. Patient rights;</u></p> <p><u>15.1. Quality and risk management;</u></p> <p><u>2. Functional safety and abortion facility maintenance; and</u></p> <p><u>16.3. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.</u></p> <p><del>B. These policies and procedures shall be based on recognized standards and guidelines. A copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request.</del></p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) consolidate the requirements for policies and procedures into a single section;</li> <li>(iii) organize the required policies and procedures by topic; and</li> <li>(iv) exempt facilities that only medication abortions from inapplicable requirements.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> </ul> |
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|     |     |   | <p>(ii) housing all policies and procedures in the section entitled “Policies and procedures” makes it easier for licensees and the public to find the requirements;</p> <p>(iii) because of the number of required policies and procedures, readability is increased when organized by topic; and</p> <p>(iv) facilities that only perform medication abortions should not have to create policies and procedures that are inapplicable.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and reduced regulatory burden for eligible facilities.</p>   |
| 170 | N/A | <p><b>12VAC5-412-170. Administrator.</b></p> <p>A. The governing body shall select an administrator who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility, including but not limited to:</p> <ol style="list-style-type: none"> <li>1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;</li> <li>2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;</li> <li>3. Ensuring the accuracy of public information materials and activities;</li> <li>4. Ensuring an effective budgeting and accounting system is implemented; and</li> <li>5. Maintaining compliance with applicable laws and regulations and implementing corrective action.</li> </ol> <p>B. Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes.</p> <p><b>12VAC5-412-170. Administrator.</b></p> <p>A. The governing body shall <u>select designate in writing one or more persons to be an administrator,</u> who shall be responsible for the <u>daily</u> managerial, operational, financial, and reporting components of the abortion facility, including <del>but not limited to:</del></p> <ol style="list-style-type: none"> <li>1. <del>Ensuring the development, implementation, and enforcement of</del> <u>Developing, implementing, and enforcing</u> all policies and procedures, including patient rights;</li> <li>2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;</li> <li>3. Ensuring the accuracy of public information materials and activities;</li> <li>4. Ensuring an effective budgeting and accounting system is implemented; and</li> <li>5. Maintaining compliance with applicable laws and regulations and implementing corrective action.</li> </ol> <p>B. <u>An abortion shall notify the OLC in writing of Any a change in the position of the administrator shall be</u></p> |



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|     |     | <p>C. A qualified individual shall be appointed in writing to act in the absence of the administrator.</p> <p>Statutory Authority<br/>                 §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>  | <p><del>reported immediately by the governing body to the department in writing no more than five working days after the change.</del></p> <p><u>C. The governing body or administrator shall appoint in writing A a qualified individual person shall be appointed in writing</u> to act in the absence of the administrator.</p> <p>Statutory Authority<br/>                 §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) clarify the designation of administrators and alternates are to be in writing; and</li> <li>(iii) give licensees a reasonable time to notify the OLC of changes in administrator.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) by requiring the designation to be written, the OLC can easily verify if the administrator requirement has been met;</li> <li>(iii) five working days is sufficient time to inform the OLC.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.</p> |
| 180 | N/A | <p><b>12VAC5-412-180. Personnel.</b></p> <p>A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document appropriate staffing by licensed</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-180. Personnel.</b></p> <p>A. <del>Each An</del> abortion facility shall <del>have a staff that:</del></p> <p><u>1. Staff its abortion facility with persons who is are</u> adequately trained and capable of providing</p>  |

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|  | <p>clinicians based on the level, intensity, and scope of services provided.</p> <p>B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable.</p> <p>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.</p> <p>D. The abortion facility shall develop, implement, and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties and appropriate to the level, intensity, and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.</p> <p>E. Job descriptions.</p> <ol style="list-style-type: none"> <li>1. Written job descriptions that adequately describe the duties of every position shall be maintained.</li> <li>2. Each job description shall include position title, authority, specific responsibilities, and minimum qualifications.</li> <li>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.</li> </ol> <p>F. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities</p> | <p>appropriate service and supervision to patients; <del>The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.</del></p> <p><u>2. Obtain written applications for employment from all employees;</u></p> <p><u>3. Obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee of the abortion facility who is not licensed by the Board of Pharmacy and whose job duties provide access to controlled substances at the abortion facility;</u></p> <p><u>4. Maintain written job descriptions that adequately describe the duties of every employee position at the abortion facility; and</u></p> <p><u>5. Maintain a personnel file for each employee at the abortion facility.</u></p> <p><del>B. The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, and appropriate professional licensure, if applicable.</del></p> <p><del>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.</del></p> <p><del>D. The abortion facility shall develop, implement, and maintain policies and procedures to document that its staff participate in initial and ongoing training and education that is directly related to staff duties and appropriate to the level, intensity, and scope of services provided. This shall include documentation of annual</del></p> |
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|  | <p>and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.</p> <p>G. Personnel policies and procedures shall include, but not be limited to:</p> <ol style="list-style-type: none"> <li>1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;</li> <li>2. Process for verifying current professional licensing or certification and training of employees or independent contractors;</li> <li>3. Process for annually evaluating employee performance and competency;</li> <li>4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and</li> <li>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.</li> </ol> <p>H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>participation in fire safety and infection prevention in-service training.</del></p> <p><del>E. Job descriptions.</del> <u>B. For each job description, an abortion facility shall:</u></p> <ol style="list-style-type: none"> <li><del>1. Written job descriptions that adequately describe the duties of every position shall be maintained.</del></li> <li><del>2. Each job description shall include</del> <u>1. Include the position title, authority, specific responsibilities, and minimum qualifications.;</u></li> <li><del>3. Job descriptions shall be reviewed</del> <u>2. Review the job description at least annually, kept current, and update as deemed necessary by the abortion facility; and</u></li> <li><del>3. given</del> <u>Give a copy to each employee and volunteer when assigned to the position and when revised.</u></li> </ol> <p><del>F. A C. For each personnel file, an abortion facility shall be maintained for each staff member. The records shall be:</del></p> <ol style="list-style-type: none"> <li><u>1. Ensure the personnel file is completely complete and accurately accurate documented.;</u></li> <li><u>2. Make the personnel file readily available, including by electronic means; and</u></li> <li><del>3. systematically organized</del> <u>Systematically organize the personnel file to facilitate the compilation and retrieval of information.;</u></li> <li><u>4. Safeguard the personnel file against loss and unauthorized use;</u></li> <li><u>5. Maintain employee health related information separately within the personnel file; and</u></li> <li><del>6. The file shall contain</del> <u>Ensure the personnel file contains a current job description that reflects the individual's person's responsibilities and work assignments, and documentation of the person's in-service education,</u></li> </ol> |
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|  |  |  | <p>and professional licensure, if applicable.</p> <p><del>G. Personnel policies and procedures shall include, but not be limited to:</del></p> <ol style="list-style-type: none"><li><del>1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;</del></li><li><del>2. Process for verifying current professional licensing or certification and training of employees or independent contractors;</del></li><li><del>3. Process for annually evaluating employee performance and competency;</del></li><li><del>4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and</del></li><li><del>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.</del></li></ol> <p><del>H. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee's personnel file.</del></p> <p>Statutory Authority<br/>§§ 32.1-12, 32.1-126.02, and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is:</p> <ol style="list-style-type: none"><li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li><li>(ii) remove language regarding personnel policies and procedures.</li></ol> |
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|     |     |   | <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) language about personnel policies and procedures has been moved to section 160, which is entitled "Policies and procedures."</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p>   |
| 190 | N/A | <p><b>12VAC5-412-190. Clinical staff.</b></p> <p>A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and nonphysician health care practitioners shall be clearly defined.</p> <p>B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience.</p> <p>C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order, and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-190. Clinical staff.</b></p> <p>A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. <u>The governing body shall specify in writing the Clinical clinical</u> privileges of physician and nonphysician health care practitioners <del>shall be clearly defined.</del></p> <p><del>B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The abortion facility shall develop, implement, and maintain policies and procedures to ensure and document that abortions that occur in the abortion facility are only performed by physicians who are qualified by training and experience.</del></p> <p><del>C. A B. An abortion facility shall ensure that physician shall:</del></p> <ol style="list-style-type: none"> <li><u>1. remain A physician, nurse practitioner, or physician assistant remains 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.;</u></li> <li><u>2. A physician, nurse practitioner, or physician assistant signs a discharge order following the administration of anesthesia,</u></li> </ol> |

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|  | <p>the patient until she is discharged from the abortion facility.</p> <p>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.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><u>after assessing the patient or receiving a report from a licensed health care practitioner indicating that the patient is safe for discharge; and</u></p> <p><u>3. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The abortion facility shall develop, implement, and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the abortion facility.</u></p> <p><u>An abortion facility that provides only medication abortions shall be exempt from this subsection.</u></p> <p><u>C. An abortion facility shall ensure that a licensed health care practitioner currently certified to perform cardiopulmonary resuscitation shall be on the premises when surgical abortions are being performed until the last patient is discharged.</u></p> <p><u>D. An abortion facility may employ Licensed 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.</u></p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <p>(i) rewrite this section in the active voice and break paragraphs with</p> |
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|     |     |   | <p>multiple requirements into subparts;</p> <ul style="list-style-type: none"> <li>(ii) clarify who is responsible for defining clinical privileges;</li> <li>(iii) permit facilities to use a nurse practitioner or physician assistant in lieu of a physician for the purposes of the proposed subsection B; and</li> <li>(iv) exempt facilities that only medication abortions from inapplicable requirements.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) reduce confusion about who has the responsibility for defining clinical privileges;</li> <li>(iii) a nurse practitioner or a physician assistant is capable of performing the tasks listed in the proposed subsection B; and</li> <li>(iv) facilities that only perform medication abortions do not use anesthesia, so requirements related to anesthesia are inapplicable.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, clarity regarding clinical privileges, increased flexibility for abortion facilities in staffing, and reduced regulatory burden for eligible facilities.</p> |
| 200 | N/A | <p><b>12VAC5-412-200. Patients' rights.</b></p> <p>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.</p> <p>B. The abortion facility shall establish and maintain complaint</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-200. Patients' rights.</b></p> <p>A. <del>Each</del> An abortion facility shall establish a protocol relating to the rights and responsibilities of patients <del>consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol that</del> shall include a process reasonably designed to inform patients of their rights and responsibilities, <del>in a language or manner they understand. Patients shall be given a copy of their</del></p>   |

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|  | <p>handling procedures which specify the:</p> <ol style="list-style-type: none"> <li>1. System for logging receipt, investigation, and resolution of complaints; and</li> <li>2. Format of the written record of the findings of each complaint investigated.</li> </ol> <p>C. The abortion facility shall designate staff responsible for complaint resolution, including:</p> <ol style="list-style-type: none"> <li>1. Complaint intake, including acknowledgment of complaints;</li> <li>2. Investigation of the complaint;</li> <li>3. Review of the investigation findings and resolution for the complaint; and</li> <li>4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</li> </ol> <p>D. Any patient seeking an abortion shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service.</p> <p>E. The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> <li>1. Abortion facility contact person; and</li> <li>2. OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.</li> </ol> <p>F. The abortion facility shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained for no less than three years.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>rights and responsibilities upon admission.</del></p> <p>B. <del>The</del> <u>An</u> abortion facility shall establish and maintain complaint handling procedures <del>which that</del> specify the:</p> <ol style="list-style-type: none"> <li>1. System for logging receipt, investigation, and resolution of complaints; and</li> <li>2. Format of the written record of the findings of each complaint investigated.</li> </ol> <p>C. <del>The</del> <u>An</u> abortion facility shall designate staff responsible for complaint resolution, including:</p> <ol style="list-style-type: none"> <li>1. Complaint intake, including acknowledgment of complaints;</li> <li>2. Investigation of the complaint;</li> <li>3. Review of the investigation findings and resolution for the complaint; and</li> <li>4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</li> </ol> <p>D. <u>At the time of admission to service, an abortion facility shall provide to Any a patient in a language or manner the patient understands seeking an abortion shall be given:</u></p> <ol style="list-style-type: none"> <li>1. <u>A copy of patient rights and responsibilities; and</u></li> <li>2. <u>a A copy of the complaint procedures, in a language or manner she understands, at the time of admission to service;</u></li> </ol> <p>E. <del>The</del> abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> <li>1. <del>Abortion</del> <u>3. The name, mailing address, and telephone number of the abortion facility contact person; and</u></li> <li>2. <del>4. The mailing address and telephone number of the OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility</del></li> </ol> |
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|     |     |   | <p>shall display a copy of this information in a conspicuous place <u>in its abortion facility</u>.</p> <p><del>F.B. The An</del> abortion facility shall maintain <u>documentation records</u> of all complaints received and the status of each complaint from date of receipt through its final resolution. <del>Records shall be maintained for, for a period of</del> no less than three years <u>after a complaint's final resolution</u>.</p> <p>Statutory Authority<br/> <u>§§ 32.1-12, 32.1-127, 32.1-137.01, and 32.1-137.05</u> of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) clarify the retention period for complaint documentation.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) the section failed to identify what event triggered the start of the three year retention period.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity regarding complaint documentation retention.</p> |
| 210 | N/A | <p>Part III<br/>                 Quality Management and Infection Prevention<br/> <b>12VAC5-412-210. Quality management.</b><br/>                 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</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p>Part III<br/>                 Quality Management and Infection Prevention<br/> <b>12VAC5-412-210. Quality management.</b><br/> <del>A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or</del></p>  |

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|  | <p>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.</p> <p>B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:</p> <ol style="list-style-type: none"> <li>1. Staffing patterns and performance;</li> <li>2. Supervision appropriate to the level of service;</li> <li>3. Patient records;</li> <li>4. Patient satisfaction;</li> <li>5. Complaint resolution;</li> <li>6. Infections, complications, and other adverse events; and</li> <li>7. Staff concerns regarding patient care.</li> </ol> <p>C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:</p> <ol style="list-style-type: none"> <li>1. A physician;</li> <li>2. A nonphysician health care practitioner;</li> <li>3. A member of the administrative staff; and</li> <li>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.</li> </ol> <p>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.</p> <p>D. Measures shall be implemented to resolve problems or concerns that have been identified.</p> <p>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</p> | <p><del>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.</del></p> <p><del>B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences</del></p> <p><u>A. An 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, and that identifies unacceptable or unexpected trends or occurrences that shall include evaluation of:</u></p> <ol style="list-style-type: none"> <li>1. Staffing patterns and performance;</li> <li>2. Supervision appropriate to the level of service;</li> <li>3. Patient records;</li> <li>4. Patient satisfaction;</li> <li>5. Complaint resolution;</li> <li>6. Infections, complications, and other adverse events; and</li> <li>7. Staff concerns regarding patient care.</li> </ol> <p><u>The program shall include process design, data collection/analysis, assessment and improvement, and evaluation.</u></p> <p><del>C.B. An abortion facility shall establish</del> <u>A a quality improvement committee responsible for the oversight and supervision of the program shall be established and.</u></p> <p><u>C. The quality improvement committee shall</u> at a minimum <del>shall</del> consist of:</p> <ol style="list-style-type: none"> <li>1. A physician <u>or independent healthcare practitioner;</u></li> <li>2. A nonphysician health care practitioner;</li> <li>3. A member of the administrative staff; and</li> <li>4. <del>An individual with demonstrated ability to</del></li> </ol> |
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|  | <p>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.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><del>represent the rights and concerns of patients. The individual</del> <u>A patient advocate, who may be a member of the abortion facility's staff.</u></p> <p><del>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.</del></p> <p><del>D. Measures shall be implemented to resolve problems or concerns that have been identified.</del></p> <p><u>E-D. The quality improvement committee shall report to the governing body:</u></p> <p><u>1. At least annually the Results results of the quality improvement program shall be reported to the licensee, which at least annually and shall include the deficiencies it has identified and its recommendations for corrections and improvements; and The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented.</u></p> <p><u>2. Immediately in writing the Identified deficiencies it has identified that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.</u></p> <p><u>E. The administrator shall implement corrective action for any deficiencies identified by the quality improvement committee and shall document in writing all corrective actions.</u></p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <p>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</p> |
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|     |     |  | <p>(ii) allow an independent healthcare practitioner to serve on the quality improvement committee in place of a physician; and</p> <p>(iii) clarify the regulatory responsibilities on the licensee, the quality improvement committee, and the administrator.</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) for the purposes of the quality improvement committee, physicians and independent healthcare practitioners are equivalent; and</p> <p>(iii) since governing bodies are responsible for overall management and administrators for daily management, reports from the quality improvement committee should go to the governing body and corrective action should be placed on administrators.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and clarity regarding on whom regulatory requirements are placed.</p> |
| 220 | N/A | <p><b>12VAC5-412-220. Infection prevention.</b></p> <p>A. The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-220. Infection prevention.</b></p> <p>A. <del>The An</del> abortion facility shall have an infection prevention plan that encompasses the <del>entire</del> abortion facility, <del>abortions</del>, and <del>all</del> services <del>provided</del> related to the provision of an <del>abortion</del>, 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</p>   |

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|  | <p>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.</p> <p>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.</p> <p>3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review.</p> <p>B. Written infection prevention policies and procedures shall include, but not be limited to:</p> <ol style="list-style-type: none"> <li>1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility;</li> <li>2. Training of all personnel in proper infection prevention techniques;</li> <li>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</li> <li>4. Use of standard precautions;</li> <li>5. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety and Health Administration;</li> <li>6. Use of personal protective equipment;</li> <li>7. Use of safe injection practices;</li> </ol> | <p><del>in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. <u>An abortion facility shall ensure at least one member of the clinical staff receives training in basic infection prevention.</u></del></p> <p><del>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.</del></p> <p><del>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.</del></p> <p><del>3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review.</del></p> <p><del>B. Written infection prevention policies and procedures shall include, but not be limited to:</del></p> <ol style="list-style-type: none"> <li><del>1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility;</del></li> <li><del>2. Training of all personnel in proper infection prevention techniques;</del></li> <li><del>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</del></li> <li><del>4. Use of standard precautions;</del></li> <li><del>5. Compliance with bloodborne pathogen</del></li> </ol> |
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|  |  | <p>8. Plans for annual retraining of all personnel in infection prevention methods;</p> <p>9. Procedures for monitoring staff adherence to recommended infection prevention practices; and</p> <p>10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.</p> <p>C. Written policies and procedures for the management of the abortion facility, equipment, and supplies shall address the following:</p> <ol style="list-style-type: none"> <li>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);</li> <li>2. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal, storage, and transport of equipment and supplies;</li> <li>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);</li> <li>4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies, and equipment;</li> <li>5. Procedures for handling/temporary storage/transport of soiled linens;</li> <li>6. Procedures for handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;</li> <li>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</li> </ol> | <p><del>requirements of the U.S. Occupational Safety and Health Administration;</del></p> <p><del>6. Use of personal protective equipment;</del></p> <p><del>7. Use of safe injection practices;</del></p> <p><del>8. Plans for annual retraining of all personnel in infection prevention methods;</del></p> <p><del>9. Procedures for monitoring staff adherence to recommended infection prevention practices; and</del></p> <p><del>10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.</del></p> <p><del>C. Written policies and procedures for the management of the abortion facility, equipment, and supplies shall address the following:</del></p> <ol style="list-style-type: none"> <li><del>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);</del></li> <li><del>2. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal, storage, and transport of equipment and supplies;</del></li> <li><del>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);</del></li> <li><del>4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies, and equipment;</del></li> <li><del>5. Procedures for handling/temporary storage/transport of soiled linens;</del></li> <li><del>6. Procedures for handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;</del></li> </ol> |
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|  |  | <p>ion 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;</p> <p>8. Procedures for appropriate disposal of nonreusable equipment;</p> <p>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</p> <p>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</p> <p>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</p> <p>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.</p> <p>D. The abortion facility shall have an employee health program that includes:</p> <ol style="list-style-type: none"> <li>1. Access to recommended vaccines;</li> <li>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;</li> <li>3. An exposure control plan for bloodborne pathogens;</li> <li>4. Documentation of screening and immunizations offered/received by employees in accordance with</li> </ol> | <p><del>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;</del></p> <p><del>8. Procedures for appropriate disposal of nonreusable equipment;</del></p> <p><del>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</del></p> <p><del>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</del></p> <p><del>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</del></p> <p><del>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.</del></p> <p><u>D.B.</u> The <u>An</u> abortion facility shall have an employee health program that includes:</p> <ol style="list-style-type: none"> <li>1. Access to <u>or referrals for</u> recommended vaccines;</li> <li>2. Procedures for <u>assuring ensuring</u> that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other</li> </ol> |
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|  |  | <p>statute, regulation, or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; and</p> <p>5. Compliance with requirements of the U.S. Occupational Safety and Health Administration for reporting of workplace-associated injuries or exposure to infection.</p> <p>E. The abortion facility shall develop, implement, and maintain policies and procedures for the following patient education, follow up, and reporting activities:</p> <ol style="list-style-type: none"> <li>1. A procedure for surveillance, documentation, and tracking of reported infections; and</li> <li>2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.</li> </ol> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>personnel employees</del> or patients;</p> <p>3. An exposure control plan for bloodborne pathogens;</p> <p>4. Documentation of screening and immunizations <del>offered/received</del> <u>offered or received</u> by employees in accordance with statute, regulation, or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; and</p> <p>5. Compliance with requirements of the U.S. Occupational Safety and Health Administration for reporting of workplace-associated injuries or exposure to infection.</p> <p><del>E. The abortion facility shall develop, implement, and maintain policies and procedures for the following patient education, follow up, and reporting activities:</del></p> <ol style="list-style-type: none"> <li><del>1. A procedure for surveillance, documentation, and tracking of reported infections; and</del></li> <li><del>2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.</del></li> </ol> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is:</p> <ol style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) remove language regarding infection prevention policies and procedures.</li> </ol> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> |
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|     |     |  | <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</p> <p>(ii) language about infection prevention policies and procedures has been moved to section 160, which is entitled "Policies and procedures."</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p>  |
| 230 | N/A | <p>Part IV<br/>Patient Care Management<br/><b>12VAC5-412-230. Patient services; patient counseling.</b></p> <p>A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider.</p> <p>B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</p> <p>C. A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant to the provisions of § 18.2-76 of the Code of Virginia.</p> <p>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on site for emergency care.</p> <p>E. The abortion facility shall offer each patient seeking an abortion, in a language or manner she understands, appropriate counseling and instruction in the abortion procedure and shall</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p>Part IV<br/>Patient Care Management<br/><b>12VAC5-412-230. Patient services; patient counseling.</b></p> <p><del>A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy meaning 13 weeks and 6 days after last menstrual period or based on an appropriate clinical estimate by a licensed health care provider.</del></p> <p><del>B. No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian, or other authorized person. If the unemancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</del></p> <p><del>C-B. An abortion facility may not permit A physician shall not perform an the performance of an abortion in its abortion facility without unless a health care practitioner who is permitted by law to perform an abortion has first obtaining obtained</del> the informed written consent of:</p> <p><u>1. the An adult patient or emancipated minor pursuant to the provisions of § 18.2-76 of the Code of Virginia; or</u></p> |

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|  |  | <p>develop, implement, and maintain policies and procedures for the provision of or referral for family planning services to its patients.</p> <p>F. There shall be an organized discharge planning process that includes an assessment of a patient's safety for discharge and discharge instructions for patients to include instructions to call or return if signs of infection develop.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><u>2. An unemancipated minor and authorized person as defined by § 16.1-241 W of the Code of Virginia; however, the consent of an authorized person is not required if the unemancipated minor has provided to the health care practitioner a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia.</u></p> <p><del>D. When abortions are being performed, a staff member currently certified to perform cardiopulmonary resuscitation shall be available on-site for emergency care.</del></p> <p><del>E.C. The An abortion facility shall offer each patient seeking an abortion, in a language or manner she the patient understands, appropriate counseling and instruction in the abortion procedure and shall develop, implement, and maintain policies and procedures for the provision of or referral for family planning services to its patients.</del></p> <p><del>F.D. There shall be An abortion facility shall have an organized discharge planning process for its abortion facility that includes an assessment of a patient's safety for discharge and discharge instructions for patients. An abortion facility only provides medication abortions shall be exempt from this subsection.</del></p> <p><u>E. An abortion facility shall provide patients with to include instructions to call or return if signs of infection or other complications develop.</u></p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) rewrite this section so as to avoid scope of practice conflicts with</li> </ul> |
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|     |     |   | <p>health profession regulations; and</p> <p>(iii) exempt facilities that only medication abortions from inapplicable requirements.</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) clarify on whom the regulatory requirements are placed; and</p> <p>(iii) facilities that only perform medication abortions do not need discharge planning.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, reduced likelihood of conflicts with other agencies' regulations, and reduced regulatory burden for eligible facilities.</p>  |
| 240 | N/A | <p><b>12VAC5-412-240. Medical testing and laboratory services.</b></p> <p>A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed for each patient.</p> <ol style="list-style-type: none"> <li>1. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.</li> <li>2. Use of any additional medical testing shall be based on an assessment of patient risk.</li> <li>3. The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to</li> </ol> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-240. Medical testing and laboratory services.</b></p> <p>A. Prior to the initiation of any abortion, <u>an abortion facility shall complete</u> a medical history and physical examination, including a <del>confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed</del> for each patient.:</p> <ol style="list-style-type: none"> <li>1. <del>Medical testing shall include</del> <u>Use of a recognized method approved by the U.S. Food and Drug Administration to confirm pregnancy; and</u></li> <li>2. <del>determination</del> <u>Determination or and</u> documentation of Rh factor.;</li> <li>2-3. <del>Use of any additional medical testing shall be based on an assessment of patient risk.</del></li> <li>3. <del>The abortion facility shall develop, implement, and maintain policies and procedures for offering screening of sexually</del></li> </ol> |

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|  | <p>clinics that provide such testing.</p> <p>4. A written report of each laboratory test and examination shall be a part of the patient's record.</p> <p>B. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) (42 CFR Part 493).</p> <ol style="list-style-type: none"> <li>1. Facilities for collecting specimens shall be available on site.</li> <li>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.</li> <li>3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.</li> </ol> <p>C. The abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy. The facility shall track and log any specimens sent for further pathologic examination.</p> <p>D. All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to clinics that provide such testing.</del></p> <p>4. A written report of each laboratory test and examination performed shall be a part of the patient's record.</p> <p>B. <u>An abortion facility shall provide Laboratory laboratory services and facilities for collecting specimens shall be provided</u> on site or through arrangement <u>a contract</u> with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 <del>(CLIA-88)</del> <u>(CLIA '88)</u> (42 CFR Part 493).</p> <ol style="list-style-type: none"> <li><del>1. Facilities for collecting specimens shall be available on site.</del></li> <li><del>2.1. If laboratory services are provided on site they shall be directed by a A</del> <u>person who qualifies as a director under CLIA-88 CLIA '88 and shall be direct on site laboratory services and ensure that all laboratory services are performed in compliance with CLIA-88 CLIA '88 standards.</u></li> <li><del>3.2. An abortion facility shall monitor</del> <u>All all</u> laboratory supplies <del>shall be monitored</del> for expiration dates, if applicable, and <del>disposed</del> <u>dispose of expired laboratory supplies properly in accordance with the manufacturer's directions for use.</u></li> </ol> <p><del>C. The abortion facility shall have policies and procedures for evaluation of all tissues removed during the abortion and for reevaluation of the patient in the event the evaluation of tissue is insufficient to confirm termination of the pregnancy. The facility shall track and log any specimens sent for further pathologic examination.</del></p> |
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|     |     |  | <p><u>D.C. An abortion facility shall manage All all tissues removed resulting from the an abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120). An abortion facility that provides only medication abortions shall be exempt from this subsection.</u></p> <p>Statutory Authority<br/> <u>§§ 32.1-12 and 32.1-127</u> of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) clarify proper disposal of expired laboratory supplies; and</li> <li>(iii) exempt facilities that only medication abortions from inapplicable requirements.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) an objective standard (i.e. manufacturer directions) is easier for licensees to comply with; and</li> <li>(iii) facilities that only perform medication abortions do not have tissues removed from a medication abortion.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, improved clarity on what the regulatory requirements are, and reduced regulatory burden for eligible facilities.</p> |
| 250 | N/A | <p><b>12VAC5-412-250. Anesthesia service.</b></p> <p>A. The anesthesia service shall comply with the office-based anesthesia provisions of the Regulations Governing the Practice of</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p>   |

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|  | <p>Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.).</p> <p>B. The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia who is certified in advanced resuscitative techniques and has met the continuing education requirements.</p> <p>C. When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration. The administration of sedation and monitoring of the patient shall be documented in the patient's medical record.</p> <p>D. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 B:</p> <ol style="list-style-type: none"> <li>1. Appropriate equipment to manage airways;</li> <li>2. Drugs and equipment to treat shock and anaphylactic reactions;</li> <li>3. Precordial stethoscope;</li> <li>4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;</li> <li>5. Continuous electrocardiograph;</li> <li>6. Devices for measuring blood pressure, heart rate, and respiratory rate;</li> <li>7. Defibrillator; and</li> <li>8. Accepted method of identifying and preventing the interchangeability of gases.</li> </ol> <p>E. Elective general anesthesia shall not be used.</p> <p>F. If deep sedation or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until the patient meets the discharge criteria.</p> | <p><b>12VAC5-412-250. Anesthesia service.</b></p> <p>A. <u>An abortion facility shall ensure that:</u></p> <ol style="list-style-type: none"> <li>1. <u>The anesthesia service shall comply with the office-based anesthesia provisions of Part VIII (18VAC85-20-310 et seq.) of the Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310 et seq.);</u></li> <li>2. <u>The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia who is certified in advanced resuscitative techniques and has met the continuing education requirements directs and supervises the anesthesia service;</u></li> <li>3. <u>When If moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor monitors the patient according to procedures consistent with such administration. The administration of sedation and monitoring of the patient shall be documented in the patient's medical record;</u></li> <li>4. <u>The licensed health care practitioner who administered the moderate or conscious sedation documents the administration of sedation and monitoring of the patient in the patient's medical record;</u></li> <li>5. <u>If deep sedation or a major conductive block is administered or if general anesthesia is administered in an emergency situation, the licensed health care practitioner who administered the anesthesia service remains present and available in the abortion</u></li> </ol> |
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|  | <p>G. In addition to the requirements of subsection D of this section, an abortion facility administering deep sedation or a major conductive block, or administering general anesthesia in an emergent situation, shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 C:</p> <ol style="list-style-type: none"> <li>1. Drugs to treat malignant hyperthermia, when triggering agents are used;</li> <li>2. Peripheral nerve stimulator, if a muscle relaxant is used; and</li> <li>3. If using an anesthesia machine, the following shall be included:             <ol style="list-style-type: none"> <li>a. End-tidal carbon dioxide monitor (capnograph);</li> <li>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;</li> <li>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;</li> <li>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;</li> <li>e. Pressure-compensated anesthesia vaporizers, designed to administer a constant nonpulsatile output, which shall not be placed in the circuit</li> </ol> </li> </ol> | <p><u>facility to monitor the patient until the patient meets the discharge criteria; and</u></p> <p><u>6. The licensed health care practitioner who administered the anesthesia service permits a patient to be discharged from anesthesia care if the patient has met specific physician-defined criteria that the health care practitioner has documented in the patient's medical record.</u></p> <p><u>An abortion facility that provides only medication abortions shall be exempt from the provisions of this subsection.</u></p> <p><del>D.B.</del> <u>An abortion facility administering that administers moderate sedation/conscious sedation or conscious sedation shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 B:</u></p> <ol style="list-style-type: none"> <li><del>1. Appropriate equipment to manage airways;</del></li> <li><del>2. Drugs and equipment to treat shock and anaphylactic reactions;</del></li> <li><del>3. Precordial stethoscope;</del></li> <li><del>4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;</del></li> <li><del>5. Continuous electrocardiograph;</del></li> <li><del>6. Devices for measuring blood pressure, heart rate, and respiratory rate;</del></li> <li><del>7. Defibrillator; and</del></li> <li><del>8. Accepted method of identifying and preventing the interchangeability of gases.</del></li> </ol> <p><del>E.C.</del> <u>An abortion facility shall not use Elective elective general anesthesia shall not be used at its abortion facility.</u></p> <p><del>F.</del> <u>If deep sedation or a major conductive block is administered or if general anesthesia is administered in an emergent situation, the licensed health care practitioner who administers the anesthesia service shall remain present and available in the facility to monitor the patient until</u></p> |
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|  |  | <p>downstream of the oxygen flush valve;</p> <p>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;</p> <p>g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and</p> <p>h. A gas evacuation system.</p> <p>H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria, and those criteria have been documented within the patient's medical record.</p> <p>Statutory Authority<br/>         § 32.1-127 of the Code of Virginia.</p> | <p><del>the patient meets the discharge criteria.</del></p> <p><del>G-D.</del> In addition to the requirements of subsection <del>D B</del> of this section, an abortion facility <del>administering that administers</del> deep sedation or a major conductive block, or <del>administering administers</del> general anesthesia in an emergent situation, shall maintain the following equipment, supplies, and pharmacological agents as required by 18VAC85-20-360 C<del>2</del>:</p> <ol style="list-style-type: none"> <li><del>1. Drugs to treat malignant hyperthermia, when triggering agents are used;</del></li> <li><del>2. Peripheral nerve stimulator, if a muscle relaxant is used; and</del></li> <li><del>3. If using an anesthesia machine, the following shall be included:</del> <ol style="list-style-type: none"> <li><del>a. End-tidal carbon dioxide monitor (capnograph);</del></li> <li><del>b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;</del></li> <li><del>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;</del></li> <li><del>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;</del></li> <li><del>e. Pressure-compensated anesthesia vaporizers, designed to administer a constant</del></li> </ol> </li> </ol> |
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|  |  |  | <p><del>nonpulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;</del><br/> <del>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;</del><br/> <del>g. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and</del><br/> <del>h. A gas evacuation system.</del></p> <p>H. The abortion facility shall develop, implement, and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria, and those criteria have been documented within the patient's medical record.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</li> <li>(ii) remove language that is duplicative of other agencies' regulations;</li> <li>(iii) rewrite this section so as to avoid scope of practice conflicts with</li> </ul> |
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|     |     |   | <p>health profession regulations; and</p> <p>(iv) exempt facilities that only medication abortions from inapplicable requirements.</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) using citations to other agencies' regulations instead of copying regulatory text prevents conflicts between regulatory requirements if the cited section is amended;</p> <p>(iii) clarify on whom the regulatory requirements are placed; and</p> <p>(iv) facilities that only perform medication abortions do not use anesthesia.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, reduced likelihood of conflicts with other agencies' regulations, and reduced regulatory burden for eligible facilities.</p> |
| 260 | N/A | <p><b>12VAC5-412-260. Administration, storage and dispensing of drugs.</b></p> <p>A. Controlled substances, as defined in § 54.1-3401 of the Code of Virginia, shall be stored, administered, and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).</p> <p>B. Drugs, as defined in § 54.1-3401 of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed, or administered by a physician.</p> <p>C. Drugs maintained in the abortion facility for daily administration shall not be expired and shall be</p> | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><b>12VAC5-412-260. Administration, storage and dispensing of drugs. (Repealed.)</b></p> <p><del>A. Controlled substances, as defined in § 54.1-3401 of the Code of Virginia, shall be stored, administered, and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).</del></p> <p><del>B. Drugs, as defined in § 54.1-3401 of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed,</del></p>   |

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|     |     | <p>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.</p> <p>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.).</p> <p>E. Records of all drugs in Schedules I-V received, sold, administered, dispensed, or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Code of Virginia.</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><del>dispensed, or administered by a physician.</del></p> <p><del>C. Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.</del></p> <p><del>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.).</del></p> <p><del>E. Records of all drugs in Schedules I-V received, sold, administered, dispensed, or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Code of Virginia.</del></p> <p><del>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</del></p> <p><b>INTENT:</b> The intent of this proposed change is to remove text that only serves as a citation to other provisions and to eliminate overreaches of the Board's authority.</p> <p><b>RATIONALE:</b> The rationale behind this proposed change is that this section presently cross-references statutory and regulatory provisions, without providing any additional substantive requirements. Additionally, subsection B encroaches on scope of practice for licensed health care practitioners, which is beyond the Board's authority.</p> <p><b>LIKELY IMPACT:</b> There is likely no impact as all the statutory provisions and regulations cited in the existing text would still apply.</p> |
| 270 | N/A | <p><b>12VAC5-412-270. Equipment and supplies.</b><br/>         An abortion facility shall maintain medical equipment and supplies</p>   | <p><b>CHANGE:</b> The Board is proposing the following changes:</p>   |

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|  |  | <p>appropriate and adequate to care for patients based on the level, scope, and intensity of services provided, to include:</p> <ol style="list-style-type: none"> <li>1. A bed or recliner suitable for recovery;</li> <li>2. Oxygen with flow meters and masks or equivalent;</li> <li>3. Mechanical suction;</li> <li>4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways;</li> <li>5. Emergency medications, intravenous fluids, and related supplies and equipment;</li> <li>6. Sterile suturing equipment and supplies;</li> <li>7. Adjustable examination light;</li> <li>8. Containers for soiled linen and waste materials with covers; and</li> <li>9. Refrigerator.</li> </ol> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> | <p><b>12VAC5-412-270. Equipment and supplies; emergencies.</b></p> <p><u>A. An abortion facility shall maintain medical equipment, and supplies, and drugs appropriate and adequate to care for patients and to manage potential emergencies based on the level, scope, and intensity of services provided, to include:</u></p> <ol style="list-style-type: none"> <li>1. A bed or recliner suitable for recovery;</li> <li>2. Oxygen with flow meters and masks or equivalent;</li> <li>3. Mechanical suction;</li> <li>4. Resuscitation equipment to include, <del>as a minimum,</del> resuscitation bags and oral airways;</li> <li>5. Emergency medications, intravenous fluids, and related supplies and equipment;</li> <li>6. Sterile suturing equipment and supplies;</li> <li>7. Adjustable examination light;</li> <li>8. Containers for soiled linen and waste materials with covers; and</li> <li>9. Refrigerator.</li> </ol> <p><u>An abortion facility that provides only medication abortions shall be exempt from subdivisions 2, 3, 6, and 7 of this subsection.</u></p> <p><u>B. An abortion facility shall employ or contract with a physician to determine the appropriate and adequate medical equipment, supplies, and drugs, consistent with the 2010 edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, as amended in 2015, 2017, and 2018.</u></p> <p><u>C. 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.</u></p> <p><u>D. If emergency transfer of a patient is necessary, an abortion facility shall ensure the responsible licensed health care practitioner provides direct communication to the</u></p> |
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|  |  |  | <p><u>appropriate receiving facility staff regarding the status of the patient, the procedure details, and the suspected complication.</u></p> <p><u>E. An abortion facility shall provide all patients of its abortion facility with contact information for a representative of the abortion facility so that an emergency department physician or treating provider may make contact with the abortion facility if complications arise.</u></p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice;</li> <li>(ii) consolidate relevant sections of the regulation;</li> <li>(iii) update references to documents incorporated by reference; and</li> <li>(iv) exempt facilities that only medication abortions from inapplicable requirements.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) it will be easier for licensees to locate regulatory requirements if equipment and supplies for both emergent and non-emergent situations are in a single section;</li> <li>(iii) ensure current industry guidelines are being used; and</li> <li>(iv) facilities that only perform medication abortions do not have to buy or maintain inapplicable equipment and supplies.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and reduced regulatory burden for eligible facilities.</p> |
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| <p>280</p> | <p>N/A</p> | <p><b>12VAC5-412-280. Emergency equipment and supplies.</b><br/>                 An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions:</p> <ol style="list-style-type: none"> <li>1. Cardiopulmonary arrest;</li> <li>2. Seizure;</li> <li>3. Respiratory distress;</li> <li>4. Allergic reaction;</li> <li>5. Narcotic toxicity;</li> <li>6. Hypovolemic shock; and</li> <li>7. Vasovagal shock.</li> </ol> <p>Statutory Authority<br/>                 § 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><del><b>12VAC5-412-280. Emergency equipment and supplies. (Repealed.)</b></del><br/> <del>An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such medical equipment, supplies, and drugs shall be determined by the physician and shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions:</del></p> <ol style="list-style-type: none"> <li><del>1. Cardiopulmonary arrest;</del></li> <li><del>2. Seizure;</del></li> <li><del>3. Respiratory distress;</del></li> <li><del>4. Allergic reaction;</del></li> <li><del>5. Narcotic toxicity;</del></li> <li><del>6. Hypovolemic shock; and</del></li> <li><del>7. Vasovagal shock.</del></li> </ol> <p><del>Statutory Authority<br/>                 § 32.1-127 of the Code of Virginia.</del></p> <p><b>INTENT:</b> The intent of this proposed change is to consolidate relevant sections of the regulation and to remove the enumerated list of conditions requiring drugs to be on hand. This requirement, without the enumerated list of conditions, has been relocated to the proposed 12VAC5-412-270(B).</p> <p><b>RATIONALE:</b> The rationale behind this proposed change is that this section already directs the licensee to “maintain...drugs appropriate to manage potential emergencies based on the level, scope, and intensity of services provided.” To then enumerate a list of conditions for which the licensee must have responsive drugs counters the self-determinative intent of the prior sentence.</p> |
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|     |     |  | <p><b>LIKELY IMPACT:</b> The likely impact of this proposed change is licensees increased flexibility in determining what potential emergencies they should be responsive to.</p>  |
| 290 | N/A | <p><b>12VAC5-412-290. Emergency services.</b></p> <p>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.</p> <p>B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.</p> <p>C. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the appropriate receiving facility staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><b>12VAC5-412-290. Emergency services. (Repealed.)</b></p> <p><del>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.</del></p> <p><del>B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.</del></p> <p><del>C. When emergency transfer is necessary, the responsible physician at the abortion facility must provide direct communication to the appropriate receiving facility staff regarding the status of the patient, the procedure details, and the suspected complication. All patients must be provided with contact information for a representative of the abortion facility, so that an emergency department physician or treating provider may make contact with a provider of the facility if late complications arise.</del></p> <p><del>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</del></p> <p><b>INTENT:</b> The intent of this proposed change is to consolidate relevant sections of the regulation and to remove duplicative information. The existing subsection B has been moved to the proposed 12VAC5-412-</p> |

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|     |     |   | <p>270(C). The existing subsection C has been moved to the proposed 12VAC5-412-270(D) and (E).</p> <p><b>RATIONALE:</b> The rationale behind this proposed change is that subsection A is largely duplicative of requirements already found in 12VAC5-412-270(A) and (B). Because there is already section that discusses equipment, supplies, and drugs, this repeal consolidates relevant sections of the regulation so licensees can find more easily locate these requirements.</p> <p><b>LIKELY IMPACT:</b> There is likely no impact as this repeal removes duplicative material and relocates the nonduplicative material to 12VAC5-412-170.</p>  |
| 300 | N/A | <p>Part V<br/>Support Services - Health Information Records and Reports<br/><b>12VAC5-412-300. Health information records.</b><br/>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:</p> <ol style="list-style-type: none"> <li>1. Patient identification;</li> <li>2. Admitting information, including patient history and physical examination;</li> <li>3. Signed consent;</li> <li>4. Confirmation of pregnancy;</li> <li>5. Procedure report to include:             <ol style="list-style-type: none"> <li>a. Physician orders;</li> <li>b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;</li> <li>c. Anesthesia record;</li> <li>d. Operative record;</li> <li>e. Surgical medication and medical treatments;</li> <li>f. Recovery room notes;</li> <li>g. Physicians' and nurses' progress notes;</li> <li>h. Condition at time of discharge;</li> </ol> </li> </ol> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p>Part V<br/><del>Support Services - Health Information</del> <u>Medical</u> Records and Reports<br/><b>12VAC5-412-300. Health information <u>Medical</u> records.</b><br/><u>A. An abortion facility shall maintain</u> <del>An an</del> accurate and complete <u>clinical <u>medical</u></u> record <del>or chart shall be maintained</del> on each patient. The <u>medical record or chart</u> shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. <u>If medically indicated, it shall include,</u> <del>it shall include,</del> but <del>not be limited to the following:</del></p> <ol style="list-style-type: none"> <li>1. Patient identification;</li> <li>2. Admitting information, including patient history and physical examination;</li> <li>3. Signed consent;</li> <li>4. Confirmation of pregnancy;</li> <li>5. Procedure report to include:             <ol style="list-style-type: none"> <li>a. Physician orders;</li> <li>b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;</li> <li>c. Anesthesia record;</li> <li>d. Operative record;</li> </ol> </li> </ol> |



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|  |  | <p>i. Patient instructions (preoperative and postoperative); and<br/> j. Names of referral physicians or agencies; and<br/> 6. Any other information required by law to be maintained in the health information record.</p> <p>Statutory Authority<br/> § 32.1-127 of the Code of Virginia.</p> | <p>e. Surgical medication and medical treatments;<br/> f. Recovery room notes;<br/> g. Physicians' and nurses' progress notes;<br/> h. Condition at time of discharge;<br/> i. Patient instructions, <del>(preoperative and postoperative)</del> <u>both preoperative and postoperative</u>; and<br/> j. Names of referral physicians or agencies; and<br/> 6. Any other information required by law to be maintained in the <del>health information</del> <u>medical</u> record.</p> <p><u>B. An abortion facility shall provide for the safe storage of medical records, or accurate and legible reproductions, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) (42 USC § 1320d et seq.).</u></p> <p>Statutory Authority<br/> §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:<br/> (i) rewrite this section in the active voice;<br/> (ii) restore "If medically indicated" to the text; and<br/> (iii) consolidate relevant sections of the regulation.</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:<br/> (i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>;<br/> (ii) if something is not medically indicated, requiring its inclusion in the medical record is unnecessary; and<br/> (iii) it will be easier for licensees to locate regulatory requirements if medical records requirements are in a single section.</p> |
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|     |     |  | <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and reduced regulatory burden for eligible facilities.</p>  |
| 310 | N/A | <p><b>12VAC5-412-310. Records storage.</b><br/>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.).</p> <p>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>  | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><b>12VAC5-412-310. Records storage. (Repealed.)</b><br/><del>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.).</del></p> <p><del>Statutory Authority<br/>§§ 32.1-12 and 32.1-127 of the Code of Virginia.</del></p> <p><b>INTENT:</b> The intent of this proposed change is to consolidate relevant sections of the regulation.</p> <p><b>RATIONALE:</b> The rationale of this proposed change is that due to the brevity of this requirement, having an entire section devoted to a single sentence requirement is unnecessary. This requirement has been relocated to the proposed 12VAC5-412-310(B).</p> <p><b>LIKELY IMPACT:</b> There is likely no impact as this requirement has been moved to another section and has not been eliminated.</p> |
| 320 | N/A | <p><b>12VAC5-412-320. Required reporting.</b><br/>A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120).<br/>B. The abortion facility shall report the following events to OLC:<br/>1. Any patient, staff, or visitor death;<br/>2. Any serious injury to a patient;<br/>3. Medication errors that necessitate a clinical</p> | <p><b>CHANGE:</b> The Board is proposing the following change:</p> <p><b>12VAC5-412-320. Required reporting.</b><br/>A. <u>Abortion facilities</u> An abortion facility shall comply with <u>and ensure all persons under its direction or control comply with</u> the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120).<br/>B. <u>The An</u> abortion facility shall report <u>the following events</u> to OLC:</p>  |

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|  | <p>intervention other than monitoring;</p> <p>4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and</p> <p>5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629).</p> <p>C. Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the:</p> <ol style="list-style-type: none"> <li>1. Abortion facility name;</li> <li>2. Type and circumstance of the event being reported;</li> <li>3. Date of the event; and</li> <li>4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.</li> </ol> <p>D. Compliance with this section does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law-enforcement or professional regulatory agencies.</p> <p>E. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC, except as required or permitted by law.</p> <p>F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under § 63.2-1509 of the Code of Virginia comply with the reporting requirements of § 63.2-1509 of the Code of Virginia.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>1. Any patient, staff, Any staff or visitor death occurring on the premises of the abortion facility;</del></p> <p><del>2. Any patient death;</del></p> <p><del>3. Any serious injury to a patient that requires medical care beyond its capabilities;</del></p> <p><del>3-4. Medication errors that necessitate a clinical intervention other than monitoring;</del></p> <p><del>4-5. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds its premises; and.</del></p> <p><del>5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-629).</del></p> <p>C. <u>An abortion facility shall provide Notification notification</u> of the events listed in subsection B of this section <del>shall be required within no more than 24 hours of</del> <u>after an event's</u> occurrence. Each notice shall contain the:</p> <ol style="list-style-type: none"> <li>1. Abortion <del>facility</del> <u>facility's</u> name;</li> <li>2. Type and circumstance of the event being reported;</li> <li>3. Date of the event; and</li> <li>4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.</li> </ol> <p>D. Compliance with this section does not relieve <del>the an</del> <u>an</u> abortion facility from complying with any other applicable reporting or notification requirements, <del>such as those relating to law-enforcement or professional regulatory agencies.</del></p> <p>E. <u>The OLC shall maintain as confidential any Records records</u> that are confidential under federal or state law <del>shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC</del></p> |
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|  |  |  | <p><u>disclose confidential records</u>, except as required or permitted by law.</p> <p>F. <del>Abortion facilities</del> <u>An abortion facility</u> shall ensure that employees <u>who are</u> mandated to report suspected child abuse or neglect <del>under § 63.2-1509 of the Code of Virginia</del> <u>or to report suspected abuse, neglect, or exploitation of adults</u> comply with the reporting requirements of § 63.2-1509 <u>or of § 63.2-1606</u> of the Code of Virginia.</p> <p>Statutory Authority<br/>         §§ <u>32.1-12</u> and <u>32.1-127</u> of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice;</li> <li>(ii) clarify what events must be reported to the OLC; and</li> <li>(iii) include suspected abuse, neglect, or exploitation of adults in subsection F.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</li> <li>(ii) specificity about what qualifies as a reportable event is reduces confusion and inadvertent noncompliance; and</li> <li>(iii) mandated reporters of suspected child abuse or neglect are often also mandated reporters of suspected abuse, neglect, or exploitation of adults.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section, reduced licensee confusion, and increased awareness by mandated reporters to report of adult abuse, neglect or exploitation.</p> |
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| <p>330</p> | <p>N/A</p> | <p>Part VI<br/>Functional Safety and Maintenance<br/><b>12VAC5-412-330. Abortion facility security and safety.</b><br/>The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to:<br/>1. Abortion facility security;<br/>2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and<br/>3. Provisions for disseminating safety related information to employees and users of the abortion facility.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><b>12VAC5-412-330. Abortion facility security and safety. (Repealed.)</b><br/><del>The abortion facility shall develop, implement, and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to:</del><br/><del>1. Abortion facility security;</del><br/><del>2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies, and services; and</del><br/><del>3. Provisions for disseminating safety related information to employees and users of the abortion facility.</del></p> <p>Statutory Authority<br/><del>§ 32.1-127 of the Code of Virginia.</del></p> <p><b>INTENT:</b> The intent of this proposed change is to consolidate relevant sections of the regulation.</p> <p><b>RATIONALE:</b> The rationale behind this proposed change is that due to there being an existing section entitled “Policies and procedures,” locating these requirements pertaining to additional policies and procedures in a separate section that occurs much later in the regulation is confusing to licensees. This requirement has been relocated to the proposed 12VAC5-412-160(D).</p> <p><b>LIKELY IMPACT:</b> There is likely no impact as this requirement has been moved to another section and has not been eliminated.</p> |
| <p>340</p> | <p>N/A</p> | <p><b>12VAC5-412-340. Disaster preparedness.</b><br/>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</p>   | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-340. Disaster preparedness.</b><br/><del>A. Each abortion facility shall develop, implement, and maintain policies and procedures to ensure reasonable precautions are taken to</del></p>  |

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|     |     | <p>provisions for evacuation of all occupants in the event of a fire or other disaster.</p> <p>B. An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.</p>  | <p><del>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.</del></p> <p>B.—An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care</p> <p>Statutory Authority<br/>         §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice; and</li> <li>(ii) remove language regarding disaster preparedness policies and procedures.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</li> <li>(ii) language about disaster preparedness policies and procedures has been moved to section 160, which is entitled “Policies and procedures.”.</li> </ul> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section.</p> |
| 350 | N/A | <p><b>12VAC5-412-350. Maintenance.</b></p> <p>A. The abortion facility’s structure, its component parts, and all equipment, such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that will allow sanitization.</p> <p>B. When patient monitoring equipment is utilized, a written</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><b>12VAC5-412-350. Maintenance.</b></p> <p><del>A. The abortion facility’s structure, its component parts, and all equipment, such as elevators, heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with nonlead-based</del></p>   |

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|  | <p>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.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><del>paint, lacquer, varnish, or shellac that will allow sanitization.</del></p> <p><del>B. When For any patient monitoring equipment is utilized at the abortion facility that the manufacturer recommends a preventative maintenance program, an abortion facility shall develop and implement a written preventive maintenance program shall be developed and implemented. that includes:</del></p> <p><del>This equipment shall be checked and/or tested</del> <u>1. Checking and testing equipment</u> in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair-;</p> <p><del>2. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly</del> <u>Thoroughly tested testing equipment</u> for proper operation <u>after any repair or alteration has been made before the equipment is returned to service-; and</u></p> <p><del>3. Maintaining Records records shall be maintained</del> on each piece of equipment to indicate its history of testing and maintenance.</p> <p>Statutory Authority<br/>§§ <del>32.1-12</del> and 32.1-127 of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> <li>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</li> <li>(ii) clarify when a maintenance program is required and by what standard the program is judged.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The</i></li> </ul> |
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|     |     |   | <p><i>Virginia Register of Regulations;</i><br/>and<br/>(ii) an objective standard (i.e. manufacturer directions) is easier for licensees to comply with.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved readability of this section and improved clarity of the regulatory requirements.</p>  |
| 360 | N/A | <p><b>12VAC5-412-360. Firefighting equipment and systems.</b><br/>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.<br/>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.<br/>C. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).</p> | <p><b>CHANGE:</b> The Board is proposing to repeal this section in its entirety:</p> <p><b>12VAC5-412-360. Firefighting equipment and systems. (Repealed.)</b><br/><del>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.<br/>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.<br/>C. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).</del></p> <p><b>INTENT:</b> The intent of this proposed change is to reduce or eliminate duplicative requirements.</p> <p><b>RATIONALE:</b> The rationale behind this proposed change is that compliance with applicable fire and safety laws and regulations would be required under the proposed amendments for 12VAC5-412-370.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is reduced confusion for licensees.</p> |



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| <p>370</p> | <p>N/A</p> | <p>Part VII<br/>Design and Construction<br/><b>12VAC5-412-370. Local and state codes and standards.</b><br/>Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, abortion facilities shall comply with Part 1 and Sections 3.1-1 through 3.1-8 and Section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia.</p> <p>Entities operating as of the effective date of this chapter as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to <u>12VAC5-550-120</u> 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.</p> <p>In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.</p> <p>Statutory Authority<br/>§ 32.1-127 of the Code of Virginia.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p>Part VII<br/>Design and Construction<br/><b>12VAC5-412-370. Local and state codes and standards.</b><br/><u>Abortion facilities All construction of new buildings and additions or major renovations to existing buildings for occupancy as an abortion facility shall comply with all applicable state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, abortion An abortion facilities facility shall comply with Part 1 and Sections 3.1-1 through 3.1-8 and Section 3.7 1.1, 1.3, and 1.4 of Part 3-1 of the 2010 2018 Guidelines for Design and Construction of Health Care Facilities Outpatient Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia.</u></p> <p><del>Entities operating as of the effective date of this chapter as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.</del></p> <p><del>In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.</del></p> <p>Statutory Authority<br/><u>§§ 32.1-12, 32.1-127, and 32.1-127.001</u> of the Code of Virginia.</p> <p><b>INTENT:</b> The intent of these proposed changes is to align building standards with <i>Whole Woman's Health v. Hellerstedt</i>, 136 S. Ct. 2292 (2016)</p> |
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|       |     |  | <p>and Melendez v. Virginia State Board of Health (Case No. CL17-1164).</p> <p><b>RATIONALE:</b> The rationale behind these proposed changes is 12VAC5-412 must comply with the law, including Virginia state court and U.S. Supreme Court decisions.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is reduced regulatory burden for licensees.</p>   |
| FORMS | N/A | <p>Application for Abortion Facility Licensure (eff. 5/03).</p> <p>OSHA Forms for Recording Work-Related Injuries and Illnesses, 2004.</p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><u>Application for Abortion Facility Licensure License Issuance, OLC-3300-F (eff. 5/03) (rev. 8/19).</u></p> <p><u>Application for Abortion Facility License Renewal, OLC-3301-F (eff. 8/19).</u></p> <p><u>Abortion Facility Notification of Change, OLC-3302-F (eff. 8/19).</u></p> <p><del>OSHA Forms for Recording Work-Related Injuries and Illnesses, 2004.</del></p> <p><b>INTENT:</b> The intent of these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) match the requested application information to match the proposed regulatory requirements;</li> <li>(ii) create a standard form for licensees to report changes; and</li> <li>(iii) remove a form that should be submitted to another agency.</li> </ul> <p><b>RATIONALE:</b> The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> <li>(i) ensure OLC is receiving only as much information is necessary for OLC to regulate abortion facilities;</li> <li>(ii) standardize the type of information provided when a reportable change is projected to occur; and</li> <li>(iii) the OSHA form is not used by OLC in administering this regulation.</li> </ul> |

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|      |     |  | <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes are improved consistency between the regulatory requirements and the OLC's forms.</p>   |
| DIBR | N/A | <p>Guidelines for Design and Construction of Health Care Facilities, 2010 Edition, Part 1 and Sections 3.1-1 through 3.1-8 and 3.7 of Part 3, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.</p> <p>Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2015, American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596 (<a href="https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/">https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/</a>)</p> <p><a href="http://www.cdc.gov/std/tg2015/default.htm">Sexually Transmitted Diseases Treatment Guidelines, 2015</a>, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="http://www.cdc.gov/std/tg2015/default.htm">http://www.cdc.gov/std/tg2015/default.htm</a>)</p> <p><a href="http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html">Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care</a>, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html">http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html</a>)</p> <p>Standards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone 1-877-223-2866, email jrcustomerservice@pbd.com</p> <p><a href="https://www.osha-slc.gov/bloodborne-pathogens-standard">Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration</a></p> | <p><b>CHANGE:</b> The Board is proposing the following changes:</p> <p><del>Guidelines for Design and Construction of Health Care Outpatient Facilities, 2010 2018 Edition, Part 1 and Sections 3.1-1 through 3.1-8 and 3.7 1.1, 1.3, and 1.4 of Part 3 1, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.</del></p> <p><del>Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2015, American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596 (<a href="https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/">https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/</a>)</del></p> <p><del><a href="http://www.cdc.gov/std/tg2015/default.htm">Sexually Transmitted Diseases Treatment Guidelines, 2015</a>, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="http://www.cdc.gov/std/tg2015/default.htm">http://www.cdc.gov/std/tg2015/default.htm</a>)</del></p> <p><del><a href="http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html">Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care</a>, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html">http://www.cdc.gov/HAI/prevent/prev-ent_pubs.html</a>)</del></p> <p><del>Guideline for Disinfection and Sterilization of Healthcare Facilities, 2008, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf">https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf</a>)</del></p> <p><del>Guidelines for Environmental Infection Control in Health-Care Facilities,</del></p> |

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|  |  |  | <p><u>2003, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf">https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf</a>)</u></p> <p><u>Guidelines for Hand Hygiene in Healthcare Settings, 2002, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf">https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf</a>)</u></p> <p><u>Guideline for Infection Control in Healthcare Personnel, 1998, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="https://stacks.cdc.gov/view/cdc/11563">https://stacks.cdc.gov/view/cdc/11563</a>)</u></p> <p><u>Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (<a href="https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf">https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf</a>)</u></p> <p><u>Standards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone 1-877-223-2866, email <a href="mailto:jrcustomerservice@pbd.com">jrcustomerservice@pbd.com</a></u></p> <p><u><a href="https://www.osha.gov/OshDoc/data/BloodborneFacts/bbfact01.pdf">Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration (<a href="https://www.osha.gov/OshDoc/data/BloodborneFacts/bbfact01.pdf">https://www.osha.gov/OshDoc/data/BloodborneFacts/bbfact01.pdf</a>)</a></u></p> <p><b>INTENT:</b> The intent of these proposed changes is to keep documents incorporated by reference current and accurate.</p> |
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|  |  |  |   |
|--|--|--|---|
|  |  |  | <p><b>RATIONALE:</b> The rationale behind these proposed changes is that abortion facilities should be held to current standards and guidelines.</p> <p><b>LIKELY IMPACT:</b> The likely impact of these proposed changes is improved patient health and safety at abortion facilities.</p> |
|--|--|--|---|

1 Project 5664 - none

2 DEPARTMENT OF HEALTH

3 Amend Regulation after Assessment and Receipt of Public Comment

4 CHAPTER 412

5 REGULATIONS FOR LICENSURE OF ABORTION FACILITIES

6 Part I

7 Definitions and Requirements for Licensure

8 **12VAC5-412-10. Definitions.**

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

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

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

17 "Administrator" means the person ~~or persons appointed~~ designated by the governing body as  
18 having the responsibility and necessary authority for the ~~overall~~ daily management of the abortion  
19 facility. Job titles may include director, executive director, office manager, or business manager.

20 "Applicant" means the person, partnership, corporation, association, organization, or  
21 professional entity that applies for initial issuance of a license to operate an abortion facility.

22 "Board" means the State Board of Health.

23 "Commissioner" means the State Health Commissioner.

24 "Department" means the Virginia Department of Health.

25 "Drug" means a drug as defined in § 54.1-3401 of the Code of Virginia.

26 "First trimester" means 13 weeks and 6 days after last menstrual period or based on an  
27 appropriate clinical estimate by a licensed health care practitioner.

28 "Governing body" means the person or group of persons designated in writing by the licensee  
29 as having the responsibility and necessary authority for the overall management of the abortion  
30 facility.

31 "Informed written consent" means ~~the knowing and voluntary written consent to abortion by a~~  
32 ~~pregnant woman of any age in accordance with~~ informed written consent as defined by § 18.2-76  
33 D of the Code of Virginia.

34 "Inspector" means an employee of the department designated by the commissioner to conduct  
35 inspections or investigations on the commissioner's behalf.

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

39 "Medication abortion" means the use of a drug to terminate the pregnancy of a woman.

40 "Minor" means a patient person ~~under the age of 18 years of age.~~

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

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

43 "OLC" means the Office of Licensure and Certification of the department.

44

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

47 "Surgical abortion" means the use of an instrument, or the combined use of an instrument and  
48 drug, to terminate the pregnancy of a woman.

49 "Working day" means any day other than a Saturday, Sunday, or federal or state holiday.

50 Statutory Authority

51 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

52 Historical Notes

53 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
54 Register Volume 33, Issue 13, eff. March 22, 2017.

55 **12VAC5-412-20. General.**

56 A. The commissioner may issue A a license to establish or operate an abortion facility shall  
57 be issued only if:

58 (i) when the 1. The applicant and the applicant's proposed abortion facility is are in  
59 compliance with all applicable federal, state, and local statutes and regulations and the  
60 provisions of this chapter; and

61 (ii) when the 2. The application fee has been received by the department OLC.

62 The commissioner shall indicate on each license whether an abortion facility may perform  
63 medication abortions, surgical abortions, or both.

64 B. No person or entity shall establish, conduct, maintain, or operate in this state,  
65 Commonwealth any abortion facility without having obtained a license. Any person establishing,  
66 conducting, maintaining, or operating an abortion facility without a license shall be subject to  
67 penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.

68 C. An abortion facility shall not assign or transfer any license issued by the commissioner  
69 pursuant to this chapter.

70 Statutory Authority

71 §§ 32.1-12, 32.1-125, and 32.1-127 of the Code of Virginia.

72 Historical Notes

73 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

74 **12VAC5-412-40. Separate license.**

75 A. An applicant intending to operate An an abortion facility operating at more than one location  
76 shall be required to obtain separate licenses for each location in at which abortion services  
77 abortions are provided.

78 B. An Abortion abortion facilities facility which have that has separate organized sections,  
79 units, or buildings to provide services of a classification covered by provisions of other state  
80 statutes or regulations, shall be required to have any additional applicable license required for  
81 that type or classification of service.

82 C. Facilities licensed as either a general hospital or an outpatient surgical hospital by the  
83 department commissioner are not subject to the provisions of this chapter.

84 Statutory Authority

85 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

86 Historical Notes

87 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

88 **12VAC5-412-50. Request for initial license issuance.**

89 A. ~~Abortion facility licenses shall be issued by the commissioner. All applications for licensure~~  
90 ~~An applicant shall be submitted initially;~~

91 1. Submit an application for initial licensure to the department's Office of Licensure and  
92 Certification (OLC) OLC;

93 2. Submit a copy of the proposed abortion facility's certificate of use and occupancy or a  
94 statement from the certified architect or engineer of the proposed abortion facility that the  
95 premises is substantially complete and eligible for a certificate of occupancy;

96 3. Identify the services that it intends to perform at its proposed abortion facility; and

97 4. Disclose to the OLC the ownership interest of the proposed abortion facility and in the  
98 case of corporations, identify by name and address all individuals or entities holding 5.0%  
99 or more of total ownership.

100 B. Each proposed abortion facility shall be ~~designated by~~ have a distinct identifying name  
101 ~~which that shall appear on the application for initial licensure. Any change of name shall be~~  
102 ~~reported to the OLC within 30 days.~~

103 C. ~~Application for initial licensure of an abortion facility shall be accompanied by a copy of the~~  
104 ~~abortion facility's certificate of use and occupancy or a statement from the facility's certified~~  
105 ~~architect or engineer that the facility is substantially complete and eligible for a certificate of~~  
106 ~~occupancy.~~

107 ~~D.C.~~ The OLC shall consider an application complete when all requested information and the  
108 ~~appropriate nonrefundable application fee are submitted~~ received by the OLC.

109 ~~E.D. An applicant shall provide~~ Written ~~written~~ notification from the applicant to OLC that it is  
110 ~~ready for the on-site survey~~ initial licensure inspection ~~must be received 30 days prior to OLC~~  
111 ~~scheduling of the initial licensure survey. The OLC shall notify Applicants for initial licensure the~~  
112 ~~applicant shall be notified of the time and date of the initial licensure survey inspection, after the~~  
113 ~~notice of readiness is received by the OLC. The OLC will conduct the initial licensure inspection~~  
114 ~~no sooner than 30 days after the OLC receives the applicant's written notification.~~

115 ~~F.E.~~ As part of the initial licensure inspection, an applicant shall:

116 1. Make available to an inspector any requested records;

117 2. Allow an inspector access to interview the agents, employees, contractors, and any  
118 person under the applicant's control, direction, or supervision; and

119 3. Permit an inspector to enter upon and into the property of any proposed abortion facility  
120 to inspect or investigate as the inspector reasonably deems necessary in order to  
121 determine the state of compliance with the provisions of this chapter and all laws  
122 administer by the board.

123 F. The OLC shall provide a written inspection report to the applicant. If the OLC cites one or  
124 more licensing violations in the written inspection report, the administrator shall submit a written  
125 plan of correction in accordance with the provisions of 12VAC5-412-110.

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

128 Statutory Authority

129 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

130 Historical Notes

131 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.



132 **12VAC5-412-60. License expiration and renewal.**

133 A. Licenses shall expire at midnight April 30 following the date of issue and shall be renewable  
134 may be renewed annually, upon filing of a renewal application and payment of the appropriate  
135 nonrefundable renewal application fee. ~~Renewal applications~~ The commissioner shall renew a  
136 license shall only be granted after a determination by the OLC determines that the applicant  
137 abortion facility is in substantial compliance with this chapter.

138 B. An abortion facility shall submit a ~~The annual license renewal application shall be submitted~~  
139 to the OLC at least no less than 60 days prior to the expiration date of the current license. A  
140 ~~renewal application submitted more than 60 days past the expiration of the current license shall~~  
141 ~~not be accepted.~~ The OLC may not accept any renewal application submitted after the expiration  
142 of the current license.

143 C. ~~Any~~ An abortion facility ~~failing that fails~~ to submit an ~~acceptable~~ a plan of correction as  
144 required in 12VAC5-412-110 shall may not be eligible for license renewal renew its license.

145 D. An abortion facility whose license has expired or is not eligible to renew its license pursuant  
146 to subsection C:

147 1. May not perform more than four first trimester abortions per month; and

148 2. Shall comply with 12VAC5-412-50 to receive a license.

149 Statutory Authority

150 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

151 Historical Notes

152 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

153 **12VAC5-412-70. ~~Return and/or Surrender of license; reissuance of license.~~**

154 A. ~~It is the responsibility of the abortion facility's governing body to maintain~~ An abortion facility  
155 shall maintain a current and accurate license at all times.

156 B. ~~An abortion facility shall give written notification~~ notify the director of the OLC in writing no  
157 less than 30 calendar days in advance of implementing any of the following ~~planned changes:~~

158 1. Change of location;

159 2. Change of ownership;

160 3. Change of name;

161 4. Introduction of surgical abortions; or

162 5. Voluntary closure.

163 ~~5. Change of administrator.~~

164 ~~6. Change of operator.~~

165 ~~Notices shall be sent to the attention of the director of the OLC.~~

166 C. ~~The~~ An abortion facility shall surrender the license issued by the commissioner shall be  
167 returned to the OLC when any of the changes listed in subsection B of this section occur upon  
168 receipt of the reissued or new license.

169 D. ~~In addition, if~~ If the an abortion facility is no longer operational, ~~or the license has been~~  
170 ~~suspended or revoked,~~ it shall:

171 1. Surrender its license shall be returned to the OLC within no more than five calendar  
172 days of after the abortion facility closing ceases operations; and

173 2. The abortion facility's Notify all patients and the OLC shall be notified where all patient  
174 records will be located no more than five calendar days after the abortion facility ceases  
175 operations.

176 ~~D.E.~~ The OLC shall determine if any changes listed in subsection B affect the terms of the  
177 license or ~~the~~ an abortion facility's continuing eligibility for a license. ~~A licensing representative~~  
178 An inspector may inspect the abortion facility during the process of evaluating a change.

179 ~~E.F.~~ The OLC shall notify in writing the abortion facility ~~abortion facility will be notified in writing~~  
180 ~~by the OLC whether~~ if the commissioner will reissue a the license ~~can be reissued~~ or a new  
181 application is needed. An abortion facility shall submit a new application at least 30 days in  
182 advance of any change of ownership or location.

183 Statutory Authority

184 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

185 Historical Notes

186 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

187 **12VAC5-412-80. Allowable variances.**

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

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

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

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

210 Upon the finding that the enforcement of one or more of these regulations would be clearly  
211 impractical, the commissioner may waive, either temporarily or permanently, the enforcement of  
212 one or more of these regulations, provided safety and patient care and services are not adversely  
213 affected.

214 Statutory Authority

215 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

216 Historical Notes

217 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
218 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.

219 **12VAC5-412-90. Right of entry.**

220 A. Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia  
221 Department of Health shall have the right to An inspector may enter upon and into the premises  
222 property of any licensed abortion facility, or any entity the department OLC has reason to believe

223 is operated or maintained as an abortion facility without a license, to inspect or investigate as the  
224 inspector reasonably deems necessary in order to determine ~~the state of~~ compliance with the  
225 ~~provisions of this chapter.~~

226 ~~B. Any such employee~~ An inspector shall ~~properly identify himself as an inspector designated~~  
227 ~~by OLC the commissioner through the presentation of appropriate credentials;~~ ~~the abortion facility~~  
228 The owner or custodian of the property may verify the identity of the inspector prior to his  
229 admission upon or into the property.

230 ~~C. Such entries and inspections shall be made~~ An inspector may enter upon and into the  
231 property with the permission of the owner or ~~person in charge or custodian;~~ If an inspector is  
232 denied entry upon and into the property, unless the commissioner or his designee may obtain an  
233 inspection warrant ~~is obtained after denial of entry from an appropriate circuit court pursuant to §~~  
234 32.1-25 of the Code of Virginia.

235 ~~If the owner, or person in charge, refuses entry, this shall be sufficient cause for immediate~~  
236 ~~revocation or suspension of the license. If the entity is unlicensed, the owner or person in charge~~  
237 ~~shall be subject to penalties and other actions pursuant to § 32.1-27 of the Code of Virginia.~~

238 Statutory Authority

239 §§ 32.1-12, 32.1-25, 32.1-27, and 32.1-127 of the Code of Virginia.

240 Historical Notes

241 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

242 **12VAC5-412-100. On-site inspection.**

243 ~~A. An~~ The OLC representative shall make periodic unannounced on-site inspections of each  
244 abortion facility as necessary, but not less often than biennially. ~~If the department finds, after~~  
245 ~~inspection, noncompliance with any provision of this chapter, the abortion facility shall receive a~~  
246 ~~written licensing report of such findings. The abortion facility shall submit a written plan of~~  
247 ~~correction in accordance with provisions of 12VAC5-412-110.~~

248 ~~B. The abortion facility shall make available to the OLC's representative~~ inspector any  
249 requested records and shall allow access to interview the agents, employees, contractors, and  
250 any person under the abortion facility's control, direction, or supervision. If copies of records are  
251 removed from the premises, the abortion facility may redact patient names and addresses of  
252 patients or personnel contained in such records shall be redacted by the abortion facility before  
253 prior to removal. The inspector shall inform the abortion facility that it may redact names and  
254 addresses of patients or personnel prior to the inspector removing copies of records from the  
255 premises.

256 ~~C. If the OLC's representative~~ an inspector arrives on the premises to conduct ~~a survey an~~  
257 inspection and ~~the administrator, the nursing director, or a person authorized to give access to~~  
258 ~~patient records is not available on the premises, such~~ the person or the designated alternate shall  
259 be available on the premises within no more than one hour of ~~after the surveyor's~~ inspector's  
260 arrival. Upon request of the inspector, the abortion facility shall provide, no more than 2 hours  
261 after the inspector's arrival:

262 1. A list of patients receiving scheduled to receive abortions and services related to the  
263 provision of an abortion on the day days of the survey inspection; and

264 2. as well as a ~~A~~ list of all of the abortion facility's patients for the previous 12 months shall  
265 be provided to the surveyor within two hours of arrival if requested.

266 ~~Failure to be available or to respond shall be grounds for penalties in accordance with § 32.1-~~  
267 ~~27 of the Code of Virginia and denial, suspension, or revocation of the facility's license in~~  
268 ~~accordance with 12VAC5-412-130.~~

269 D. The OLC shall provide a written inspection report to the administrator. If the OLC cites one  
270 or more licensing violations in the written inspection report, the administrator shall submit a written  
271 plan of correction in accordance with the provisions of 12VAC5-412-110.

272 Statutory Authority

273 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

274 Historical Notes

275 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
276 Register Volume 33, Issue 13, eff. March 22, 2017; amended, Virginia Register Volume 35, Issue  
277 17, eff. May 15, 2019.

278 **12VAC5-412-110. Plan of correction.**

279 A. Upon receipt of a written licensing inspection report, ~~each abortion facility~~ the administrator  
280 or his designee shall prepare a written plan of correction addressing each licensing violation cited  
281 at the time of inspection.

282 B. The administrator shall submit, ~~within 15 working days of receipt of the inspection report,~~  
283 an acceptable to the OLC a written plan of correction as determined by the OLC no more than 15  
284 working days after receipt of the inspection report. The plan of correction shall contain for each  
285 licensing violation cited:

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

288 2. The expected correction date, not to exceed ~~30~~ 45 working days from the exit date of  
289 the survey inspection;

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

292 4. The signature and title of the person responsible for the validity of the ~~report~~ plan of  
293 correction, and the date of the signature.

294 C. ~~The administrator OLC shall be notified~~ notify the administrator whenever if the OLC  
295 determines any item in the plan of correction is ~~determined to be unacceptable. Failure to submit~~  
296 an acceptable plan of correction may result in a penalty in accordance with § 32.1-27 of the Code  
297 of Virginia or in denial, revocation, or suspension of a license in accordance with 12VAC5-412-  
298 130.

299 D. Upon request of the OLC, an applicant or licensee shall produce evidence that all or part  
300 of a plan of correction has been implemented. The OLC may conduct an inspection to verify any  
301 portion of a plan of correction.

302 E. ~~The administrator shall be responsible for assuring~~ ensure the plan of correction is  
303 implemented and monitored so that compliance is maintained.

304 Statutory Authority

305 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

306 Historical Notes

307 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

308 **12VAC5-412-120. OLC complaint Complaint investigations.**

309 A. The OLC shall investigate ~~any~~ complaints regarding alleged violations of this chapter  
310 applicable. The OLC shall determine if an investigation requires an on-site inspection. In making  
311 this determination, the OLC shall consider several factors, to include:

312 1. If the complainant has first-hand knowledge of the alleged incident;

313 2. The abortion facility's regulatory history, including the number of substantiated prior  
314 complaints;

315 3. If the OLC has recently inspected the abortion facility, and if the incident would have  
316 been observed during the prior inspection; and

317 4. The nature of the complaint, including degree of potential serious harm to patients.

318 When the investigation is complete, the OLC shall notify the abortion facility and the  
319 complainant, if known, ~~will be notified~~ in writing of the findings of the investigation.

320 ~~B. As required by the OLC For any licensing violation cited during a complaint investigation,~~  
321 ~~the administrator shall submit a plan of correction for any deficiencies found during a complaint~~  
322 ~~investigation in accordance with 12VAC5-412-110 and shall be responsible for assuring the plan~~  
323 ~~of correction is implemented and monitored so that compliance is maintained.~~

324 Statutory Authority

325 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

326 Historical Notes

327 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

328 **12VAC5-412-130. Violation of this chapter or applicable law; denial, revocation, or**  
329 **suspension of license.**

330 ~~A. When the department determines~~ The commissioner may deny, suspend, or revoke the  
331 license to operate an abortion facility in accordance with the Administrative Process Act (§ 2.2-  
332 4000 et seq. of the Code of Virginia) if the commissioner determines that an abortion facility an  
333 applicant or licensee is:

334 ~~(i) in~~ 1. In violation of this chapter or § 32.1-125.01, 32.1-125.4, or 32.1-135.2 of the Code  
335 of Virginia; or

336 ~~(ii) is permitting~~ 2. Permitting, aiding, or abetting the commission of any illegal act in the  
337 abortion facility, the department may deny, suspend, or revoke the license to operate an  
338 abortion facility in accordance with § 32.1-135 of the Code of Virginia.

339 Suspension of a license shall be for an indefinite time in all cases.

340 ~~B. If a license or certification is revoked as herein provided, a new license or certification may~~  
341 ~~be issued by the commissioner~~ Upon receipt of a completed application and a nonrefundable  
342 application fee, the commissioner may issue a new license to an abortion facility that has had its  
343 license to operate an abortion facility revoked if the commissioner determines that:

344 1. after satisfactory evidence is submitted to him that the The conditions upon which  
345 revocation was based have been corrected; and

346 2. after proper inspection has been made and The applicant is in compliance with this  
347 chapter and §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia~~hereunder~~  
348 has been obtained.

349 The abortion facility shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory  
350 to the commissioner or his designee. The commissioner or his designee may conduct an  
351 inspection prior to making a determination.

352 ~~C. Suspension of a license shall in all cases be for an indefinite time.~~ The commissioner may  
353 partially or completely restore a suspended license to an abortion facility when he if the  
354 commissioner determines that:

355 1. the The conditions upon which suspension was based have been corrected; and

356 2. that the The interests of the public will not be jeopardized by resumption of operation.

357 The abortion facility shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory  
358 to the commissioner or his designee. The commissioner or his designee may conduct an  
359 inspection prior to making a determination. No additional fee shall be required for restoring such  
360 a license pursuant to this subsection.

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

364 Statutory Authority

365 §§ 32.1-12, 32.1-127, and 32.1-135 of the Code of Virginia.

366 Historical Notes

367 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
368 Register Volume 33, Issue 13, eff. March 22, 2017.

369 Part II

370 Organization and Management

371 **12VAC5-412-140. Management and administration.**

372 A. The abortion facility shall comply with:

373 1. This chapter ~~(12VAC5-412)~~;

374 2. §§ 32.1-125.01, 32.1-125.4, and 32.1-135.2 of the Code of Virginia; and

375 3. The abortion facility's policies and procedures.

376 B. ~~The abortion facility~~ applicant or licensee shall submit or make available to the  
377 commissioner or his designee any reports and information necessary to establish compliance with  
378 this chapter.

379 ~~C. The abortion facility shall permit OLC inspectors to conduct inspections to:~~

380 1. ~~Verify application information;~~

381 2. ~~Determine compliance with this chapter and applicable law;~~

382 3. ~~Review necessary records and documents; and~~

383 4. ~~Investigate complaints.~~

384 ~~D. An abortion facility shall give written notification 30 calendar days in advance of~~  
385 ~~implementing any of the following planned changes:~~

386 1. ~~Change of location.~~

387 2. ~~Change of ownership.~~

388 3. ~~Change of name.~~

389 4. ~~Voluntary closure.~~

390 5. ~~Change of administrator.~~

391 6. ~~Change of operator.~~

392 ~~Notices shall be sent to the attention of the director of the OLC.~~

393 ~~E. The C. An abortion facility shall post its~~ current license from the ~~department~~ commissioner  
394 ~~shall be posted~~ at all times in a place readily visible and accessible to the public.

395 ~~F.D.~~ Each abortion facility shall post notice that:

396 1. Alerts possible witnesses or victims of human trafficking of the existence of a human  
397 trafficking hotline to alert possible witnesses or victims of human trafficking to the  
398 availability of a as an available means to gain assistance or report crimes; and

399 2. ~~This notice shall be~~ is in a place readily visible and accessible to the public, such as the  
400 patient admitting area or public or patient restrooms.

401 The notice shall meet the requirements of § 40.1-11.3 C of the Code of Virginia.

402 Statutory Authority

403 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

404 Historical Notes

405 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
406 Register Volume 35, Issue 4, eff. November 14, 2018.

407 **12VAC5-412-150. Governing body.**

408 A. Each abortion facility shall ~~have~~ designate in writing a governing body responsible for the  
409 overall management and control of the operation of the abortion facility.

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

414 ~~C.~~B. The governing body shall:

415 ~~provide~~ 1. Provide facilities, personnel, and other resources necessary to meet patient  
416 and program needs; and

417 ~~D. The governing body shall have~~ 2. Have a formal organizational plan with written bylaws.  
418 ~~These shall that~~ clearly set forth organization, duties and responsibilities, accountability,  
419 and relationships of professional management, clinical staff, and other personnel. ~~The~~  
420 ~~bylaws shall identify the person or organizational body responsible for formulating policies.~~

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

422 1. A statement of purpose;

423 2. Description of the functions and duties of the governing body ~~or other legal authority~~;

424 3. A statement of authority and responsibility delegated to the administrator and to the  
425 clinical staff;

426 4. Provision for selection and appointment of clinical staff and granting of clinical  
427 privileges; ~~and~~

428 5. Provision of guidelines for relationships among the governing body, the administrator,  
429 and the clinical staff; and

430 6. The identity of the person or organizational body responsible for formulating policies  
431 and procedures pursuant to 12VAC5-412-160.

432 Statutory Authority

433 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

434 Historical Notes

435 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

436 **12VAC5-412-160. Policies and procedures.**

437 A. ~~Each abortion facility~~ A governing body shall:

438 1. develop Approve, implement, and maintain documented policies and procedures as  
439 specified in this section that are based on recognized standards and guidelines, which  
440 shall be readily available on the premises;

441 ~~and shall be reviewed~~ 2. Review all policies and procedures at least annually with the  
442 administrator and appropriate clinical staff;

443 ~~and updated~~ 3. Update policies and procedures as deemed necessary by the governing  
444 body; and

445 4. Document in writing the annual review process and recommendations for changes or  
446 updates.

447 A member of the clinical staff with training and expertise in infection prevention shall  
448 participate in the annual review of the infection prevention policies and procedures to ensure they  
449 comply with applicable regulations and standards.

450 B. The personnel policies and procedures shall include but shall not be limited to the following  
451 topics:

452 1. Personnel; Written job descriptions that meet the requirements of 12VAC5-412-180 B  
453 4;

454 2. Verifying current professional licensing or certification and training of employees or  
455 independent contractors;

456 3. Obtaining a criminal background check;

457 4. Evaluating at least annually employee performance and competency;

458 5. Verifying that independent contractors and their employees meet the personnel  
459 qualifications of the abortion facility;

460 6. Reporting licensed and certified health care practitioners for violations of their licensing  
461 or certification standards to the appropriate board within the Department of Health  
462 Professions;

463 7. Staff participation in initial and ongoing training and education that is directly related to  
464 staff duties and appropriate to the level, intensity, and scope of services provided;

465 8. Staff participation in annual fire safety and infection prevention in-service training and  
466 the process by which training is documented; and

467 9. Appropriate staffing by licensed clinicians based on the level, intensity, and scope of  
468 services provided and the process by which staffing is documented.

469 C. The patient and clinical services policies and procedures shall include:

470 1. Ensuring and documenting that only health care practitioners who are permitted by law  
471 and are qualified by training and experience are performing abortions in the abortion  
472 facility;

473 2. Types of elective services performed in the abortion facility;

474 3. Types of anesthesia that may be used;

475 4. Content and completion of medical records;

476 5. Documentation in the patient's medical record of and criteria for evaluating a patient for  
477 discharge from anesthesia care, including:

478 a. Stable vital signs;

479 b. Responsiveness and orientation;

480 c. Ability to move voluntarily;

481 d. Controlled pain; and

482 e. Minimal nausea and vomiting;

483 6. Admissions Patient intake evaluation, to comply with subsection A of 12VAC5-412-240;

484 7. and discharges Discharges, including criteria for evaluating the patient before  
485 admission and for medical stability before discharge;

486 8. Ensuring that adequately trained health care practitioners remain with the patient until  
487 discharged from the abortion facility;

488 5-9. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code  
489 of Virginia prior to the initiation of any procedures an abortion;

490 6-10. When to use sonography to assess patient risk;



491 7. Infection prevention;  
492 8. Quality and risk management;  
493 9-11. Management and effective response to medical ~~and/or~~ or surgical emergency;  
494 12. The secure and temperature-controlled storage of drugs and the disposal of expired  
495 drugs;  
496 13. Patient rights;  
497 14. Provision of or referral for family planning services to the abortion facility's patients;  
498 15. Evaluation of all tissues removed during an abortion and for reevaluation of the patient  
499 if the evaluation of tissue is insufficient to confirm termination of the pregnancy; and  
500 16. Tracking and logging any tissue specimens sent for further pathologic examination.  
501 An abortion facility that provides only medication abortions shall be exempt from subdivisions  
502 3, 5, 6, 7, 15, and 16 of this subsection.  
503 D. The safety and security policies and procedures shall include:  
504 1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs,  
505 supplies, and services;  
506 2. Provisions for disseminating safety-related information to employees and users of the  
507 abortion facility;  
508 ~~10-3.~~ Management and effective response to fire;  
509 ~~11.~~ Ensuring compliance with all applicable federal, state, and local laws;  
510 ~~12-4.~~ Abortion facility security; and  
511 ~~13-5.~~ Disaster preparedness, to include provisions for evacuation of all occupants in the  
512 event of a disaster, exercise of the disaster preparedness plan not less than annually, and  
513 documentation of disaster preparedness exercises.  
514 E. A member of the clinical staff with training and expertise in infection prevention shall  
515 participate in the development of infection prevention policies and procedures. The governing  
516 body shall document the process for development, implementation, and maintenance of infection  
517 prevention policies and procedures and the regulations or guidance documents on which they are  
518 based. The infection prevention policies and procedures shall include:  
519 1. Screening incoming patients for acute infectious illnesses and applying appropriate  
520 measures to prevent transmission of community-acquired infection within the abortion  
521 facility;  
522 2. Initial training, annual retraining, and use of standard precautions recommended by the  
523 U.S. Centers for Disease Control and Prevention by all employees and independent  
524 contractors, including:  
525 a. Correct hand-washing technique, including indications for use of soap and water,  
526 and use of alcohol-based hand rubs;  
527 b. Compliance with bloodborne pathogen requirements of the U.S. Occupational  
528 Safety and Health Administration; and  
529 c. Use of personal protective equipment;  
530 3. Use of safe injection practices recommended by the U.S. Centers for Disease Control  
531 and Prevention;  
532 4. Monitoring staff adherence to standard precautions;  
533 5. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based  
534 hand rubs, disposable towels or hot air driers);

535 6. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal,  
536 storage, and transport of equipment and supplies;

537 7. Storage for cleaning agents, such as locked cabinets or rooms for chemicals used for  
538 cleaning, in accordance with product-specific instructions;

539 8. Use of cleaning agents, such as dilution, contact time, and management of accidental  
540 exposures, in accordance with product-specific instructions;

541 9. Handling, storing, and transporting clean linens, clean or sterile supplies, and  
542 equipment;

543 10. Handling, temporary storage, and transport of soiled linens;

544 11. Handling, storing, processing, and transporting regulated medical waste in accordance  
545 with applicable regulations;

546 12. Processing of each type of reusable medical equipment between uses on different  
547 patients, with reference to the manufacturer's recommendations and any applicable state  
548 or national infection control guidelines, and addressing:

549 a. The level of cleaning, disinfecting, or sterilizing to be used for each type of  
550 equipment;

551 b. The process by which cleanliness, disinfection, or sterilization is achieved; and

552 c. The method for verifying that the recommended level of cleanliness, disinfection, or  
553 sterilization has been achieved;

554 13. Maintenance, repair, and disposal of equipment and supplies in accordance with  
555 manufacturer recommendations;

556 14. Cleaning of environmental surfaces with appropriate cleaning products;

557 15. An effective pest control program, managed in accordance with local health and  
558 environmental regulations;

559 16. Other infection prevention procedures necessary to prevent or control transmission of  
560 an infectious agent in the abortion facility as recommended or required by the department;

561 17. Surveillance, documentation, and tracking of reported infections; and

562 18. Reporting conditions to the local health department in accordance with the Regulations  
563 for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.

564 F. The management and administration policies and procedures shall include:

565 14. Patient rights;

566 15.1. Quality and risk management;

567 2. Functional safety and abortion facility maintenance; and

568 16.3. Identification of the administrator and methods established by the governing body  
569 for holding the administrator responsible and accountable.

570 ~~B. These policies and procedures shall be based on recognized standards and guidelines. A~~  
571 ~~copy of the policies and procedures approved by the governing body and revisions thereto shall~~  
572 ~~be made available to the OLC upon request.~~

573 Statutory Authority

574 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

575 Historical Notes

576 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

577 **12VAC5-412-170. Administrator.**

578 A. The governing body shall ~~select~~ designate in writing one or more persons to be an  
579 administrator, who shall be responsible for the daily managerial, operational, financial, and  
580 reporting components of the abortion facility, including ~~but not limited to:~~

- 581 1. ~~Ensuring the development, implementation, and enforcement of~~ Developing,  
582 implementing, and enforcing all policies and procedures, including patient rights;  
583 2. Employing qualified personnel and ensuring appropriate personnel orientation, training,  
584 education, and evaluation;  
585 3. Ensuring the accuracy of public information materials and activities;  
586 4. Ensuring an effective budgeting and accounting system is implemented; and  
587 5. Maintaining compliance with applicable laws and regulations and implementing  
588 corrective action.

589 B. An abortion facility shall notify the OLC in writing of Any a change in the position of the  
590 administrator ~~shall be reported immediately by the governing body to the department in writing no~~  
591 more than five working days after the change.

592 C. The governing body or administrator shall appoint in writing A a qualified individual person  
593 ~~shall be appointed in writing to act in the absence of the administrator.~~

594 Statutory Authority

595 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

596 Historical Notes

597 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

598 **12VAC5-412-180. Personnel.**

599 A. ~~Each An~~ abortion facility shall ~~have a staff that:~~

- 600 1. Staff its abortion facility with persons who is are adequately trained and capable of  
601 providing appropriate service and supervision to patients; ~~The abortion facility shall~~  
602 ~~develop, implement, and maintain policies and procedures to ensure and document~~  
603 ~~appropriate staffing by licensed clinicians based on the level, intensity, and scope of~~  
604 ~~services provided.~~  
605 2. Obtain written applications for employment from all employees;  
606 3. Obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia  
607 on any compensated employee of the abortion facility who is not licensed by the Board of  
608 Pharmacy and whose job duties provide access to controlled substances at the abortion  
609 facility;  
610 4. Maintain written job descriptions that adequately describe the duties of every employee  
611 position at the abortion facility; and  
612 5. Maintain a personnel file for each employee at the abortion facility.

613 B. ~~The abortion facility shall obtain written applications for employment from all staff. The~~  
614 ~~abortion facility shall obtain and verify information on the application as to education, training,~~  
615 ~~experience, and appropriate professional licensure, if applicable.~~

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

619 D. ~~The abortion facility shall develop, implement, and maintain policies and procedures to~~  
620 ~~document that its staff participate in initial and ongoing training and education that is directly~~  
621 ~~related to staff duties and appropriate to the level, intensity, and scope of services provided. This~~

622 shall include documentation of annual participation in fire safety and infection prevention in-  
623 service training.

624 ~~E. Job descriptions.~~ B. For each job description, an abortion facility shall:

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

627 2. ~~Each job description shall include~~ 1. Include the position title, authority, specific  
628 responsibilities, and minimum qualifications.;

629 3. ~~Job descriptions shall be reviewed~~ 2. Review the job description at least annually, kept  
630 ~~current, and update as deemed necessary by the abortion facility;~~ and

631 3. given Give a copy to each employee and volunteer when assigned to the position and  
632 when revised.

633 ~~F. A C. For each personnel file, an abortion facility shall be maintained for each staff member.~~  
634 ~~The records shall be:~~

635 1. Ensure the personnel file is completely complete and accurately accurate documented;;

636 2. Make the personnel file readily available, including by electronic means; and

637 3. systematically organized Systematically organize the personnel file to facilitate the  
638 compilation and retrieval of information.;

639 4. Safeguard the personnel file against loss and unauthorized use;

640 5. Maintain employee health related information separately within the personnel file; and

641 6. The file shall contain Ensure the personnel file contains a current job description that  
642 reflects the individual's person's responsibilities and work assignments, and  
643 documentation of the person's in-service education, and professional licensure, if  
644 applicable.

645 ~~G. Personnel policies and procedures shall include, but not be limited to:~~

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

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

650 3. ~~Process for annually evaluating employee performance and competency;~~

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

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

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

659 Statutory Authority

660 §§ 32.1-12, 32.1-126.02, and 32.1-127 of the Code of Virginia.

661 Historical Notes

662 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
663 Register Volume 33, Issue 13, eff. March 22, 2017; amended, Virginia Register Volume 35, Issue  
664 17, eff. May 15, 2019.

665 **12VAC5-412-190. Clinical staff.**

666 A. Physicians and nonphysician health care practitioners shall constitute the clinical staff. The  
667 governing body shall specify in writing the Clinical clinical privileges of physician and nonphysician  
668 health care practitioners ~~shall be clearly defined.~~

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

674 ~~C. A B. An abortion facility shall ensure that physician shall:~~

675 ~~1. remain A physician, nurse practitioner, or physician assistant remains~~ on the premises  
676 ~~until all patients are medically stable, sign the discharge order, and be readily available~~  
677 ~~and accessible until the last patient is discharged.;~~

678 ~~2. A physician, nurse practitioner, or physician assistant signs a discharge order following~~  
679 ~~the administration of anesthesia, after assessing the patient or receiving a report from a~~  
680 ~~licensed health care practitioner indicating that the patient is safe for discharge; and~~

681 ~~3. Licensed health care practitioners trained in post-procedure assessment shall remain~~  
682 ~~on the premises until the last patient has been discharged. The physician shall give a~~  
683 ~~discharge order after assessing a patient or receiving a report from such trained health~~  
684 ~~care practitioner indicating that a patient is safe for discharge. The abortion facility shall~~  
685 ~~develop, implement, and maintain policies and procedures that ensure there is an~~  
686 ~~appropriate evaluation of medical stability prior to discharge of the patient and that~~  
687 ~~adequate trained health care practitioners remain with the patient until she is discharged~~  
688 ~~from the abortion facility.~~

689 ~~An abortion facility that provides only medication abortions shall be exempt from this~~  
690 ~~subsection.~~

691 ~~C. An abortion facility shall ensure that a licensed health care practitioner currently certified~~  
692 ~~to perform cardiopulmonary resuscitation shall be on the premises when surgical abortions are~~  
693 ~~being performed until the last patient is discharged.~~

694 ~~D. An abortion facility may employ Licensed licensed~~ practical nurses, working under direct  
695 supervision and direction of a physician or a registered nurse, ~~may be employed as components~~  
696 of the clinical staff.

697 Statutory Authority

698 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

699 Historical Notes

700 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
701 Register Volume 33, Issue 13, eff. March 22, 2017.

702 **12VAC5-412-200. Patients' rights.**

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

708 B. ~~The~~ An abortion facility shall establish and maintain complaint handling procedures which  
709 that specify the:

710 1. System for logging receipt, investigation, and resolution of complaints; and

- 711 2. Format of the written record of the findings of each complaint investigated.
- 712 C. ~~The An~~ abortion facility shall designate staff responsible for complaint resolution, including:
- 713 1. Complaint intake, including acknowledgment of complaints;
- 714 2. Investigation of the complaint;
- 715 3. Review of the investigation findings and resolution for the complaint; and
- 716 4. Notification to the complainant of the proposed resolution within 30 days from the date
- 717 of receipt of the complaint.
- 718 D. ~~At the time of admission to service, an abortion facility shall provide to Any a~~ patient in a
- 719 ~~language or manner the patient understands seeking an abortion shall be given;~~
- 720 1. ~~A copy of patient rights and responsibilities; and~~
- 721 ~~2. a A~~ copy of the complaint procedures, in a language or manner she understands, at the
- 722 ~~time of admission to service.;~~
- 723 E. ~~The abortion facility shall provide each patient or her designee with the name, mailing~~
- 724 ~~address, and telephone number of the:~~
- 725 1. ~~Abortion 3.~~ The name, mailing address, and telephone number of the abortion facility
- 726 contact person; and
- 727 2. ~~4.~~ The mailing address and telephone number of the OLC Complaint Unit, including the
- 728 toll-free complaint hotline number. Patients may submit complaints anonymously to the
- 729 OLC. The abortion facility shall display a copy of this information in a conspicuous place
- 730 in its abortion facility.
- 731 F. ~~B.~~ The An abortion facility shall maintain documentation records of all complaints received
- 732 and the status of each complaint from date of receipt through its final resolution. ~~Records shall be~~
- 733 maintained for, for a period of no less than three years after a complaint's final resolution.
- 734 Statutory Authority
- 735 §§ 32.1-12, 32.1-127, 32.1-137.01, and 32.1-137.05 of the Code of Virginia.
- 736 Historical Notes
- 737 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia
- 738 Register Volume 33, Issue 13, eff. March 22, 2017; amended, Virginia Register Volume 35, Issue
- 739 17, eff. May 15, 2019.

### Part III

#### Quality Management and Infection Prevention

#### 742 12VAC5-412-210. Quality management.

743 ~~A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-~~

744 ~~assessment program of the quality and appropriateness of care or services provided, including~~

745 ~~services provided under contract or agreement. The program shall include process design, data~~

746 ~~collection/analysis, assessment and improvement, and evaluation. The findings shall be used to~~

747 ~~correct identified problems and revise policies and practices, as necessary.~~

748 ~~B. The following shall be evaluated to assure adequacy and appropriateness of services, and~~

749 ~~to identify unacceptable or unexpected trends or occurrences~~ A. An abortion facility shall

750 implement an ongoing, comprehensive, integrated, self-assessment program of the quality and

751 appropriateness of care or services provided, including services provided under contract or

752 agreement, and that identifies unacceptable or unexpected trends or occurrences that shall

753 include evaluation of:

- 754 1. Staffing patterns and performance;
- 755 2. Supervision appropriate to the level of service;

- 756 3. Patient records;  
757 4. Patient satisfaction;  
758 5. Complaint resolution;  
759 6. Infections, complications, and other adverse events; and  
760 7. Staff concerns regarding patient care.

761 The program shall include process design, data collection/analysis, assessment and  
762 improvement, and evaluation.

763 ~~C-B. An abortion facility shall establish~~ A a quality improvement committee responsible for the  
764 oversight and supervision of the program ~~shall be established and.~~

765 C. The quality improvement committee shall at a minimum ~~shall~~ consist of:

- 766 1. A physician or independent healthcare practitioner;  
767 2. A nonphysician health care practitioner;  
768 3. A member of the administrative staff; and  
769 4. ~~An individual with demonstrated ability to represent the rights and concerns of patients.~~  
770 The individual A patient advocate, who may be a member of the abortion facility's staff.

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

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

774 E-D. The quality improvement committee shall report to the governing body:

- 775 1. At least annually the Results results of the quality improvement program ~~shall be~~  
776 ~~reported to the licensee, which at least annually and shall include the deficiencies it has~~  
777 ~~identified and its recommendations for corrections and improvements.; and The report~~  
778 ~~shall be acted upon by the governing body and the facility. All corrective actions shall be~~  
779 ~~documented.~~  
780 2. Immediately in writing the Identified deficiencies it has identified that jeopardize patient  
781 safety shall be reported immediately in writing to the licensee by the quality improvement  
782 committee.

783 E. The administrator shall implement corrective action for any deficiencies identified by the  
784 quality improvement committee and shall document in writing all corrective actions.

785 Statutory Authority

786 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

787 Historical Notes

788 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

789 **12VAC5-412-220. Infection prevention.**

790 A. ~~The An~~ abortion facility shall have an infection prevention plan that encompasses the entire  
791 abortion facility, abortions, and all services provided related to the provision of an abortion, and  
792 which is consistent with the provisions of the current edition of "Guide to Infection Prevention in  
793 Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for  
794 Disease Control and Prevention. An individual with training and expertise in infection prevention  
795 shall participate in the development of infection prevention policies and procedures and shall  
796 review them to assure they comply with applicable regulations and standards. An abortion facility  
797 shall ensure at least one member of the clinical staff receives training in basic infection prevention.

- 798 1. ~~The process for development, implementation, and maintenance of infection prevention~~  
799 ~~policies and procedures and the regulations or guidance documents on which they are~~  
800 ~~based shall be documented.~~

801 ~~2. All infection prevention policies and procedures shall be reviewed at least annually by~~  
802 ~~the administrator and appropriate members of the clinical staff. The annual review process~~  
803 ~~and recommendations for changes/updates shall be documented in writing.~~

804 ~~3. A designated person in the abortion facility shall have received training in basic infection~~  
805 ~~prevention, and shall also be involved in the annual review.~~

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

807 ~~1. Procedures for screening incoming patients and visitors for acute infectious illnesses~~  
808 ~~and applying appropriate measures to prevent transmission of community-acquired~~  
809 ~~infection within the abortion facility;~~

810 ~~2. Training of all personnel in proper infection prevention techniques;~~

811 ~~3. Correct hand-washing technique, including indications for use of soap and water and~~  
812 ~~use of alcohol-based hand rubs;~~

813 ~~4. Use of standard precautions;~~

814 ~~5. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety~~  
815 ~~and Health Administration;~~

816 ~~6. Use of personal protective equipment;~~

817 ~~7. Use of safe injection practices;~~

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

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

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

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

825 ~~1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based~~  
826 ~~hand rubs, disposable towels or hot air driers);~~

827 ~~2. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal,~~  
828 ~~storage, and transport of equipment and supplies;~~

829 ~~3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals~~  
830 ~~used for cleaning) and product-specific instructions for use of cleaning agents (e.g.,~~  
831 ~~dilution, contact time, management of accidental exposures);~~

832 ~~4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies,~~  
833 ~~and equipment;~~

834 ~~5. Procedures for handling/temporary storage/transport of soiled linens;~~

835 ~~6. Procedures for handling, storing, processing, and transporting regulated medical waste~~  
836 ~~in accordance with applicable regulations;~~

837 ~~7. Procedures for the processing of each type of reusable medical equipment between~~  
838 ~~uses on different patients. The procedure shall address: (i) the level of~~  
839 ~~cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process~~  
840 ~~(e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying~~  
841 ~~that the recommended level of disinfection/sterilization has been achieved. The procedure~~  
842 ~~shall reference the manufacturer's recommendations and any applicable state or national~~  
843 ~~infection control guidelines;~~

844 ~~8. Procedures for appropriate disposal of nonreusable equipment;~~

845 ~~9. Policies and procedures for maintenance/repair of equipment in accordance with~~  
846 ~~manufacturer recommendations;~~



- 847 ~~10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;~~  
848 ~~11. An effective pest control program, managed in accordance with local health and~~  
849 ~~environmental regulations; and~~  
850 ~~12. Other infection prevention procedures necessary to prevent/control transmission of an~~  
851 ~~infectious agent in the abortion facility as recommended or required by the department.~~

852 ~~D.B.~~ The An abortion facility shall have an employee health program that includes:

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

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

- 866 1. ~~A procedure for surveillance, documentation, and tracking of reported infections; and~~
- 867 2. ~~Policies and procedures for reporting conditions to the local health department in~~  
868 ~~accordance with the Regulations for Disease Reporting and Control (12VAC5-90),~~  
869 ~~including outbreaks of disease.~~

870 Statutory Authority

871 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

872 Historical Notes

873 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
874 Register Volume 33, Issue 13, eff. March 22, 2017; amended, Virginia Register Volume 35, Issue  
875 17, eff. May 15, 2019.

#### 876 Part IV

#### 877 Patient Care Management

#### 878 **12VAC5-412-230. Patient services; patient counseling.**

879 ~~A. Abortions performed in abortion facilities shall be performed only on patients who are within~~  
880 ~~the first trimester of pregnancy meaning 13 weeks and 6 days after last menstrual period or based~~  
881 ~~on an appropriate clinical estimate by a licensed health care provider.~~

882 ~~B. No person may perform an abortion upon an unemancipated minor unless informed written~~  
883 ~~consent is obtained from the minor and the minor's parent, guardian, or other authorized person.~~  
884 ~~If the unemancipated minor elects not to seek the informed written consent of an authorized~~  
885 ~~person, a copy of the court order authorizing the abortion entered pursuant to § 16.1-241 of the~~  
886 ~~Code of Virginia shall be obtained prior to the performance of the abortion.~~

887 ~~C.A. An abortion facility may not permit~~ A physician shall not perform an the performance of  
888 an abortion in its abortion facility without unless a health care practitioner who is permitted by law  
889 to perform an abortion has first obtaining obtained the informed written consent of:

- 890 1. the An adult patient or emancipated minor pursuant to the provisions of § 18.2-76 of the  
891 Code of Virginia.; or

892 2. An unemancipated minor and authorized person as defined by § 16.1-241 W of the  
893 Code of Virginia; however, the consent of an authorized person is not required if the  
894 unemancipated minor has provided to the health care practitioner a copy of the court order  
895 authorizing the abortion entered pursuant to § 16.1-241 of the Code of Virginia.

896 ~~D. When abortions are being performed, a staff member currently certified to perform~~  
897 ~~cardiopulmonary resuscitation shall be available on site for emergency care.~~

898 ~~E.B. The An abortion facility shall offer each patient seeking an abortion, in a language or~~  
899 ~~manner she the patient understands, appropriate counseling and instruction in the abortion~~  
900 ~~procedure and shall develop, implement, and maintain policies and procedures for the provision~~  
901 ~~of or referral for family planning services to its patients.~~

902 ~~F.C. There shall be An abortion facility shall have an organized discharge planning process~~  
903 ~~for its abortion facility that includes an assessment of a patient's safety for discharge and~~  
904 ~~discharge instructions for patients. An abortion facility that provides only medication abortions~~  
905 ~~shall be exempt from this subsection.~~

906 ~~D. An abortion facility shall provide patients with to include instructions to call or return if signs~~  
907 ~~of infection or other complications develop.~~

908 Statutory Authority

909 §§ ~~32.1-12~~ and 32.1-127 of the Code of Virginia.

910 Historical Notes

911 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
912 Register Volume 33, Issue 13, eff. March 22, 2017.

913 **12VAC5-412-240. Medical testing and laboratory services.**

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

918 1. ~~Medical testing shall include Use of a recognized method approved by the U.S. Food~~  
919 ~~and Drug Administration to confirm pregnancy; and~~

920 ~~2. determination Determination or and documentation of Rh factor.;~~

921 ~~2-3. Use of any additional medical testing shall be based on an assessment of patient risk.~~

922 ~~3. The abortion facility shall develop, implement, and maintain policies and procedures for~~  
923 ~~offering screening of sexually transmitted diseases consistent with current guidelines~~  
924 ~~issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring~~  
925 ~~patients to clinics that provide such testing.~~

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

928 B. An abortion facility shall provide Laboratory laboratory services and facilities for collecting  
929 specimens shall be provided on site or through arrangement a contract with a laboratory certified  
930 to provide the required procedures under the Clinical Laboratory Improvement Amendments of  
931 1988 (~~CLIA-88~~) (CLIA '88) (42 CFR Part 493).

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

933 ~~2-1. If laboratory services are provided on site they shall be directed by a A person who~~  
934 ~~qualifies as a director under CLIA-88 CLIA '88 and shall be direct on site laboratory~~  
935 ~~services and ensure that all laboratory services are performed in compliance with CLIA-~~  
936 ~~88 CLIA '88 standards.~~

937 ~~3.2. An abortion facility shall monitor~~ All all laboratory supplies shall be monitored for  
938 expiration dates, if applicable, and ~~disposed~~ dispose of expired laboratory supplies  
939 properly in accordance with the manufacturer's directions for use.

940 ~~C. The abortion facility shall have policies and procedures for evaluation of all tissues removed~~  
941 ~~during the abortion and for reevaluation of the patient in the event the evaluation of tissue is~~  
942 ~~insufficient to confirm termination of the pregnancy. The facility shall track and log any specimens~~  
943 ~~sent for further pathologic examination.~~

944 ~~D.C. An abortion facility shall manage~~ All all tissues removed resulting from the an abortion  
945 ~~procedure shall be managed~~ in accordance with requirements for medical waste pursuant to the  
946 Regulated Medical Waste Management Regulations (9VAC20-120). An abortion facility that  
947 provides only medication abortions shall be exempt from this subsection.

948 Statutory Authority

949 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

950 Historical Notes

951 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
952 Register Volume 33, Issue 13, eff. March 22, 2017.

953 **12VAC5-412-250. Anesthesia service.**

954 A. An abortion facility shall ensure that:

955 1. The anesthesia service shall ~~comply~~ complies with the office-based anesthesia  
956 provisions of Part VIII (18VAC85-20-310 et seq.) of the Regulations Governing the  
957 Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (18VAC85-20-310  
958 et seq.);

959 ~~B.2. The anesthesia service shall be directed by and under the supervision of a~~ A  
960 physician licensed in Virginia who is certified in advanced resuscitative techniques and  
961 has met the continuing education requirements directs and supervises the anesthesia  
962 service;

963 ~~C.3. When~~ If moderate sedation or conscious sedation is administered, the licensed health  
964 care practitioner who administers the anesthesia shall ~~routinely monitor~~ monitors the  
965 patient according to procedures consistent with such administration. ~~The administration of~~  
966 ~~sedation and monitoring of the patient shall be documented in the patient's medical~~  
967 ~~record;~~

968 4. The licensed health care practitioner who administered the moderate or conscious  
969 sedation documents the administration of sedation and monitoring of the patient in the  
970 patient's medical record;

971 5. If deep sedation or a major conductive block is administered or if general anesthesia is  
972 administered in an emergency situation, the licensed health care practitioner who  
973 administered the anesthesia service remains present and available in the abortion facility  
974 to monitor the patient until the patient meets the discharge criteria; and

975 6. The licensed health care practitioner who administered the anesthesia service permits  
976 a patient to be discharged from anesthesia care if the patient has met specific physician-  
977 defined criteria that the health care practitioner has documented in the patient's medical  
978 record.

979 An abortion facility that provides only medication abortions shall be exempt from the provisions  
980 of this subsection.

981 ~~D.B. An abortion facility administering~~ that administers moderate sedation/conscious sedation  
982 or conscious sedation shall maintain the ~~following~~ equipment, supplies, and pharmacological  
983 agents as required by 18VAC85-20-360 B;

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

993 ~~E.C. An abortion facility shall not use Elective elective general anesthesia shall not be used~~  
994 ~~at its abortion facility.~~

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

999 ~~G.D. In addition to the requirements of subsection D B of this section, an abortion facility~~  
1000 ~~administering that administers deep sedation or a major conductive block, or administering~~  
1001 ~~administers general anesthesia in an emergency situation, shall maintain the following equipment,~~  
1002 ~~supplies, and pharmacological agents as required by 18VAC85-20-360 C:~~

- 1003 1. ~~Drugs to treat malignant hyperthermia, when triggering agents are used;~~  
1004 2. ~~Peripheral nerve stimulator, if a muscle relaxant is used; and~~  
1005 3. ~~If using an anesthesia machine, the following shall be included:~~  
1006 a. ~~End-tidal carbon dioxide monitor (capnograph);~~  
1007 b. ~~In-circuit oxygen analyzer designed to monitor oxygen concentration within~~  
1008 ~~breathing circuit by displaying oxygen percent of the total respiratory mixture;~~  
1009 c. ~~Oxygen failure protection devices (fail-safe system) that have the capacity to~~  
1010 ~~announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to~~  
1011 ~~discontinue other gases when the pressure of the supply of oxygen is reduced;~~  
1012 d. ~~Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and~~  
1013 ~~therefore only a single anesthetic agent can be actualized on any anesthesia machine~~  
1014 ~~at one time;~~  
1015 e. ~~Pressure-compensated anesthesia vaporizers, designed to administer a constant~~  
1016 ~~nonpulsatile output, which shall not be placed in the circuit downstream of the oxygen~~  
1017 ~~flush valve;~~  
1018 f. ~~Flow meters and controllers, which can accurately gauge concentration of oxygen~~  
1019 ~~relative to the anesthetic agent being administered and prevent oxygen mixtures of~~  
1020 ~~less than 21% from being administered;~~  
1021 g. ~~Alarm systems for high (disconnect), low (subatmospheric), and minimum~~  
1022 ~~ventilatory pressures in the breathing circuit for each patient under general anesthesia;~~  
1023 ~~and~~  
1024 h. ~~A gas evacuation system.~~

1025 ~~H. The abortion facility shall develop, implement, and maintain policies and procedures~~  
1026 ~~outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs,~~  
1027 ~~responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea~~  
1028 ~~and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner~~

1029 ~~providing the anesthesia care and shall occur only when the patient has met specific physician-~~  
1030 ~~defined criteria, and those criteria have been documented within the patient's medical record.~~

1031 Statutory Authority

1032 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

1033 Historical Notes

1034 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia

1035 Register Volume 33, Issue 13, eff. March 22, 2017.

1036 **12VAC5-412-260. Administration, storage and dispensing of drugs. (Repealed.)**

1037 ~~A. Controlled substances, as defined in § 54.1-3401 of the Code of Virginia, shall be stored,~~  
1038 ~~administered, and dispensed in accordance with federal and state laws. The dispensing of drugs,~~  
1039 ~~excluding manufacturers' samples, shall be in accordance with Chapter 33 (§ 54.1-3300 et seq.)~~  
1040 ~~of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-~~  
1041 ~~20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances~~  
1042 ~~(18VAC110-30).~~

1043 ~~B. Drugs, as defined in § 54.1-3401 of the Code of Virginia, whose intended use is to induce~~  
1044 ~~a termination of pregnancy shall only be prescribed, dispensed, or administered by a physician.~~

1045 ~~C. Drugs maintained in the abortion facility for daily administration shall not be expired and~~  
1046 ~~shall be properly stored in enclosures of sufficient size with restricted access to authorized~~  
1047 ~~personnel only. Drugs shall be maintained at appropriate temperatures in accordance with~~  
1048 ~~definitions in 18VAC110-20-10.~~

1049 ~~D. The mixing, diluting, or reconstituting of drugs for administration shall be in accordance~~  
1050 ~~with regulations of the Board of Medicine (18VAC85-20-400 et seq.).~~

1051 ~~E. Records of all drugs in Schedules I-V received, sold, administered, dispensed, or otherwise~~  
1052 ~~disposed of shall be maintained in accordance with federal and state laws, to include the inventory~~  
1053 ~~and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Code of Virginia.~~

1054 Statutory Authority

1055 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

1056 Historical Notes

1057 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

1058 **12VAC5-412-270. Equipment and supplies; emergencies.**

1059 A. An abortion facility shall maintain medical equipment, and supplies, and drugs appropriate  
1060 and adequate to care for patients and to manage potential emergencies based on the level, scope,  
1061 and intensity of services provided, to include:

1062 1. A bed or recliner suitable for recovery;

1063 2. Oxygen with flow meters and masks or equivalent;

1064 3. Mechanical suction;

1065 4. Resuscitation equipment to include, ~~as a minimum,~~ resuscitation bags and oral airways;

1066 5. Emergency medications, intravenous fluids, and related supplies and equipment;

1067 6. Sterile suturing equipment and supplies;

1068 7. Adjustable examination light;

1069 8. Containers for soiled linen and waste materials with covers; and

1070 9. Refrigerator.

1071 An abortion facility that provides only medication abortions shall be exempt from subdivisions  
1072 2, 3, 6, and 7 of this subsection.

1073 B. An abortion facility shall employ or contract with a physician to determine the appropriate  
1074 and adequate medical equipment, supplies, and drugs, consistent with the 2010 edition of the  
1075 American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency  
1076 Cardiovascular Care, as amended in 2015, 2017, and 2018.

1077 C. An abortion facility that performs abortions using intravenous sedation shall provide  
1078 equipment and services to render emergency resuscitative and life-support procedures pending  
1079 transfer of the patient to a hospital.

1080 D. If emergency transfer of a patient is necessary, an abortion facility shall ensure the  
1081 responsible licensed health care practitioner provides direct communication to the appropriate  
1082 receiving facility staff regarding the status of the patient, the procedure details, and the suspected  
1083 complication.

1084 E. An abortion facility shall provide all patients of its abortion facility with contact information  
1085 for a representative of the abortion facility so that an emergency department physician or treating  
1086 provider may make contact with the abortion facility if complications arise.

1087 Statutory Authority

1088 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

1089 Historical Notes

1090 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

1091 **12VAC5-412-280. ~~Emergency equipment and supplies. (Repealed.)~~**

1092 ~~An abortion facility shall maintain medical equipment, supplies, and drugs appropriate and~~  
1093 ~~adequate to manage potential emergencies based on the level, scope, and intensity of services~~  
1094 ~~provided. Such medical equipment, supplies, and drugs shall be determined by the physician and~~  
1095 ~~shall be consistent with the current edition of the American Heart Association's Guidelines for~~  
1096 ~~Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a~~  
1097 ~~minimum, those to treat the following conditions:~~

1098 ~~1. Cardiopulmonary arrest;~~

1099 ~~2. Seizure;~~

1100 ~~3. Respiratory distress;~~

1101 ~~4. Allergic reaction;~~

1102 ~~5. Narcotic toxicity;~~

1103 ~~6. Hypovolemic shock; and~~

1104 ~~7. Vasovagal shock.~~

1105 ~~Statutory Authority~~

1106 ~~§ 32.1-127 of the Code of Virginia.~~

1107 ~~Historical Notes~~

1108 ~~Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia~~

1109 ~~Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.~~

1110 **12VAC5-412-290. ~~Emergency services. (Repealed.)~~**

1111 ~~A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the~~  
1112 ~~premises adequate monitoring equipment, suction apparatus, oxygen, and related items for~~  
1113 ~~resuscitation and control of hemorrhage and other complications.~~

1114 ~~B. An abortion facility that performs abortions using intravenous sedation shall provide~~  
1115 ~~equipment and services to render emergency resuscitative and life-support procedures pending~~  
1116 ~~transfer of the patient to a hospital. Such medical equipment and services shall be consistent with~~

1117 ~~the current edition of the American Heart Association's Guidelines for Cardiopulmonary~~  
1118 ~~Resuscitation and Emergency Cardiovascular Care.~~

1119 ~~C. When emergency transfer is necessary, the responsible physician at the abortion facility~~  
1120 ~~must provide direct communication to the appropriate receiving facility staff regarding the status~~  
1121 ~~of the patient, the procedure details, and the suspected complication. All patients must be~~  
1122 ~~provided with contact information for a representative of the abortion facility, so that an emergency~~  
1123 ~~department physician or treating provider may make contact with a provider of the facility if late~~  
1124 ~~complications arise.~~

1125 ~~Statutory Authority~~

1126 ~~§ 32.1-127 of the Code of Virginia.~~

1127 ~~Historical Notes~~

1128 ~~Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia~~  
1129 ~~Register Volume 33, Issue 13, eff. March 22, 2017.~~

1130 ~~Part V~~

1131 ~~Support Services – Health Information Medical Records and Reports~~

1132 ~~**12VAC5-412-300. Health information Medical records.**~~

1133 ~~A. An abortion facility shall maintain An an accurate and complete ~~clinical~~ medical record ~~or~~~~  
1134 ~~chart shall be maintained on each patient. The medical record ~~or chart~~ shall contain sufficient~~  
1135 ~~information to satisfy the diagnosis or need for the medical or surgical service. If medically~~  
1136 ~~indicated, ~~it~~ shall include, ~~but not be limited to the following~~:~~

1137 ~~1. Patient identification;~~

1138 ~~2. Admitting information, including patient history and physical examination;~~

1139 ~~3. Signed consent;~~

1140 ~~4. Confirmation of pregnancy;~~

1141 ~~5. Procedure report to include:~~

1142 ~~a. Physician orders;~~

1143 ~~b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;~~

1144 ~~c. Anesthesia record;~~

1145 ~~d. Operative record;~~

1146 ~~e. Surgical medication and medical treatments;~~

1147 ~~f. Recovery room notes;~~

1148 ~~g. Physicians' and nurses' progress notes;~~

1149 ~~h. Condition at time of discharge;~~

1150 ~~i. Patient instructions, ~~(preoperative and postoperative)~~ both preoperative and~~  
1151 ~~postoperative; and~~

1152 ~~j. Names of referral physicians or agencies; and~~

1153 ~~6. Any other information required by law to be maintained in the ~~health information~~ medical~~  
1154 ~~record.~~

1155 ~~B. An abortion facility shall provide for the safe storage of medical records, or accurate and~~  
1156 ~~legible reproductions, in accordance with the Health Insurance Portability and Accountability Act~~  
1157 ~~(HIPAA) (42 USC § 1320d et seq.).~~

1158 ~~Statutory Authority~~

1159 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

1160 ~~Historical Notes~~

1161 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
1162 Register Volume 33, Issue 13, eff. March 22, 2017.

1163 **12VAC5-412-310. Records storage. (Repealed.)**

1164 ~~Provisions shall be made for the safe storage of medical records or accurate and eligible~~  
1165 ~~reproductions thereof according to applicable federal and state law, including the Health~~  
1166 ~~Insurance Portability and Accountability Act (42 USC § 1320d et seq.).~~

1167 ~~Statutory Authority~~

1168 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

1169 ~~Historical Notes~~

1170 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

1171 **12VAC5-412-320. Required reporting.**

1172 ~~A. Abortion facilities~~ An abortion facility shall comply with and ensure all persons under its  
1173 direction or control comply with the fetal death and induced termination of pregnancy reporting  
1174 provisions in the Board of Health Regulations Governing Vital Records (12VAC5-550-120).

1175 ~~B. The~~ An abortion facility shall report ~~the following events~~ to OLC:

1176 1. ~~Any patient, staff,~~ Any staff or visitor death occurring on the premises of the abortion  
1177 facility;

1178 2. Any patient death;

1179 3. Any serious injury to a patient that requires medical care beyond its capabilities;

1180 ~~3.4.~~ Medication errors that necessitate a clinical intervention other than monitoring; and

1181 4. ~~5.~~ A death or significant injury of a patient or staff member resulting from a physical  
1182 assault that occurs ~~within or on abortion facility grounds~~ its premises; and

1183 5. ~~Any other incident reported to the malpractice insurance carrier or in compliance with~~  
1184 ~~the federal Safe Medical Devices Act of 1990 (21 USC § 301 et seq. - Pub. L. No. 101-~~  
1185 ~~629).~~

1186 C. An abortion facility shall provide Notification notification of the events listed in subsection  
1187 B of this section ~~shall be required within~~ no more than 24 hours ~~of~~ after an event's occurrence.  
1188 Each notice shall contain the:

1189 1. ~~Abortion facility~~ facility's name;

1190 2. Type and circumstance of the event being reported;

1191 3. Date of the event; and

1192 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent  
1193 recurrence.

1194 D. Compliance with this section does not relieve ~~the~~ an abortion facility from complying with  
1195 any other applicable reporting or notification requirements, ~~such as those relating to law-~~  
1196 ~~enforcement or professional regulatory agencies.~~

1197 E. ~~The OLC shall maintain as confidential any Records records~~ that are confidential under  
1198 federal or state law ~~shall be maintained as confidential by the OLC and shall not be further~~  
1199 ~~disclosed by the OLC~~ disclose confidential records, except as required or permitted by law.

1200 F. ~~Abortion facilities~~ An abortion facility shall ensure that employees who are mandated to  
1201 report suspected child abuse or neglect ~~under § 63.2-1509 of the Code of Virginia or to report~~  
1202 suspected abuse, neglect, or exploitation of adults comply with the reporting requirements of  
1203 § 63.2-1509 or of § 63.2-1606 of the Code of Virginia.

1204 ~~Statutory Authority~~

1205 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~



1206 Historical Notes

1207 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
1208 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.

1209 Part VI

1210 Functional Safety and Maintenance

1211 **12VAC5-412-330. ~~Abortion facility security and safety. (Repealed.)~~**

1212 ~~The abortion facility shall develop, implement, and maintain policies and procedures to ensure~~  
1213 ~~safety within the abortion facility and on its grounds and to minimize hazards to all occupants.~~  
1214 ~~The policies and procedures shall include, but not be limited to:~~

1215 ~~1. Abortion facility security;~~

1216 ~~2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs,~~  
1217 ~~supplies, and services; and~~

1218 ~~3. Provisions for disseminating safety related information to employees and users of the~~  
1219 ~~abortion facility.~~

1220 Statutory Authority

1221 ~~§ 32.1-127 of the Code of Virginia.~~

1222 Historical Notes

1223 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
1224 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.

1225 **12VAC5-412-340. Disaster preparedness.**

1226 ~~A. Each abortion facility shall develop, implement, and maintain policies and procedures to~~  
1227 ~~ensure reasonable precautions are taken to protect all occupants from hazards of fire and other~~  
1228 ~~disasters. The policies and procedures shall include provisions for evacuation of all occupants in~~  
1229 ~~the event of a fire or other disaster.~~

1230 ~~B. An abortion facility that participates in community disaster planning shall establish plans,~~  
1231 ~~based on its capabilities, to meet its responsibilities for providing emergency care.~~

1232 Statutory Authority

1233 ~~§§ 32.1-12 and 32.1-127 of the Code of Virginia.~~

1234 Historical Notes

1235 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013.

1236 **12VAC5-412-350. Maintenance.**

1237 ~~A. The abortion facility's structure, its component parts, and all equipment, such as elevators,~~  
1238 ~~heating, cooling, ventilation, and emergency lighting, shall be kept in good repair and operating~~  
1239 ~~condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All~~  
1240 ~~wooden surfaces shall be sealed with nonlead-based paint, lacquer, varnish, or shellac that will~~  
1241 ~~allow sanitization.~~

1242 ~~B. When For any patient monitoring equipment is utilized at the abortion facility that the~~  
1243 ~~manufacturer recommends a preventative maintenance program, an abortion facility shall~~  
1244 ~~develop and implement a written preventive maintenance program shall be developed and~~  
1245 ~~implemented. that includes:~~

1246 ~~This equipment shall be checked and/or tested 1. Checking and testing equipment in~~  
1247 ~~accordance with manufacturer's specifications at periodic intervals, not less than annually,~~  
1248 ~~to ensure proper operation and a state of good repair.;~~

1249 ~~2. After repairs and/or alterations are made to any equipment, the equipment shall be~~  
1250 ~~thoroughly~~ Thoroughly tested testing equipment for proper operation after any repair or  
1251 alteration has been made before it the equipment is returned to service-; and  
1252 3. Maintaining Records records shall be maintained on each piece of equipment to indicate  
1253 its history of testing and maintenance.

1254 Statutory Authority

1255 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

1256 Historical Notes

1257 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
1258 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.

1259 **12VAC5-412-360. Firefighting equipment and systems. (Repealed.)**

1260 A. ~~Each abortion facility shall establish a monitoring program for the internal enforcement of~~  
1261 ~~all applicable fire and safety laws and regulations and shall designate a responsible employee for~~  
1262 ~~the monitoring program.~~

1263 B. ~~All fire protection and alarm systems and other firefighting equipment shall be inspected~~  
1264 ~~and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code~~  
1265 ~~(§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.~~

1266 C. ~~All corridors and other means of egress or exit from the building shall be maintained clear~~  
1267 ~~and free of obstructions in accordance with the current edition of the Virginia Statewide Fire~~  
1268 ~~Prevention Code (§ 27-94 et seq. of the Code of Virginia).~~

1269 Historical Notes

1270 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; repealed, Virginia  
1271 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.

1272 **Part VII**

1273 **Design and Construction**

1274 **12VAC5-412-370. Local and state codes and standards.**

1275 ~~Abortion facilities~~ All construction of new buildings and additions or major renovations to  
1276 existing buildings for occupancy as an abortion facility shall comply with all applicable state and  
1277 local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code  
1278 (13VAC5-63). In addition, abortion An abortion facilities facility shall comply with Part 1 and  
1279 Sections 3.1-1 through 3.1-8 and Section 3.7 Sections 1.1, 1.3, and 1.4 of Part 3 1 of the 2010  
1280 2018 Guidelines for Design and Construction of Health Care Outpatient Facilities of the Facilities  
1281 Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building  
1282 Code pursuant to § 32.1-127.001 of the Code of Virginia.

1283 ~~Entities operating as of the effective date of this chapter as identified by the department~~  
1284 ~~through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-~~  
1285 ~~120 or other means and that are now subject to licensure may be licensed in their current buildings~~  
1286 ~~if such entities submit a plan with the application for licensure that will bring them into full~~  
1287 ~~compliance with this provision within two years from the date of licensure.~~

1288 ~~In order to determine whether the abortion facility is in compliance with this provision, the~~  
1289 ~~commissioner may obtain additional information from the facility or its architect concerning the~~  
1290 ~~design and construction of the facility.~~

1291 Statutory Authority

1292 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

1293 Historical Notes

- 1294 Derived from Virginia Register Volume 29, Issue 19, eff. June 20, 2013; amended, Virginia  
1295 Register Volume 33, Issue 13, eff. March 22, 2017; Volume 35, Issue 17, eff. May 15, 2019.
- 1296 FORMS (12VAC5-412)
- 1297 Application for Abortion Facility Licensure License Issuance, OLC-3300-F (eff. 5/03) (rev.  
1298 8/19).
- 1299 Application for Abortion Facility License Renewal, OLC-3301-F (eff. 8/19).
- 1300 Abortion Facility Notification of Change, OLC-3302-F (eff. 8/19).
- 1301 OSHA Forms for Recording Work-Related Injuries and Illnesses, 2004.
- 1302 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-412)
- 1303 Guidelines for Design and Construction of Health-Care Outpatient Facilities, 2010 2018  
1304 Edition, Part 4 and Sections 3.1-4 through 3.1-8 and 3.7 1.1, 1.3, and 1.4 of Part 3 1, Facilities  
1305 Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C.
- 1306 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2015,  
1307 American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231-4596  
1308 (<https://eccguidelines.heart.org/index.php/circulation/cpr-ecc-guidelines-2/>)
- 1309 Sexually Transmitted Diseases Treatment Guidelines, 2015, Centers for Disease Control and  
1310 Prevention, U.S. Department of Health and Human Services  
1311 (<http://www.cdc.gov/std/tg2015/default.htm>)
- 1312 Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care,  
1313 Centers for Disease Control and Prevention, U.S. Department of Health and Human Services  
1314 ([http://www.cdc.gov/HAI/prevent/prevent\\_pubs.html](http://www.cdc.gov/HAI/prevent/prevent_pubs.html))
- 1315 Guideline for Disinfection and Sterilization of Healthcare Facilities, 2008, Centers for Disease  
1316 Control and Prevention, U.S. Department of Health and Human Services  
1317 (<https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>)
- 1318 Guidelines for Environmental Infection Control in Health-Care Facilities, 2003, Centers for  
1319 Disease Control and Prevention, U.S. Department of Health and Human Services  
1320 (<https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>)
- 1321 Guidelines for Hand Hygiene in Healthcare Settings, 2002, Centers for Disease Control and  
1322 Prevention, U.S. Department of Health and Human Services  
1323 (<https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>)
- 1324 Guideline for Infection Control in Healthcare Personnel, 1998, Centers for Disease Control  
1325 and Prevention, U.S. Department of Health and Human Services  
1326 (<https://stacks.cdc.gov/view/cdc/11563>)
- 1327 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in  
1328 Healthcare Settings, 2007, Centers for Disease Control and Prevention, U.S. Department of  
1329 Health and Human Services (https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-  
1330 guidelines-H.pdf)
- 1331 Standards for Ambulatory Care, Rights and Responsibilities of the Individual, 2011, The Joint  
1332 Commission, 1515 W. 22nd Street, Suite 1300W, Oak Brook, IL 60523, telephone  
1333 1-877-223-2866, email jrcustomerservice@pbd.com
- 1334 Bloodborne Pathogens - OSHA's Bloodborne Pathogens Standard, OSHA Fact Sheet and  
1335 Quick Reference Guide, 2011 U.S. Occupational Safety and Health Administration  
1336 ([https://www.osha.gov/OshDoc/data\\_BloodborneFacts/bbfact01.pdf](https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact01.pdf))

# 1.1 Introduction

*Appendix material, shown in shaded boxes at the bottom of the page, is advisory only.*

## ■ 1.1-1 General

### \*1.1-1.1 Application

The provisions of this chapter shall apply to all new construction and major renovation projects in outpatient facilities.

### \*1.1-1.2 Minimum Standards for New Facilities and Major Renovations

1.1-1.2.1 Each chapter in this document contains information intended as minimum standards for design and construction of new outpatient facilities and major renovations of existing outpatient facilities.

\*1.1-1.2.2 Standards set forth in the *Guidelines* shall be considered minimum and do not prohibit designing facilities and systems that exceed these requirements where desired by the governing body of the health care facility.

## ■ 1.1-2 New Construction

Projects with any of the following scopes of work shall be considered new construction and shall comply

with the requirements in the *Guidelines for Design and Construction of Outpatient Facilities*:

1.1-2.1 Site preparation for and construction of entirely new structures and systems

1.1-2.2 Structural additions to existing facilities that result in an increase of occupied floor area

1.1-2.3 Change in function in an existing space

## ■ 1.1-3 Renovation

### 1.1-3.1 General

#### 1.1-3.1.1 Compliance Requirements

1.1-3.1.1.1 Where renovation or replacement work is done in an existing facility, all new work or additions or both shall comply with applicable sections of the *Guidelines* and local, state, and federal codes.

1.1-3.1.1.2 Major renovation projects. Projects with either of the following scopes of work shall be considered a major renovation and shall comply with the requirements for new construction in the *Guidelines*

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**A1.1-1.1 Application.** This document covers outpatient facilities common to communities in the United States. Facilities with unique services will require special consideration. However, sections herein may be applicable for parts of any facility and may be used where appropriate.

### **A1.1-1.2 Performance vs. prescriptive standards.**

The minimum standards in the *Guidelines* have been established to obtain a desired performance result. Prescriptive limitations (such as exact minimum dimensions or quantities), when given, describe a condition that is commonly recognized as a practical standard for normal operation. For example, reference to a room or area by the patient, equipment, or staff activity that identifies its use avoids the

need for complex descriptions of procedures for appropriate functional programming.

**A1.1-1.2.2** The *Guidelines* text is not intended to restrict innovation and improvement in design or construction techniques. Accordingly, authorities adopting these standards as code may approve plans and specifications that contain deviations if they determine the applicable intent or objective of the standards has been met. For more information, see sections 1.1-3.1.2 (Exceptions) and 1.1-6 (Equivalency Concepts). Final implementation of *Guidelines* requirements may be subject to decisions of the authority having jurisdiction.

for *Design and Construction of Outpatient Facilities* to the extent possible as determined by the authority having jurisdiction:

- (1) A series of planned changes and updates to the physical plant of an existing facility
- (2) A renovation project that includes modification of an entire building or an entire area in a building to accommodate a new use or occupancy

**1.1-3.1.1.3 Conversion projects.** When a building is converted from one occupancy type to another, it shall comply with the new construction requirements.

#### 1.1-3.1.1.4 Building system projects

- (1) Only the altered, renovated, or modernized portion of an existing building system or individual component shall be required to meet the installation and equipment requirements in the *Guidelines*.

- (2) When such construction impairs the performance of the balance of an affected building system, upgrades to that system shall be required beyond the limits of the project to the extent required to maintain existing operational performance.

#### \*1.1-3.1.2 Exceptions

**1.1-3.1.2.1** Where major structural elements make total compliance impractical or impossible, exceptions shall be considered.

**\*1.1-3.1.2.2** Minor renovation or replacement work shall be permitted to be exempted from the requirements in Section 1.1-3.1.1 (Compliance Requirements) provided they do not reduce the level of health and safety in an existing facility.

#### \*1.1-3.1.3 Phased Projects

These standards shall not be construed as prohibiting a single phase of improvement.

- d. Cosmetic changes or upgrades to an existing space do not require an upgrade of the entire space.
- e. Improvements to a building system or a space that cannot reasonably meet the requirements of this document should be permitted provided the improvement does not impair other systems or functions of the building.
- f. Existing systems that are not in strict compliance with the provisions of this document should be permitted to continue in use, unless the AHJ has determined that such use constitutes a distinct hazard to life.
- g. Replacement of mechanical, electrical, plumbing, and fire protection equipment and infrastructure for maintenance purposes due to the failure or degraded performance of the components being replaced should be permitted provided the health and safety in the facility is maintained at existing levels.

**A1.1-3.1.3 Phased projects.** As an example, a facility may plan to replace a flammable ceiling with noncombustible material but lack funds to do other corrective work. However, the *Guidelines* standards are not intended as encouragement to ignore deficiencies when resources are available to correct life-threatening problems. See Section 1.1-6 (Equivalency Concepts).

In renovation projects and additions to existing facilities, only that portion of the total facility affected by the project shall be required to comply with applicable sections of the *Guidelines*.

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**A1.1-3.1.2 Nonconforming conditions.** When renovating or expanding existing facilities, it is not always practical or financially feasible to renovate or upgrade an entire existing facility to totally conform with requirements in the *Guidelines*. Therefore, authorities having jurisdiction are permitted to grant approval to renovate portions of a structure, space, or system if facility operations and patient safety in renovated and existing areas are not jeopardized by existing features of areas retained without complete corrective measures.

This recommendation does not guarantee an AHJ will grant an exception, but attempts to minimize restrictions on those improvements where total compliance would create an unreasonable hardship and would not substantially improve safety.

**A1.1-3.1.2.2 Exceptions for minor renovations or replacement work.** The project types described below are examples of minor renovations or replacement work that are not likely to reduce the level of health and safety in an existing facility.

- a. Routine repairs and maintenance to buildings, systems, or equipment. This project type does not require improvements to building features or systems.
- b. Replacement of building furnishings and movable or fixed equipment. These projects only require improvements to building systems that serve the equipment being replaced and only to the extent necessary to provide sufficient capacity for the replacement.
- c. Minor changes to the configuration of an existing space do not require upgrade of the entire space.

### 1.1-3.1.4 Temporary Waivers

When parts of an existing facility essential to continued overall facility operation cannot comply with particular standards during a renovation project, a temporary waiver of those standards shall be permitted as determined by the authority having jurisdiction if patient care and safety will not be jeopardized as a result.

### 1.1-3.2 Facilities Subject to Compliance with the *Guidelines*

#### 1.1-3.2.1 Affected Areas

In renovation projects and additions to existing facilities, only that portion of the total facility affected by the project shall be required to comply with applicable sections of the *Guidelines*.

#### \*1.1-3.2.2 Unaffected Areas

Existing portions of the facility and associated building systems that are not included in a renovation project but are essential to the functionality or code compliance of the renovated spaces shall, at minimum, comply with the applicable occupancy chapter of NFPA 101: *Life Safety Code*®.

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**A1.1-3.2.2** When construction is complete, the facility should satisfy functional requirements for its classification (e.g., outpatient surgery facility, dialysis center, etc.) in an environment that will provide acceptable care and safety to all occupants.

#### **A1.1-4.1 Design standards for accessibility.**

Users of outpatient health care facilities often have very different accessibility needs than the typical adult with disabilities addressed by federal model standards and guidelines that focus on design for the disabled. Patients in an outpatient facility, especially elderly patients, due to their stature, reach, and strength characteristics, may require the assistance of caregivers during transfer maneuvers. Designs that follow some prescriptive requirements in model accessibility standards place both older persons and caregivers at greater risk of injury than facility designs that would be considered noncompliant. Thus, flexibility in applying federal model guidelines should be permitted to support the use of assistive configurations that address the need for transfer assistance.

a. *Federal accessibility standards.* The Americans with Disabilities Act (ADA), which became law in 1990, extends comprehensive civil rights protection to individuals with disabilities. Under Titles II and III of the ADA, health care facilities are required to comply with the Americans with Disabilities Act Standards for Accessible Design for

### 1.1-3.3 Undiminished Safety

Renovations, including new additions, shall not diminish the safety level that existed prior to the start of the work. However, a safety level that exceeds that required for new facilities is not required.

### 1.1-3.4 Long-Range Improvement

1.1-3.4.1 Nothing in the *Guidelines* shall be construed as placing restrictions on a facility that chooses to do work or alterations as part of a phased long-range safety improvement plan.

1.1-3.4.2 All hazards to life and safety and all areas of noncompliance with applicable codes and regulations shall be corrected as soon as possible in accordance with a plan of correction.

## ■ 1.1-4 Government Regulations

### \*1.1-4.1 Design Standards for Accessibility

### \*1.1-4.2 Regulations for Earthquake-Resistant Design for New Buildings

alterations and new construction. The *Uniform Federal Accessibility Standards* (UFAS) also provides criteria for accessible design.

Individual federal agencies provide direction on applicable criteria to be used for the design of federal facilities.

b. *State and local accessibility standards.* Many state and local jurisdictions have adopted ICC A117.1: *Accessible and Usable Buildings and Facilities*, which is also available for use in providing quality design for the disabled. However, some state and local standards for accessibility and usability are more stringent than ADA, UFAS, or ICC/ANSI A117.1. Designers and owners, therefore, are responsible for verification of all applicable requirements.

**A1.1-4.2 Seismic standards.** The seismic provisions in ASCE/SEI 7: *Minimum Design Loads and Associated Criteria for Buildings and Other Structures* are based on the National Earthquake Hazards Reduction Program (NEHRP) provisions developed by the National Institute of Building Science's Building Seismic Safety Council for the Federal Emergency Management Agency. The following seismic standards are essentially equivalent to the ASCE/SEI 7 provisions:

- NEHRP Recommended Seismic Provisions for New Buildings and Other Structures*
- International Building Code*

**\*1.1-4.3 Flood Protection**

**\*1.1-4.4 National Standards for the Protection of Patient Health Information**

**1.1-4.5 Environmental Regulations**

**\*1.1-4.5.1 Federal Environmental Regulations**

**\*1.1-4.5.2 State and Local Environmental Regulations**

**■ 1.1-5 Building Codes and Standards**

**1.1-5.1 Safe Environment**

Every outpatient facility shall provide and maintain a safe environment for patients, staff, and the public.

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**A1.1-4.3** Executive Order 11988: Flood Protection, dated May 24, 1977, was issued to minimize financial loss from flood damage to facilities constructed with federal assistance.

**A1.1-4.4 HIPAA.** The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996. HIPAA consists of three major parts: the Privacy Rule, Transaction and Code Sets, and the Security Rule. The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the requirement of HIPAA. Within HHS, the Office of Civil Rights (OCR) has responsibility for enforcement of the HIPAA regulations. HHS may provide direction and clarification on the Privacy Rule and Security Rule.

HIPAA does not preempt or override laws that grant individuals even greater privacy protection. Additionally, covered entities are free to retain or adopt more protective policies or practices.

Ultimately, designers and owners are responsible for developing policies and procedures for verification of all applicable requirements that appropriately limit access to personal health information without sacrificing the quality of health care.

**A1.1-4.5.1** The principal federal environmental statutes likely to be applied to outpatient health care facilities include the following:

- a. Clean Air Act (CAA)
- b. National Environmental Policy Act (NEPA)
- c. Occupational Safety and Health Act (OSHA)
- d. Resource Conservation and Recovery Act (RCRA)
- e. Safe Drinking Water Act (SDWA)
- f. Superfund Amendments and Reauthorization Act (SARA)
- g. Toxic Substance Control Act (TSCA)

**A1.1-4.5.2 State and local environmental regulations.** The U.S. Department of Health and Human Services, U.S.

**\*1.1-5.2 Code Compliance**

**1.1-5.2.1** In the absence of state or local requirements, the project shall comply with approved nationally recognized building codes except as modified in the latest edition of NFPA 101: *Life Safety Code* and/or herein.

**\*1.1-5.2.2** Code material referred to in the *Guidelines* is contained in the edition of the referenced code current when this edition of the *Guidelines* was published.

**■ 1.1-6 Equivalency Concepts**

**\*1.1-6.1** Although the *Guidelines* is adopted as a regulatory standard by many jurisdictions, it is the intent of the document to permit and promote equivalency concepts.

Environmental Protection Agency (EPA) regional offices, and other federal, state, or local authorities having jurisdiction can provide information on state and local regulations pertaining to environmental pollution that may affect the design, construction, or operation of health care facilities, including management of industrial chemicals, pharmaceuticals, radionuclides, and waste as well as trash, noise, and traffic (including air traffic).

**A1.1-5.2** References made in the *Guidelines* to appropriate model codes and standards do not, generally, duplicate wording of the referenced codes. National Fire Protection Association (NFPA) standards are the basic standards of reference, but other codes and/or standards may be included as part of the *Guidelines*. See Section 1.1-8 (Codes, Standards, and Other Documents Referenced in the *Guidelines*).

**A1.1-5.2.2** The latest revision of code material is usually a clarification of intent and/or general improvement in safety concepts and may be used as an explanatory document for earlier code editions.

Questions of applicability should be addressed as the need occurs. The version of a code adopted by a jurisdiction may be different. Confirm the version adopted in a specific location with the authority having jurisdiction.

**A1.1-6.1 Equivalency concepts.** When contemplating equivalency allowances, the authority having jurisdiction may use a variety of expert sources to make equivalency findings and may document the reasons for approval or denial of equivalency to the requester.

Operational methods and procedures, design criteria, and/or clinical functional variations other than those that appear in the *Guidelines* may be approved by the authority having jurisdiction when the health care organization can effectively demonstrate that the intent of the *Guide-*

**1.1-6.2** Nothing in this document shall be construed as restricting innovations that provide an equivalent level of performance with these standards, provided that no other safety element or system is compromised to establish equivalency.

### ■ 1.1-7 English/Metric Measurements

**1.1-7.1** Where measurements are a part of this document, the English units given shall constitute the basic requirement. Approximately equivalent metric units are provided in parentheses after the English units.

**1.1-7.2** Either method shall be consistently used throughout design and construction of a project.

### ■ 1.1-8 Codes, Standards, and Other Documents Referenced in the Guidelines

Listed in this section are codes and standards that have been referenced in whole or in part in the various sections of this document as well as documents from which *Guidelines* concepts have been adopted.

Users of the *Guidelines* are encouraged to consult these publications for further information as may be necessary to achieve the final product. The editions cited are those available at the time of publication. Later editions will normally be acceptable where requirements for function and safety are not reduced; however, editions of different dates may have portions renumbered or retitled. Care must be taken to ensure that appropriate sections are used.

**U.S. Access Board** ([www.access-board.gov](http://www.access-board.gov)). *Also see* Americans with Disabilities Act. *Uniform Federal Accessibility Standards* (UFAS) ([www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-aba-standards/ufas](http://www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-aba-standards/ufas))

#### **Acoustical Society of America**

([www.acousticalsociety.org](http://www.acousticalsociety.org))

ANSI/ASA S2.71: *Guide to the Evaluation of Human Exposure to Vibration in Buildings* (2012)  
ANSI/ASA S3.5: *Methods for Calculation of the Speech Intelligibility Index* (2017)  
ANSI/ASA S12.9: *Quantities and Procedures for Description and Measurement of Environmental Sound, Part 2: "Measurement of Long-Term, Wide-Area Sound"* (2013)

#### **Acoustics Research Council, Acoustics Working Group** ([www.speechprivacy.org](http://www.speechprivacy.org))

"Sound & Vibration: Design Guidelines for Health Care Facilities" (2010) (<https://fgireadonly.madcad.com/library/FGI-SoundVibration-2010/>)

#### **American Association of Birth Centers**

([www.birthcenters.org](http://www.birthcenters.org))

*Standards for Birth Centers* (2016)

#### **American College of Emergency Physicians**

([www.acep.org](http://www.acep.org))

"Geriatric Emergency Department Guidelines" (<https://www.acep.org/geriEDguidelines/#sm.0002dkhsf298el310tl2bxtwo6drf>)

#### **American College of Obstetricians and Gynecologists** ([www.acog.org](http://www.acog.org)) and **American Academy of Pediatrics** ([www.aap.org](http://www.aap.org))

*Guidelines for Perinatal Care*, 8th ed. (2017)

#### **American College of Radiology** ([www.acr.org](http://www.acr.org))

Kanal, Emanuel, et al. "ACR Guidance Document on MR Safe Practices: 2013." *Journal of Magnetic Resonance Imaging* 37:501-30 (2013). ([www.ismrm.org/smrt/files/24011\\_ftf.pdf](http://www.ismrm.org/smrt/files/24011_ftf.pdf))

#### **American Institute of Steel Construction**

([www.aisc.org](http://www.aisc.org))

Design Guide 11: *Vibrations of Steel-Framed Structural Systems Due to Human Activity*, 2nd ed. (2016)

#### APPENDIX (continued)

*lines* is met and the variation does not reduce the safety or operational effectiveness of the facility below that required by the exact language of the *Guidelines*.

In all cases where specific limits are described, equivalent solutions will be acceptable if the authority having jurisdiction approves them as meeting the intent of the *Guidelines*.



## 1.1 INTRODUCTION

- American National Standards Institute**  
([www.ansi.org](http://www.ansi.org))  
ANSI S1.1: *Acoustical Terminology* (2013)
- American Society of Civil Engineers/Structural Engineering Institute** ([www.asce.org](http://www.asce.org))  
ASCE/SEI 7: *Minimum Design Loads and Associated Criteria for Buildings and Other Structures* (2016)
- American Society for Healthcare Engineering (ASHE)** ([www.ashe.org](http://www.ashe.org))  
*Health Facility Commissioning Guidelines* (2010)
- American Society of Heating, Refrigerating and Air-Conditioning Engineers** ([www.ashrae.org](http://www.ashrae.org))  
ASHRAE Guideline 12: *Minimizing the Risk of Legionellosis Associated with Building Water Systems* (2000)  
*ASHRAE Handbook—HVAC Applications* (2017)  
ANSI/ASHRAE/IES Standard 90.1: *Energy Standard for Buildings Except Low-Rise Residential Buildings* (2016)  
ANSI/ASHRAE/ASHE Standard 170: *Ventilation of Health Care Facilities* (2017)  
ANSI/ASHRAE Standard 188: *Legionellosis: Risk Management for Building Water Systems* (2015)  
ANSI/ASHRAE/USGBC/IES 189.1: *Standard for the Design of High-Performance Green Buildings, Except Low-Rise Residential Buildings* (2014)  
ANSI/ASHRAE/ASHE Standard 189.3: *Design, Construction, and Operation of Sustainable High-Performance Health Care Facilities* (2017)
- American Society of Mechanical Engineers** ([www.asme.org](http://www.asme.org))  
ANSI/ASME A17.1/CSA B44: *Safety Code for Elevators and Escalators* (2016)  
ANSI/ASME A17.3: *Safety Code for Existing Elevators and Escalators* (2015)
- American Society for Testing and Materials**  
([www.astm.org](http://www.astm.org))  
D1193-06: *Standard Specification for Reagent Water* (2011)  
E1130-16: *Standard Test Method for Objective Measurement of Speech Privacy in Open Plan Spaces Using Articulation Index* (2016)  
E2638-10: *Standard Test Method for Objective Measurement of the Speech Privacy Provided by a Closed Room* (2010)
- American Water Works Association** ([www.awwa.org](http://www.awwa.org))  
AWWA M14: *Backflow Prevention and Cross-Connection Control: Recommended Practices*, 4th ed. (2015)
- Americans with Disabilities Act**, U.S. Department of Justice, Civil Rights Division ([www.ada.gov](http://www.ada.gov)). Also see U.S. Access Board.  
*ADA Standards for Accessible Design* (2010)
- Association for the Advancement of Medical Instrumentation** ([www.aami.org](http://www.aami.org))  
ANSI/AAMI/ISO 13959: *Water for Hemodialysis and Related Therapies* (2014)  
ANSI/AAMI/ISO 26722: *Water Treatment Equipment for Hemodialysis and Related Therapies* (2014)
- Business and Institutional Furniture Manufacturers Association** ([www.bifma.org](http://www.bifma.org))  
Furniture standards (<http://www.bifma.org/standards/index.html>)
- The Center for Health Design** ([www.healthdesign.org](http://www.healthdesign.org))  
Calkins, M. P., et al. "Contribution of the Designed Environment to Fall Risk in Hospitals" (2012). (<https://www.healthdesign.org/chd/research/contribution-designed-environment-fall-risk-hospitals>)  
Joseph, A., et al. "Designing for Patient Safety: Developing Methods to Integrate Patient Safety Concerns in the Design Process" (2012). (<https://www.healthdesign.org/chd/research/designing-patient-safety-developing-methods-integrate-patient-safety-concerns-design-pr>)  
Safety Risk Assessment Toolkit ([www.healthdesign.org/sra](http://www.healthdesign.org/sra))
- Centers for Disease Control and Prevention**  
([www.cdc.gov](http://www.cdc.gov))  
*Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 5th ed. (December 2009) ([www.cdc.gov/biosafety/publications/index.htm](http://www.cdc.gov/biosafety/publications/index.htm))  
"Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005." *Morbidity and Mortality Weekly Report* (MMWR) 2005:54 (No. RR-17). ([www.cdc.gov/mmwr/PDF/rr/rr5417.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf))

- “Guidelines for Environmental Infection Control in Health-Care Facilities” (2003) (<https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html>)
- “Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets,” Appendix A to *Biosafety in Microbiological and Biomedical Laboratories* ([www.cdc.gov/biosafety/publications/index.htm](http://www.cdc.gov/biosafety/publications/index.htm))
- Centers for Medicare & Medicaid Services** ([www.cms.gov](http://www.cms.gov))
- Clinical Laboratory Improvement Amendments (CLIA) ([www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html))
- Concrete Reinforcing Steel Institute (CRSI)** ([www.crsi.org](http://www.crsi.org))
- Design Guide for Vibrations of Reinforced Concrete Floor Systems* (2014)
- U.S. Department of Health and Human Services** ([www.hhs.gov](http://www.hhs.gov)) and **U.S. Department of Justice** ([www.justice.gov](http://www.justice.gov))
- “Americans with Disabilities Act: Access to Medical Care for Individuals with Mobility Disabilities” ([https://www.ada.gov/medicare\\_mobility\\_ta/medicare\\_ta.htm](https://www.ada.gov/medicare_mobility_ta/medicare_ta.htm))
- U.S. Department of Housing and Urban Development** ([www.hud.gov](http://www.hud.gov))
- The Noise Guidebook* (2009) (<https://www.hudexchange.info/resource/313/hud-noise-guidebook>)
- U.S. Department of Veterans Affairs, National Center for Patient Safety** ([www.va.gov](http://www.va.gov))
- “Falls Prevention Toolkit” (<https://www.patientsafety.va.gov/professionals/onthejob/falls.asp>)
- Environmental Protection Agency** ([www.epa.gov](http://www.epa.gov))
- “Safe Storage and Handling of Swimming Pool Chemicals” (2001) (<https://www.epa.gov/rmp/chemical-safety-alert-safe-storage-and-handling-swimming-pool-chemicals>)
- Facility Guidelines Institute** ([www.fgiguideelines.org](http://www.fgiguideelines.org))
- Hunt, J. M., and D. M. Sine. “Behavioral Health Design Guide” (2017)
- “Patient Handling and Movement Assessments: A White Paper” (2010)
- Federal Aviation Administration** ([www.faa.gov](http://www.faa.gov))
- Advisory Circular 150/5390-2C: *Heliport Design* (2012) ([www.faa.gov/documentLibrary/media/Advisory\\_Circular/150\\_5390\\_2c.pdf](http://www.faa.gov/documentLibrary/media/Advisory_Circular/150_5390_2c.pdf))
- Federal Emergency Management Agency** ([www.fema.gov](http://www.fema.gov))
- Executive Order 11988: Floodplain Management  
FEMA P-750: *NEHRP [National Earthquake Hazards Reduction Program] Recommended Seismic Provisions for New Buildings and Other Structures* (2009) ([www.fema.gov/media-library-data/20130726-1730-25045-1580/femap\\_750.pdf](http://www.fema.gov/media-library-data/20130726-1730-25045-1580/femap_750.pdf))
- Green Guide for Health Care™** ([www.gghc.org](http://www.gghc.org))
- Green Building Initiative**
- ANSI/GBI 01: *Green Building Assessment Protocol for Commercial Buildings* (2010)
- Illuminating Engineering Society** ([www.ies.org](http://www.ies.org))
- ANSI/IES RP-28: *Lighting and the Visual Environment for Seniors and the Low Vision Population* (2016)
- ANSI/IES RP-29: *Lighting for Hospitals and Healthcare Facilities* (2016)
- International Association for Healthcare Security & Safety** ([www.iahss.org](http://www.iahss.org))
- Security Design Guidelines for Healthcare Facilities* (2016)
- International Code Council** ([www.iccsafe.org](http://www.iccsafe.org))
- ICC A117.1: *Accessible and Usable Buildings and Facilities* (2017)
- International Building Code* (2018)
- International Green Construction Code* (2012)
- International Electrotechnical Commission** ([www.iec.ch](http://www.iec.ch))
- IEC Standard 60601-2-33: *Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis* (2010)

**International Safety Equipment Association**

(www.safetyequipment.org)

ANSI/ISEA Z358.1: *American National Standard for Emergency Eyewash and Shower Equipment* (2014)**The Joint Commission** (www.jointcommission.org)

“Improving Patient and Worker Safety: Opportunities for Synergy, Collaboration, and Innovation” (2012)

**National Council on Radiation Protection & Measurements** (www.ncrponline.org)Report No. 102: *Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)* (1989)Report No. 116: *Limitation of Exposure to Ionizing Radiation* (1993)Report No. 144: *Radiation Protection for Particle Accelerator Facilities* (2003)Report No. 147: *Structural Shielding Design for Medical X-Ray Imaging Facilities* (2004)Report No. 151: *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities* (2005)**National Fire Protection Association** (www.nfpa.org)NFPA 10: *Standard for Portable Fire Extinguishers* (2018)NFPA 13: *Standard for the Installation of Sprinkler Systems* (2016)NFPA 30: *Flammable and Combustible Liquids Code* (2015)NFPA 70: *National Electrical Code*® (2017)NFPA 72: *National Fire Alarm and Signaling Code* (2016)NFPA 82: *Standard on Incinerators and Waste and Linen Handling Systems and Equipment* (2014)NFPA 90A: *Standard for the Installation of Air-Conditioning and Ventilating Systems* (2018)NFPA 99: *Health Care Facilities Code* (2015)NFPA 101: *Life Safety Code*® (2015)NFPA 110: *Standard for Emergency and Standby Power Systems* (2016)NFPA 111: *Standard on Stored Electrical Energy Emergency and Standby Power Systems* (2016)NFPA 400: *Hazardous Materials Code* (2016)**National Institute of Occupational Safety and Health** (www.cdc.gov/niosh)

DHHS (NIOSH) Publication 97-111: “Selecting,

Evaluating, and Using Sharps Disposal Containers” (January 1998) (www.cdc.gov/niosh/docs/97-111)

**New York State Office of Mental Health**

“Patient Safety Standards, Materials and Systems Guidelines,” 18th ed. (2017) (https://www.omh.ny.gov/omhweb/patient\_safety\_standards)

**Nuclear Regulatory Commission** (www.nrc.gov/reading-rm/doc-collections/cfr/)*Code of Federal Regulations*, Title 10—Energy, Chapter 1—Nuclear Regulatory Commission

- Part 20 (10 CFR 20), Standards for Protection Against Radiation
- Part 35 (10 CFR 35), Medical Use of Byproduct Material

**Occupational Safety and Health Administration,**

U.S. Department of Labor (www.osha.gov)

*Code of Federal Regulations*, Title 29—OSHA

Regulations, Part 1910 (29 CFR 1910):

*Occupational Safety and Health Standards* (www.osha.gov/pls/oshaweb/owastand.display\_standard\_group?p\_toc\_level=1&cp\_part\_number=1910)**U.S. Pharmacopeial Convention** (www.usp.org)*U.S. Pharmacopeia-National Formulary* (USP-NF)

general chapters:

- <795>: Pharmaceutical Compounding—Nonsterile Preparations
- <797>: Pharmaceutical Compounding—Sterile Preparations
- <800>: Hazardous Drugs—Handling in Healthcare Settings
- <1066>: Physical Environments that Promote Safe Medication Use

**The Robert Wood Johnson Foundation**

Joynt, J., and B. Kimball, “Innovative Care Delivery Models: Identifying New Models that Effectively Leverage Nurses” (Health Workforce Solutions, 2008). For a summary, see “New Website Profiles 24 Innovative Nursing-Driven Models of Health Care Delivery” (https://www.rwjf.org/en/library/research/2009/03/new-web-site-profiles-24-innovative-nursing-driven-models-of-hea.html).

**Society for Experiential Graphic Design** (segd.org)

“Universal Symbols in Health Care: Developing a

Symbols-Based Wayfinding System: Implementation Guidebook” ([https://segd.org/sites/default/files/segd\\_hj\\_00\\_full\\_workbook\\_1.pdf](https://segd.org/sites/default/files/segd_hj_00_full_workbook_1.pdf))

# 1.3 Site

*Appendix material, shown in boxes at the bottom of the page, is advisory only.*

## ■ 1.3-1 General

### 1.3-1.1 Application

The provisions of this chapter shall apply to all outpatient facility projects.

## ■ \*1.3-2 Location

### \*1.3-2.1 Availability of Transportation

Where site design is part of the project scope, building and parking locations, adjacencies, and access points shall be integrated with on-site and off-site vehicular and pedestrian patterns and transportation services.

### \*1.3-2.2 Security

Outpatient facilities shall have security measures for patients, families, personnel, and the public that are

consistent with the conditions and risks inherent in the location of the facility.

### 1.3-2.3 Availability of Utilities

Outpatient facilities shall have access to utilities (water, gas, sewer, electricity) to meet requirements in the facility chapters in this document.

#### 1.3-2.3.1 Water Supply

The water supply shall have the capacity to provide for normal usage and to meet fire-fighting requirements.

#### 1.3-2.3.2 Electricity

The electricity provided shall be of stable voltage and frequency.

## ■ \*1.3-3 Site Features

### A1.3-3 Landscape design features

- a. Outdoor water features. Where provided, open water features should be equipped to safely manage water quality to protect the public from infectious or irritating aerosols.
- b. Landscape and gardens. Use and availability of views and other access to nature should be considered in the design of the physical environment, as indicated in Section 1.2-5.4.2 (Views of and Access to Nature). Subject to site constraints, health care organizations should consider opportunities to promote physical activity and/or outdoor uses for staff and visitors.

Therapeutic uses of landscape elements such as healing gardens or natural landscapes should be integrated into health care facilities wherever possible. Consider a range of uses, including roof gardens, horticulture therapy gardens, walking trails, etc., to provide diverse outdoor experiences.

Indigenous and low maintenance landscape materials and plants should be specified to reduce the use of water for irrigation and the life cycle costs of maintenance. See appendix section A1.2-6.2.1.4-d (Potable water quality and conservation—Irrigation water) for more information.

## APPENDIX

**A1.3-2 Access.** Site design should encourage access by all facility users by integrating building and parking locations to support individuals arriving on foot, bicycle, and public transportation as well as in a vehicle.

**A1.3-2.1 Availability of transportation.** Facilities should be located convenient to public transportation where available, unless acceptable alternate methods of transportation to public facilities and services are provided. The transportation plan should support alternatives to fossil-fueled single-occupancy vehicles, including preferred van/ carpool parking, bike parking and changing facilities, alternative vehicle fueling stations, and nearby transit access.

**A1.3-2.2 Security plan.** The development of a site security plan should reflect the principles of crime prevention through environmental design (CPTED). More detailed information can be found in *Security Design Guidelines for Healthcare Facilities*, published by the International Association for Healthcare Security & Safety. For information on development of a project security plan, see Section 1.2-4.7 (Security Risk Assessment).

**1.3-3.1 Signage**

Site signage shall be provided to direct people unfamiliar with the facility to parking areas and entrances.

**\*1.3-3.2 Lighting**

Site lighting shall be provided for the patient path of travel.

**1.3-3.3 Roads and Walkways****1.3-3.3.1 Roads**

Paved roads shall be provided within the property for access to all entrances and to loading areas.

**1.3-3.3.2 Pedestrian Walkways**

Paved walkways shall be provided for pedestrian traffic.

**1.3-3.4 Parking****\*1.3-3.4.1 General**

**1.3-3.4.1.1** Outpatient facilities shall provide parking capacity to meet the needs of patients, personnel, and the public.

**1.3-3.4.1.2** Parking needs shall be evaluated for each new facility, major addition, or major change in function.

**1.3-3.4.2** In the absence of local parking standards or ordinances, refer to individual chapters governing specific facility types for required parking capacity. In all instances, review individual chapters for requirements

for dedicated emergency vehicle, patient transfer, and service parking.

**\*1.3-3.4.3** Unless otherwise prohibited by individual chapters, reduction of parking requirements shall be permitted, as acceptable to local authorities having jurisdiction.

**\*1.3-3.5 Emergency Access**

**1.3-3.5.1** Freestanding emergency facilities shall have the emergency access well marked to facilitate entry from public roads or streets serving the site.

**1.3-3.5.2** Access to emergency services shall be located to incur minimal damage from floods and other natural disasters. For additional information, see appendix section A1.2-6.5-b (Design to support emergency preparedness and management—Flood protection).

**1.3-3.6 Transfer Support Features****1.3-3.6.1 Heliports**

Where heliports are provided, they shall meet the requirements in this section.

**\*1.3-3.6.1.1** Heliport landing pads and flight approach paths shall comply with applicable regulations governing placement, safety features, lighting, fencing, and other site elements.

**\*1.3-3.6.1.2** Facilities with heliports shall incorporate noise mitigation strategies to meet the acoustic requirements outlined in the *Guidelines*. See Section 1.2-6.1 (Acoustic Design).

**A1.3-3.5** Other vehicular or pedestrian traffic should not conflict with access to the emergency services.

**A1.3-3.6.1.1** Refer to FAA Advisory Circular 150/5390-2C: *Heliport Design* for information on design of heliports for health care facilities.

**A1.3-3.6.1.2 Noise considerations for heliports.** The location of heliports on a health care facility site should be evaluated for noise impacts on the facility and community. Heliports can be located at ground level on the site or on a building roof. Helicopter noise at nearby residences and at the health care facility buildings requires special consideration under the following conditions:

- a. Where helicopter sound levels exceed 80 dBA at nearby residences. (This generally occurs when the slant distance from the helicopter

**APPENDIX**

**A1.3-3.2 Site lighting.** Lighting controls should permit zoned operation, allowing facilities to provide multiple lighting levels or to designate night parking nearer the building. Lighting design for the site, roadway, and parking lots should control glare and minimize light pollution of the night sky or surrounding properties.

**A1.3-3.4.1** Dedicated patient and staff parking should be provided where possible. Additional parking considerations should be provided for emergency services patients.

**A1.3-3.4.3** Parking requirements may be reduced in locations convenient to pedestrians, public transportation, or public parking facilities or where carpool, shuttle bus, or other alternative transportation arrangements have been developed.

## ■ \*1.3-4 Environmental Pollution Control

The design, construction, renovation, expansion,

### APPENDIX (continued)

- to the residence is 700 feet (213.36 meters) or less. Slant distance is the minimum distance in feet directly between a residence and a helicopter at its closest approach. Patient transport agencies expecting to use the heliport can provide guidance on slant distances for various helicopter approaches. Helicopter approaches to a heliport are influenced by wind direction and locations of nearby buildings.)
- b. Where the number of helicopter operations exceeds three per day
  - c. Where there are likely to be more than two helicopter flights per week between the hours of 10:00 p.m. and 7:00 a.m.
  - d. Where the slant distance to the nearest residence is 1,000 feet (304.80 meters) or less
  - e. Where the heliport is atop a building. (Special attention to the design of building windows is required when helicopters will land on the building. Sound levels at windows directly below the flight path to the roof can exceed 90 dBA and may require special acoustical glazing.)
  - f. Where the heliport is located on the ground and situated so that helicopters will approach within 500 feet (152.40 meters) of a building
  - g. Where military helicopters, which often are larger than civilian medevac helicopters, are expected to use the heliport more than once per week

Helicopters, particularly military helicopters and large civilian helicopters, can induce low frequency vibration in building windows and facades that can vibrate building fixtures and furnishings. Such vibration is generally not acceptable; however, it can be difficult to predict. As a guide, unacceptable vibration can occur when low frequency sound levels (16–31 Hz) exceed 75 dB and when helicopters are within 500 feet (152.40 meters) of buildings.

**A1.3-4 Environmental pollution control.** The design, construction, renovation, expansion, equipment, and operation of outpatient facilities are subject to provisions of several federal environmental pollution control laws and associated agency regulations. In addition, many states have enacted statutes and regulations that are substantially equivalent to or more stringent than federal regulations, thereby implementing national priorities under local jurisdiction as well as incorporating local priorities (e.g., air quality related to incinerators and gas sterilizers; underground storage tanks; hazardous materials and waste storage, handling, and disposal; storm water control; medical waste storage and disposal; and asbestos in building materials). Consult the appropriate U.S. Department of Health and Human Services (DHHS) and U.S. Environmental Protection Agency (EPA) regional offices and any other federal, state, or local authorities having jurisdiction for applicable state and local regulations pertaining to environmental pollution that may affect the design, construction, or operation of the outpatient

equipment, and operation of outpatient facilities shall meet the provisions of applicable government environmental pollution control laws and associated agency regulations.

facility, including management of industrial chemicals, pharmaceuticals, radionuclides, and waste from the facility, as well as trash, noise, and traffic (including air traffic).

- a. *Permits.* Outpatient facilities regulated under federal, state, and local environmental pollution laws may be required to support permit applications with appropriate documentation of proposed impacts and mitigations.

Such documentation typically is reported in an environmental impact statement (EIS) with respect to potential effects on the environment and in a health risk assessment (HRA) with respect to potential impacts on public health. The HRA may constitute a part or an appendix of the EIS. The scope of the EIS and the HRA typically is determined in consultation with appropriate regulatory agency personnel and, if required, includes a meeting to which members of the interested public are invited to express their concerns.

Once the EIS and/or HRA scope has been established, a protocol document should be prepared for agency approval.

- The protocol should describe the scope and procedures to be used to conduct the assessment(s).
- The EIS and/or HRA should be prepared in accordance with a final protocol approved by the appropriate agency or agencies. Approval is most likely to be obtained in a timely manner and with minimum revisions if standard methods are initially proposed for use in the EIS and/or HRA. Standard methods suitable for specific assessment tasks are set forth in EPA documents.

- b. *Mercury elimination.* Mercury encountered during construction or demolition of outpatient facilities (e.g., mercury accumulated in P-traps, air-handling units, sumps, etc.) should be collected and properly stored, recycled, or disposed of.

Many states and municipalities have enacted bans on the sale of mercury-containing devices and equipment. Outpatient facility projects should comply with local codes and standards.

In new construction, mercury-containing equipment, including thermostats, switching devices, CFL lamps, and other building system sources should not be used.

For renovation of outpatient facilities, health care organizations should develop a plan to phase out mercury-containing sources and upgrade current mercury-containing lamps to low- or no-mercury lamp technology.

- c. *Release of toxic substances from equipment.* Equipment should minimize the release of chlorofluorocarbons (CFCs) and any potentially toxic substances that may be used in their place. For example, the design of air-conditioning systems should specify CFC alternatives and recovery systems as may be practicable.

# 1.4 Equipment

*Appendix material, which appears in shaded boxes at the bottom of the page, is advisory only.*

## ■ \*1.4-1 General

### 1.4-1.1 Application

This chapter shall apply to all outpatient facility projects.

### 1.4-1.2 Equipment List

An equipment list shall be developed and maintained throughout the design development process and included in the contract documents to assist in overall coordination of the acquisition, installation, and relocation of equipment.

**1.4-1.2.1** The equipment list shall include all items of equipment necessary to operate the facility.

**1.4-1.2.2** The equipment list shall include the classifications identified in Section 1.4-2 (Equipment Classification).

**1.4-1.2.3** The equipment list shall specify whether the items are:

**1.4-1.2.3.1** New owner-furnished and owner-installed

**1.4-1.2.3.2** New owner-furnished and contractor-installed

**1.4-1.2.3.3** New contractor-furnished and contractor-installed

**1.4-1.2.3.4** Existing salvaged, reconditioned, relocated, and owner-installed

**1.4-1.2.3.5** Existing salvaged, reconditioned, relocated, and contractor-installed

**1.4-1.2.3.6** Existing salvaged, relocated, and owner-installed

**1.4-1.2.3.7** Existing salvaged, relocated, and contractor-installed

**1.4-1.2.3.8** Not-in-contract

### 1.4-1.3 Documentation Requirements

#### \*1.4-1.3.1 Provisions for Equipment

**1.4-1.3.1.1** The drawings or other project documentation shall indicate provisions for installation of fixed or movable equipment that requires dedicated building services or special structures and illustrate how the major equipment will function in the space.

**1.4-1.3.1.2** An equipment utility location drawing shall be produced to locate all services for equipment that requires floor space and mechanical connections.

#### \*1.4-1.3.2 Not-in-Contract (NIC) Equipment

**1.4-1.3.2.1 Design development documents.** Equipment that is not included in the construction contract

#### APPENDIX

**A1.4-1** Equipment will vary to suit individual construction projects; therefore, careful planning is important to assure the equipment chosen is accommodated in the project design.

**A1.4-1.3.1 Cable placement.** Placement of cables from receptacles to portable equipment should be considered during design so that circulation and safety can be maintained.

**A1.4-1.3.2 NIC equipment.** Some equipment may not be included in the construction contract but may require coordination during construction.



but requires mechanical or electrical service connections or construction modifications shall be identified on the design development documents to facilitate coordination with the architectural, mechanical, and electrical phases of construction.

**1.4-1.3.2.2 Construction documents.** All equipment shall be identified in the construction documents as owner-provided or not-in-contract for purposes of coordination.

#### 1.4-1.3.3 Final Equipment Selections

When final selections are made, the construction documents shall be revised to show the equipment placed in service and physical, structural, and infrastructure requirements needed to support the equipment.

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#### A1.4-2 Equipment types

- a. *Building service equipment.* Building service equipment includes items such as heating, ventilation, and air-conditioning equipment; electrical power distribution equipment; emergency power generation equipment; energy/utility management systems; conveying systems; security systems and devices; and other equipment with a primary function of building service (e.g., humidification equipment, filtration equipment, chillers, boilers, fire pumps, etc.).
- b. *Fixed equipment.* Fixed equipment includes items that are permanently affixed to the building or permanently connected to a service distribution system that is designed and installed for the specific use of the equipment. Fixed equipment may require special structural designs, mechanical and electrical provisions, shielding, or other considerations.
  - Fixed medical equipment. This includes items such as fume hoods, sterilizers, imaging equipment, radiotherapy booths, lithotripters, hydrotherapy tanks, audiometry testing chambers, surgical and special procedure lights, ceiling-mounted surgical booms, and ceiling-mounted mechanical patient lifting devices.
  - Fixed nonmedical equipment. This includes items such as walk-in refrigerators, kitchen cooking equipment, serving lines, conveyors, mainframe computers, laundry, and similar equipment.
- c. *Movable equipment.* Movable equipment includes items that require floor space but are portable. Examples are items such as wheeled equipment (e.g., beds), portable items, office-type furnishings, and diagnostic or monitoring equipment. Movable equipment may require special structural design or access, mechanical and electrical connections, shielding, or other considerations.
  - Movable medical equipment. This includes items such as portable X-ray, electroencephalogram (EEG), and

#### ■ \*1.4-2 Equipment Classification

Equipment to be used in projects shall be classified as building service equipment, fixed equipment, or movable equipment.

#### ■ 1.4-3 Equipment Requirements

##### \*1.4-3.1 Major Technical Equipment

Coordination of locations for and installation of major technical equipment shall be documented to facilitate coordination between the governing body, building designer, installer, construction contractors, and others.

electrocardiogram (EKG) equipment; dialysis machines; treadmill and exercise equipment; pulmonary function equipment; operating tables; laboratory centrifuges; examination and treatment tables; and similar equipment.

- Movable non-medical equipment. This includes items such as personal computer stations, printers and copiers, patient care area furnishings, food service trucks, case carts and distribution carts, and other portable equipment.
- Furniture and equipment size. Furnishings and equipment (e.g., beds, exam tables, exam chairs, gurneys) impact clearance requirements. As furnishings and equipment vary based on clinical needs, patient size, manufacturer, and model, it is important that furnishings and equipment be selected for planning purposes by the operator of the facility.

##### A1.4-3.1 Major technical equipment

- a. Major technical equipment includes specialized equipment (medical or nonmedical) that is customarily installed by the manufacturer or vendor. Examples of major technical equipment include items such as X-ray and other imaging equipment, radiation therapy equipment, lithotripters, audiometry testing chambers, computers, pneumatic tube systems, and similar items.
- b. Major technical equipment may require special structural designs, mechanical and electrical provisions, clearances, or other considerations. The facility design should accommodate paths of travel for easy removal and replacement of large equipment such as linear accelerators, CT scan equipment, and MRI equipment.
- c. The placement and size of major technical equipment may affect functional aspects of the space where the equipment is located, such as required clearances and access to functional components (e.g., control panels, light switches, etc.).

**\*1.4-3.2 Electronic Equipment**

Computerized equipment, such as all imaging equipment/modalities, multiphasic laboratory analyzing units, and computers, shall be protected from power surges and spikes that might damage the equipment or software programs.

## ■ 1.4-4 Space Requirements for Equipment

**\*1.4-4.1 Fixed Equipment and Building Service Equipment**

Where building service equipment is part of the project scope, space for accessing and servicing building service and other fixed equipment shall be provided on any side of the equipment required by the manufacturer.

**1.4-4.2 Movable and Portable Equipment**

**1.4-4.2.1** The following shall be considered during facility planning and design:

**1.4-4.2.1.1** Locations for placement of equipment requiring floor space and mechanical connections

**1.4-4.2.1.2** Locations for the power required for electrical connections where portable equipment is expected to be used

**1.4-4.2.2** See Section 1.4-1.3.1 (Provisions for Equipment) for drawing requirements.

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**A1.4-3.2 Constant power for electronic equipment.** Consideration should be given to the addition of an uninterruptible power supply where loss of data input might compromise patient care.

**A1.4-4.1 Space requirements for fixed equipment and building service equipment.** Space should be provided to support use, access, and servicing of data, communications, and distribution/control rooms; servers; printers; and ancillary equipment or as required by other adopted codes.



# COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. Norman Oliver, MD, MA  
STATE HEALTH COMMISSIONER

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

## MEMORANDUM

DATE: July 15, 2019

TO: Virginia State Board of Health

FROM: Robert A. K. Payne, JD  
Director, Office of Licensure and Certification

SUBJECT: Final Regulatory Action – Updating the chapter following periodic review of State Medical Facilities Plan (12VAC 5-230)

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Enclosed for your review is the Final Regulatory Action for the State Medical Facilities Plan (12VAC5-230).

This regulatory action will update the State Medical Facilities Plan in order to correct the definition of “cardiac catheterization” and add definitions for “simple,” “complex” and “diagnostic” cardiac catheterizations as well as updating the definition of a Diagnostic Equivalent Procedure to reflect the differentiation. New review criteria will also be added for projects relating to those services and the new differentiation. The action will also make the appropriate changes to the occupancy standard utilized for determining the need for new nursing home beds.

The Board of Health is requested to approve the Final Regulations. Should the Board of Health approve the Final Regulations, they will be submitted for Executive Branch review, as specified by the Administrative Process Act. Following Executive Branch review and approval, the regulations will be published in the *Virginia Register of Regulations* and on the Virginia Regulatory Town Hall website and a 30 day final adoption period will begin. The amendments to the State Medical Facilities Plan will become effective at the close of the final adoption period.



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

## Final Regulation Agency Background Document

|   |   |
|---|---|
| <b>Agency name</b>                                    | Virginia Board of Health                                |
| <b>Virginia Administrative Code (VAC) citation(s)</b> | 12 VAC 5-230  |
| <b>Regulation title(s)</b>                            | State Medical Facilities Plan                           |
| <b>Action title</b>                                   | Update the regulatory chapter following periodic review |
| <b>Date this document prepared</b>                    | July 15, 2019   |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

This regulatory action will update the State Medical Facilities Plan to correct the definition of “cardiac catheterization” and add definitions for “simple therapeutic”, “complex therapeutic”, and “diagnostic” cardiac catheterizations, as well as update the definition of a Diagnostic Equivalent Procedure to reflect the differentiation between the types of cardiac catheterization. New review criteria will also be added for projects relating to cardiac catheterization and the new differentiation. The action will also make the appropriate changes to the occupancy standard utilized for determining the need for new nursing home beds.

### 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.*

“Board” means the State Board of Health  
“SMFP” means State Medical Facilities Plan

### Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

---

### Mandate and Impetus

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.*

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This final action follows the Proposed Stage published in the *Register* on January 8, 2018. The impetus that prompted the initiation of the action was the 2014 Task Force review of the SMFP.

### Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity’s overall regulatory authority.*

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The regulation is promulgated under the authority of § 32.1-102.2 of the Code of Virginia. Section 32.1-102.2 of the Code of Virginia requires the Board to promulgate regulations that establish concise procedures for the prompt review of applications for certificates of public need consistent with Article 1.1 of Chapter 4 of Title 32.1. Section 32.1-102.2 of the Code of Virginia further requires the Board to promulgate regulations which establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas.

### Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it’s intended to solve.*

---

It is necessary to amend these regulations to update definitions within the regulations related to cardiac catheterization and update the occupancy standard utilized for determining the need for new nursing home beds.

Updated regulations to implement the State Medical Facilities Plan are essential to protect the health of Virginians as the Board has determined that excess capacity or underutilization of medical facilities are

detrimental to both cost effectiveness and quality of medical services in Virginia. The Board seeks to promote the availability and accessibility of proven technologies through planned geographical distribution of medical facilities; the development and maintenance of services and access to those services by all Virginians who need them without respect to their ability to pay; the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs. The Board wishes to discourage the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.

## Substance

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

This regulatory action:

- Amends the existing definitions for “Cardiac Catheterization” and “Diagnostic Equivalent Procedure (DEP)”;
- Adds new definitions for “Diagnostic Cardiac Catheterization”, “Complex Therapeutic Cardiac Catheterization”, and “Simple Therapeutic Cardiac Catheterization”;
- Establishes requirements for proposals to provide simple and complex therapeutic cardiac catheterization;
- Amends requirements for calculating need for additional nursing facility beds in a health planning district by requiring the analysis of both the average and median occupancy levels of Medicaid-certified nursing facility beds; and
- Reduces the occupancy level required to approve expansion of beds in an existing nursing facility from 93 percent to 90 percent.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The primary advantages of the regulatory action to the public are that the criteria for demonstrating public need for the included facilities will more closely reflect changes in technology, as well as application of service and utilization patterns, and will therefore help increase access to the services for the citizens of the Commonwealth. The Board does not foresee any disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of access to health care services. There are no disadvantages associated with the proposed regulatory action in relation to the agency or the Commonwealth.

## Requirements More Restrictive than Federal

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.*

There is no change in the information reported in the *Requirements that is more restrictive than the federal* section of the Agency Background Document from the previous stage.

**Agencies, Localities, and Other Entities Particularly Affected**

*Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.*

There is no change in the information reported in the *Localities particularly affected* or *Economic Impact* sections of the Agency Background Document from the previous stage.

**Public Comment**

*Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.*

| <b>Commenter</b>  | <b>Comment</b>   | <b>Agency response</b>                                  |
|---|--|---|
| Susan Puglisi, on behalf of the Department of Medical Assistance Services | <p>DMAS indicated concerns with the amendments to 12VAC5-230-610</p> <p>The Department is concerned with the change from permissive to mandatory language. DMAS believes this change will cause an unintended and undesired consequence. When two or more facilities apply for a certificate of public need (COPN) and the certificate is only issued to one facility, the other applicant(s) could simply wait and reapply for a certificate. The occupancy of the facility that was issued a certificate would be excluded from the calculation, which means the newly built facility would not have had a chance to ramp up to meet the previously identified need. This would allow a calculated identified need to stand for two application periods. During the second application period, the certificate that was issued to meet the need would not be taken into account.</p> | VDH concurs with the recommended change to Section 610. |

|  |   |   |
|--|---|---|
|  | <p>DMAS suggests changing the language in the following manner:</p> <p>“Exception: When there are facilities that have been in operation less than <del>three years</del> <u>one year</u> in the health planning district, their occupancy [<del>can shall</del> <u>can</u>] be excluded from the calculation of average occupancy <del>if the facilities had an annual occupancy of at least 93% in one of its first three years of operation.</del>”</p> <p>Allowing the exception to be permissive once again.</p>   |   |
| <p>Thomas J. Stallings,<br/>HCA Virginia</p>                                       | <p>Mr. Stallings expressed concerns that the language being amended could be applied retrospectively to limit the operations of cardiac catheterization providers already authorized to provide services before the effective date of the regulations. He noted that SMFP language is not to be used to limit how COPN-approved cardiac catheterization providers can use their approved laboratories.</p>  | <p>VDH will not retroactively enforce newly amended SMFP language to change or limit the operations of COPN-approved cardiac catheterization providers.</p>   |
| <p>R. Brent Rawlings,<br/>Virginia Hospital<br/>and Healthcare<br/>Association</p> | <p>Mr. Rawlings also expressed concerns that the language being amended could be applied retrospectively to limit the operations of cardiac catheterization providers already authorized to provide services before the effective date of the regulations. He noted that SMFP language is not to be used to limit how COPN-approved cardiac catheterization providers can use their approved laboratories.</p> <p>He recommended that VDH re-assign the cardiac catheterization regulations to the 2018 Task Force.</p> | <p>VDH will not retroactively enforce newly amended SMFP language to change or limit the operations of COPN-approved cardiac catheterization providers.</p> <p>These changes were developed as a result of a previous SMFP Task Force and review.</p> |

**Detail of Changes Made Since the Previous Stage**

*Please list all changes that made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. \* Please put an asterisk next to any substantive changes.*



| Current chapter-section number | New chapter-section number, if applicable | New requirement from previous stage | Updated new requirement since previous stage  | Change, intent, rationale, and likely impact of updated requirements   |
|--------------------------------|---|-------------------------------------|---|--|
| 12VAC5-230-610                 |   |                                     | <p>“Exception: When there are facilities that have been in operation less than <del>three years</del> <u>one year</u> in the health planning district, their occupancy [<del>can shall</del> <u>can</u>]* be excluded from the calculation of average occupancy if <del>the facilities had an annual occupancy of at least 93% in one of its first three years of operation.</del>”</p> | <p>This change is to allow the exception to remain permissive, instead of changing it to a requirement. See Susan Puglisi’s comment above for rationale.</p> |

1 **Project 4417 - Proposed**

2 **DEPARTMENT OF HEALTH**  
3 **Amend Regulations Following Periodic Review**

4  
5 **Part I**  
6 **Definitions and General Information**

7 **12VAC5-230-10. Definitions.**

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

10 "Acute psychiatric services" means hospital-based inpatient psychiatric services provided in  
11 distinct inpatient units in general hospitals or freestanding psychiatric hospitals.

12 "Acute substance abuse disorder treatment services" means short-term hospital-based  
13 inpatient treatment services with access to the resources of (i) a general hospital, (ii) a psychiatric  
14 unit in a general hospital, (iii) an acute care addiction treatment unit in a general hospital licensed  
15 by the Department of Health, or (iv) a chemical dependency specialty hospital with acute care  
16 medical and nursing staff and life support equipment licensed by the Department of ~~Mental~~  
17 Behavioral Health, Mental Retardation and Substance Abuse Developmental Services.

18 "Bassinet" means an infant care station, including warming stations and isolettes.

19 "Bed" means that unit, within the complement of a medical care facility, subject to COPN  
20 review as required by Article 1.1 (§ 32.1-102.1 et seq.) of the Code of Virginia and designated for  
21 use by patients of the facility or service. For the purposes of this chapter, bed does include cribs  
22 and bassinets used for pediatric patients; but does not include cribs and bassinets in the newborn  
23 nursery or neonatal special care setting.

24 "Cardiac catheterization" means ~~a~~ an invasive procedure where a flexible tube is inserted into  
25 the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the  
26 heart chambers or coronary arteries. Cardiac A cardiac catheterization may include therapeutic  
27 intervention, be conducted for diagnostic or therapeutic purposes but does not include a simple  
28 right heart catheterization for monitoring purposes as might be performed in an electrophysiology  
29 laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right  
30 electrode catheter.

31 "Commissioner" means the State Health Commissioner.

32 "Competing applications" means applications for the same or similar services and facilities  
33 that are proposed for the same health planning district, or same health planning region for projects  
34 reviewed on a regional basis, and are in the same batch review cycle.

35 "Complex therapeutic cardiac catheterization" means the performance of cardiac  
36 catheterization for the purpose of correcting or improving certain conditions that have been  
37 determined to exist in the heart or great arteries or veins of the heart, specifically catheter-based  
38 procedures for structural treatment to correct congenital or acquired structural or valvular  
39 abnormalities.

40 "Computed tomography" or "CT" means a noninvasive diagnostic technology that uses  
41 computer analysis of a series of cross-sectional scans made along a single axis of a bodily  
42 structure or tissue to construct an image of that structure.

43 "Continuing care retirement community" or "CCRC" means a retirement community consistent  
44 with the requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

45 "COPN" means a Medical Care Facilities Certificate of Public Need for a project as required  
46 in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

47 "COPN program" means the Medical Care Facilities Certificate of Public Need Program  
48 implementing Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

49 "DEP" means diagnostic equivalent procedure, a method for weighing the relative value of  
50 various cardiac catheterization procedures as follows: a diagnostic procedure cardiac  
51 catheterization equals 1 DEP, a simple therapeutic procedure cardiac catheterization equals 2  
52 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a  
53 pediatric procedure complex therapeutic cardiac catheterization equals 2 5 DEPs. A multiplier of  
54 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization  
55 equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a  
56 pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)

57 "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the  
58 purpose of detecting and identifying defects in the great arteries or veins of the heart or  
59 abnormalities in the heart structure, whether congenital or acquired.

60 "Direction" means guidance, supervision, or management of a function or activity.

61 "Gamma knife®" means the name of a specific instrument used in stereotactic radiosurgery.

62 "Health planning district" means the same contiguous areas designated as planning districts  
63 by the Virginia Department of Housing and Community Development or its successor.

64 "Health planning region" means a contiguous geographic area of the Commonwealth as  
65 designated by the State Board of Health with a population base of at least 500,000 persons,  
66 characterized by the availability of multiple levels of medical care services, reasonable travel time  
67 for tertiary care, and congruence with planning districts.

68 "Health system" means an organization of two or more medical care facilities, including ~~but~~  
69 ~~not limited to~~ hospitals, that are under common ownership or control and are located within the  
70 same health planning district, or health planning region for projects reviewed on a regional basis.

71 "Hospital" means a medical care facility licensed as an inpatient hospital or outpatient surgical  
72 center by the Department of Health or as a psychiatric hospital by the Department of ~~Mental~~  
73 ~~Behavioral~~ Health, ~~Mental Retardation~~, and ~~Substance Abuse~~ Developmental Services.

74 "ICF/MR" means an intermediate care facility for the mentally retarded.

75 "Indigent" means any person whose gross family income is equal to or less than 200% of the  
76 federal Nonfarm Poverty Level or income levels A through E of 12VAC5-200-10 and who is  
77 uninsured.

78 "Inpatient" means a patient who is hospitalized longer than 24 hours for health or health  
79 related services.

80 "Intensive care beds" or "ICU" means inpatient beds located in the following units or  
81 categories:

82 1. General intensive care units are those units where patients are concentrated by reason  
83 of serious illness or injury regardless of diagnosis. Special lifesaving techniques and  
84 equipment are immediately available and patients are under continuous observation by  
85 nursing staff;

86 2. Cardiac care units, also known as Coronary Care Units or CCUs, are units staffed and  
87 equipped solely for the intensive care of cardiac patients; and

88 3. Specialized intensive care units are any units with specialized staff and equipment for  
89 the purpose of providing care to seriously ill or injured patients based on age selected  
90 categories of diagnoses, including units established for burn care, trauma care,  
91 neurological care, pediatric care, and cardiac surgery recovery, but does not include  
92 bassinets in neonatal special care units.

93 "Lithotripsy" means a noninvasive therapeutic procedure to (i) crush renal and biliary stones  
94 using shock waves, (i.e., renal lithotripsy) or (ii) treat certain musculoskeletal conditions and to  
95 relieve the pain associated with tendonitis, (i.e., orthopedic lithotripsy).

96 "Long-term acute care hospital" or "LTACH" means an inpatient hospital that provides care  
97 for patients who require a length of stay greater than 25 days and is, or proposes to be, certified  
98 by the Centers for Medicare and Medicaid Services as a long-term care inpatient hospital  
99 pursuant to 42 CFR Part 412. An LTACH may be either a ~~free-standing~~ freestanding facility or  
100 located within an existing or host hospital.

101 "Magnetic resonance imaging" or "MRI" means a noninvasive diagnostic technology using a  
102 nuclear spectrometer to produce electronic images of specific atoms and molecular structures in  
103 solids, especially human cells, tissues and organs.

104 "Medical rehabilitation" means those services provided consistent with 42 CFR 412.23 and  
105 412.24.

106 "Medical/surgical" means those services available for the care and treatment of patients not  
107 requiring specialized services.

108 "Minimum survival rates" means the base percentage of transplant recipients who survive at  
109 least one year or for such other period of time as specified by the United Network for Organ  
110 Sharing (UNOS).

111 "Neonatal special care" means care for infants in one or more of the higher service levels  
112 designated in 12VAC5-410-443 ~~of the Rules and Regulations for the Licensure of Hospitals.~~

113 "Nursing facility" means those facilities or components thereof licensed to provide long-term  
114 nursing care.

115 "Obstetrical services" means the distinct organized program, equipment and care related to  
116 pregnancy and the delivery of newborns in inpatient facilities.

117 "Off-site replacement" means the relocation of existing beds or services from an existing  
118 medical care facility site to another location within the same health planning district.

119 "Open heart surgery" means a surgical procedure requiring the use or immediate availability  
120 of a heart-lung bypass machine or "pump." The use of the pump during the procedure  
121 distinguishes "open heart" from "closed heart" surgery.

122 "Operating room" means a room used solely or principally for the provision of surgical  
123 procedures involving the administration of anesthesia, multiple personnel, recovery room access,  
124 and a fully controlled environment.

125 "Operating room use" means the amount of time a patient occupies an operating room and  
126 includes room preparation and cleanup time.

127 "Operating room visit" means one session in one operating room in an inpatient hospital or  
128 outpatient surgical center, which may involve several procedures. Operating room visit may be  
129 used interchangeably with "operation" or "case."

130 "Outpatient" means a patient who visits a hospital, clinic, or associated medical care facility  
131 for diagnosis or treatment, but is not hospitalized 24 hours or longer.

132 "Pediatric" means patients younger than 18 years of age. Newborns in nurseries are excluded  
133 from this definition.

134 "Perinatal services" means those resources and capabilities that all hospitals offering general  
135 level newborn services as described in 12VAC5-410-443 ~~of the Rules and Regulations for the~~  
136 ~~Licensure of Hospitals~~ must provide routinely to newborns.

137 "PET/CT scanner" means a single machine capable of producing a PET image with a  
138 concurrently produced CT image overlay to provide anatomic definition to the PET image. For the  
139 purpose of granting a COPN, the State Board of Health pursuant to § 32.1-102.2 A 6 of the Code

140 of Virginia has designated PET/CT as a specialty clinical service. A PET/CT scanner shall be  
141 reviewed under the PET criteria as an enhanced PET scanner unless the CT unit will be used  
142 independently. In such cases, a PET/CT scanner that will be used to take independent PET and  
143 CT images will be reviewed under the applicable PET and CT services criteria.

144 "Planning horizon year" means the particular year for which bed or service needs are  
145 projected.

146 "Population" means the census figures shown in the most current series of projections  
147 published by a demographic entity as determined by the commissioner.

148 "Positron emission tomography" or "PET" means a noninvasive diagnostic or imaging modality  
149 using the computer-generated image of local metabolic and physiological functions in tissues  
150 produced through the detection of gamma rays emitted when introduced ~~radio-nuclides~~  
151 radionuclides decay and release positrons. A PET device or scanner may include an integrated  
152 CT to provide anatomic structure definition.

153 "Primary service area" means the geographic territory from which 75% of the patients of an  
154 existing medical care facility originate with respect to a particular service being sought in an  
155 application.

156 "Procedure" means a study or treatment or a combination of studies and treatments identified  
157 by a distinct ~~ICD-9~~ ICD-10 or CPT code performed in a single session on a single patient.

158 "Qualified" means meeting current legal requirements of licensure, registration, or certification  
159 in Virginia or having appropriate training, including competency testing, and experience  
160 commensurate with assigned responsibilities.

161 "Radiation therapy" means treatment using ionizing radiation to destroy diseased cells and for  
162 the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or  
163 chemotherapy.

164 "Relevant reporting period" means the most recent 12-month period, prior to the beginning of  
165 the applicable batch review cycle, for which data is available from VHI or a demographic entity as  
166 determined by the commissioner.

167 "Rural" means territory, population, and housing units that are classified as "rural" by the  
168 Bureau of the Census of the ~~United States~~ U.S. Department of Commerce, Economic and  
169 Statistics Administration.

170 "Simple therapeutic cardiac catheterization" means the performance of cardiac catheterization  
171 for the purpose of correcting or improving certain conditions that have been determined to exist  
172 in the heart, specifically catheter-based treatment procedures for relieving coronary artery  
173 narrowing.

174 "SMFP" means the state medical facilities plan as contained in Article 1.1 (§ 32.1-102.1 et  
175 seq.) of Chapter 4 of Title 32.1 of the Code of Virginia used to make medical care facilities and  
176 services needs decisions.

177 "Stereotactic radiosurgery" or "SRS" means the use of external radiation in conjunction with  
178 a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.  
179 SRS may be delivered in a single session or in a fractionated course of treatment up to five  
180 sessions.

181 "Stereotactic radiotherapy" or "SRT" means more than one session of stereotactic  
182 radiosurgery.

183 "Substance abuse disorder treatment services" means services provided to individuals for the  
184 prevention, diagnosis, treatment, or palliation of chemical dependency, which may include  
185 attendant medical and psychiatric complications of chemical dependency. Substance abuse

186 disorder treatment services are licensed by the Department of ~~Mental Behavioral Health, Mental~~  
187 ~~Retardation, and Substance Abuse Developmental Services.~~

188 "Supervision" means to direct and watch over the work and performance of others.

189 "Use rate" means the rate at which an age cohort or the population uses medical facilities and  
190 services. The rates are determined from periodic patient origin surveys conducted for the  
191 department by the regional health planning agencies, or other health statistical reports authorized  
192 by Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia.

193 "VHI" means the health data organization defined in § 32.1-276.4 of the Code of Virginia and  
194 under contract with the Virginia Department of Health.

195 **12VAC5-230-420. Nonemergent cardiac catheterization.**

196 ~~Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal~~  
197 ~~puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures,~~  
198 ~~diagnostic pericardiocentesis or therapeutic procedures should be approved only when open~~  
199 ~~heart surgery services are available on-site in the same hospital in which the proposed non-~~  
200 ~~emergent cardiac service will be located.~~

201 A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac  
202 catheterization are not required to offer open heart surgery service available on-site in the same  
203 hospital in which the proposed simple therapeutic service will be located. However, these  
204 programs shall adhere to the requirements described in subdivisions 1 through 9 of this  
205 subsection.

206 The programs shall:

207 1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality  
208 Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data  
209 Registry to monitor quality and outcomes;

210 2. Adhere to strict patient-selection criteria;

211 3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of  
212 which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by  
213 American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for  
214 Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;

215 4. Use only AHA/ACC-qualified operators who meet the standards for training and  
216 competency;

217 5. Demonstrate appropriate planning for program development and complete both a  
218 primary PCI development program and an elective PCI development program that  
219 includes routine care process and case selection review;

220 6. Develop and maintain a quality and error management program;

221 7. Provide PCI 24 hours a day, seven days a week;

222 8. Develop and maintain necessary agreements with a tertiary facility that must agree to  
223 accept emergent and nonemergent transfers for additional medical care, cardiac surgery,  
224 or intervention; and

225 9. Develop and maintain agreements with an ambulance service capable of advanced life  
226 support and intra-aortic balloon pump transfer that guarantees a 30-minute or less  
227 response time.

228 B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic  
229 cardiac catheterization should be approved only when open heart surgery services are available  
230 on-site in the same hospital in which the proposed complex therapeutic service will be located.  
231 Additionally, these complex therapeutic cardiac catheterization programs will be required to

232 participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack  
233 Coalition.

234 **12VAC5-230-610. Need for new service.**

235 A. A health planning district should be considered to have a need for additional nursing facility  
236 beds when:

237 1. The bed need forecast exceeds the current inventory of existing and authorized beds  
238 for the health planning district; and

239 2. The ~~average~~ median annual occupancy of all existing and authorized Medicaid-certified  
240 nursing facility beds in the health planning district was at least 93%, and the average  
241 annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in  
242 the health planning district was at least 90%, excluding the bed inventory and utilization  
243 of the Virginia Veterans Care Centers.

244 Exception: When there are facilities that have been in operation less than ~~three years~~ one  
245 year in the health planning district, their occupancy [ ~~can shall can~~ ] be excluded from the  
246 calculation of average occupancy ~~if the facilities had an annual occupancy of at least 93% in one~~  
247 ~~of its first three years of operation.~~

248 B. No health planning district should be considered in need of additional beds if there are  
249 unconstructed beds designated as Medicaid certified. This presumption of 'no need' for additional  
250 beds extends for three years from the issuance date of the certificate.

251 C. The bed need forecast will be computed as follows:

252  $PDBN = (UR64 \times PP64) + (UR69 \times PP69) + (UR74 \times PP74) + (UR79 \times PP79) + (UR84 \times$   
253  $PP84) + (UR85 \times PP85)$

254 Where:

255  $PDBN =$  Planning district bed need.

256  $UR64 =$  The nursing home bed use rate of the population aged 0 to 64 in the health  
257 planning district as determined in the most recent nursing home patient origin study  
258 authorized by VHI.

259  $PP64 =$  The population aged 0 to 64 projected for the health planning district three years  
260 from the current year as most recently published by a demographic program as  
261 determined by the commissioner.

262  $UR69 =$  The nursing home bed use rate of the population aged 65 to 69 in the health  
263 planning district as determined in the most recent nursing home patient origin study  
264 authorized by VHI.

265  $PP69 =$  The population aged 65 to 69 projected for the health planning district three years  
266 from the current year as most recently published by ~~the~~ a demographic program as  
267 determined by the commissioner.

268  $UR74 =$  The nursing home bed use rate of the population aged 70 to 74 in the health  
269 planning district as determined in the most recent nursing home patient origin study  
270 authorized by VHI.

271  $PP74 =$  The population aged 70 to 74 projected for the health planning district three years  
272 from the current year as most recently published by a demographic program as  
273 determined by the commissioner.

274  $UR79 =$  The nursing home bed use rate of the population aged 75 to 79 in the health  
275 planning district as determined in the most recent nursing home patient origin study  
276 authorized by VHI.

277 PP79 = The population aged 75 to 79 projected for the health planning district three years  
278 from the current year as most recently published by a demographic program as  
279 determined by the commissioner.

280 UR84 = The nursing home bed use rate of the population aged 80 to 84 in the health  
281 planning district as determined in the most recent nursing home patient origin study  
282 authorized by VHI.

283 PP84 = The population aged 80 to 84 projected for the health planning district three years  
284 from the current year as most recently published by a demographic program as  
285 determined by the commissioner.

286 UR85+ = The nursing home bed use rate of the population aged 85 and older in the health  
287 planning district as determined in the most recent nursing home patient origin study  
288 authorized by VHI.

289 PP85+ = The population aged 85 and older projected for the health planning district three  
290 years from the current year as most recently published by a demographic program as  
291 determined by the commissioner.

292 Health planning district bed need forecasts will be rounded as follows:

| Health Planning District Bed Need | Rounded Bed Need |
|-----------------------------------|------------------|
| 1–29                              | 0                |
| 30–44                             | 30               |
| 45–84                             | 60               |
| 85–104                            | 90               |
| 105–134                           | 120              |
| 135–164                           | 150              |
| 165–194                           | 180              |
| 195–224                           | 210              |
| 225+                              | 240              |

293 Exception: When a health planning district has:

294 1. Two or more nursing facilities;

295 2. Had ~~an average~~ a median annual occupancy rate ~~in excess~~ of 93% of all existing and  
296 authorized Medicaid-certified nursing facility beds and an annual average occupancy rate  
297 of at least 90% of all existing and authorized Medicaid-certified nursing facility beds for  
298 each of the most recent two years for which bed utilization has been reported to VHI; and

299 3. Has a forecasted bed need of 15 to 29 beds, then the bed need for this health planning  
300 district will be rounded to 30.

301 D. No new freestanding nursing facilities of less than 90 beds should be authorized. However,  
302 consideration may be given to a new freestanding facility with fewer than 90 nursing facility beds  
303 when the applicant can demonstrate that such a facility is justified based on a locality's preference  
304 for such smaller facility and there is a documented poor distribution of nursing facility beds within  
305 the health planning district.

306 E. When evaluating the capital cost of a project, consideration may be given to projects that  
307 use the current methodology as determined by the Department of Medical Assistance Services.



308 F. Preference may be given to projects that replace outdated and functionally obsolete  
309 facilities with modern facilities that result in the more cost-efficient resident services in a more  
310 aesthetically pleasing and comfortable environment.

311 **12VAC5-230-620. Expansion of services.**

312 Proposals to increase an existing nursing ~~facility~~ facility's bed capacity should not be approved  
313 unless the facility has operated for at least two years and the average annual occupancy of the  
314 facility's existing beds was at least ~~93%~~ 90% in the relevant reporting period as reported to VHI.

315 Note: Exceptions will be considered for facilities that operated at less than ~~93%~~ 90% average  
316 annual occupancy in the most recent year for which bed utilization has been reported when the  
317 facility offers short stay services causing an average annual occupancy lower than ~~93%~~ 90% for  
318 the facility.

319 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-230)

320 [ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories,](#)  
321 [American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac](#)  
322 [Catheterization, JACC Vol. 18 No. 5, November 1, 1991: 1149-82](#)



# COMMONWEALTH of VIRGINIA

Department of Health

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RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA  
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR  
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## MEMORANDUM

DATE: May 29, 2019

TO: Virginia State Board of Health

FROM: Robert A. K. Payne, JD  
Director, Office of Licensure and Certification

SUBJECT: Fast Track Amendments – Certificate of Quality Assurance for Managed Care Health Insurance Plans

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Enclosed for your review is a Fast Track action to amend the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees regulations (12VAC5-408-10 *et seq.*) to reflect the requirements of Chapter 703 of the 2018 Acts of Assembly.

This legislation amended the Code of Virginia by adding § 38.2-3407.10:1, which requires certain health insurance carriers to establish protocols and procedures for reimbursing new provider applicants, after being credentialed by the carrier, for health care services provided to covered persons during the period in which the applicant's completed credentialing application was pending.

For clarity and consistency with the current regulatory framework, several definitions were updated in 12VAC5-408-10. In the Provider credentialing and recredentialing (12VAC5-408-170), subsection F was removed as it is in conflict with Chapter 703 (2018) and subsections O through S were added.

The Board of Health is requested to approve the Fast Track Regulations. Should the Board of Health approve the Fast Track Action the proposed amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30 day public comment period will begin. Fifteen days after the close of the public comment period the Regulations will become effective.



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

## Fast-Track Regulation Agency Background Document

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| <b>Agency name</b>                                    | Virginia Board of Health   |
| <b>Virginia Administrative Code (VAC) citation(s)</b> | 12VAC5-408   |
| <b>Regulation title(s)</b>                            | Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees |
| <b>Action title</b>                                   | Amend regulations to conform to Ch.703 of the 2018 Acts of Assembly              |
| <b>Date this document prepared</b>                    | 4/18/2019  |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

Chapter 703 (2018 Acts of Assembly) amended the Code of Virginia by adding § 38.2-3407.10:1, which requires health insurance carriers that credential physicians in their networks to establish protocols and procedures for reimbursing new provider applicants for health care services provided to covered persons during the period in which the applicant's completed credentialing application is pending, provided that the new provider applicant is ultimately approved by the health insurance carrier. The State Board of Health is also exercising its authority under § 32.1-137.2(C) of the Code of Virginia to ensure the protocols and procedures cover non-physician providers, since Managed Care Health Insurance Plan licensees also credential non-physician providers. In order to submit claims to the carrier for services provided during that time period, the new provider applicant must notify the covered person in advance of providing care that the carrier is in the process of obtaining and verifying the required credentialing documentation. Additionally, carriers are not required to reimburse the new provider applicant for any care rendered if the credentialing application is not approved or the carrier is otherwise unwilling to

contract with the new provider applicant. If payment is made by the carrier to a new provider applicant or any entity that employs or engages the new provider applicant for a covered service, the patient is only responsible for any copayment, coinsurance, or deductibles permitted under the insurance contract with the carrier or participating provider agreement with the new provider applicant.

Existing regulations prohibit providers from seeing covered persons or entering into a contractual relationship with the MCHIP licensee before the credentialing process is complete and thus conflict with the provisions of Ch. 703 (2018).

The Virginia Department of Health is utilizing this Fast Track action to amend the regulation for Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees (12VAC5-408-10 *et seq.*) to reflect these new requirements.

### 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.*

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“Board” means the Virginia Board of Health.  
“MCHIP” means Managed Care Health Insurance Plan.  
“VDH” means Virginia Department of Health.

### Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

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### Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, “mandate” has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”*

*As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.*

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Chapter 703 of the 2018 Acts of Assembly requires health insurance carriers to create reasonable protocols to reimburse new provider applicants for care provided to covered persons during the time period between submission of a completed credentialing application and approval of the application by the MCHIP licensee.

Enactment Clause 2 of Ch. 703 (2018) mandates the VDH to “revise and reenact the regulations promulgated pursuant to § 32.1-137.1 of the Code of Virginia regarding managed care health insurance plans consistent with the provisions of [the] act.” As this action is being used to conform to the intent of a statutory mandate, VDH believes the proposed regulatory action will be noncontroversial, allowing use of the Fast-Track process.

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.*

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This regulation is promulgated under the authority of §§ 32.1-12 and 32.1-137.3 of the Code of Virginia. Section 32.1-12 of the Code of Virginia grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.” Section 32.1-137.3 of the Code of Virginia directs VDH to promulgate regulations governing the quality of care provided to covered persons by a managed care health insurance plan licensee.

Subsection C of § 32.1-137.2 of the Code of Virginia states that “[n]o certificate of quality assurance may be issued or renewed unless...the Commissioner is satisfied...that...the managed care health insurance plan licensee has in place and complies with...reasonable and adequate standards and procedures for credentialing and recredentialing the providers with whom it contracts...and (x) such other requirements as the Board may establish by regulation consistent with this article.”

## Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.*

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Ch. 703 (2018 Acts of Assembly) adds § 38.2-3407.10:1 to the Code of Virginia, creating the statutory requirements for reimbursement for services rendered during pendency of a physician's credentialing application, as described in this document. VDH is subject to the legislative mandate to promulgate regulations consistent with the act. MCHIP licensees employ or otherwise contract with and credential providers other than physicians, such as physician assistants and nurse practitioners. As such, and under the authority in Va. Code § 32.1-137.2(C) cited in the Legal Basis section, the provisions regarding reimbursement were expanded to include other credentialed providers in addition to physicians.

The change will update a portion of the credentialing process to conform to the Code and will allow new provider applicants to begin seeing covered persons.

## Substance

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

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In the Section 10, the definitions of “health care provider” or “provider,” “managed care plan,” “new provider applicant,” and “participating provider” are added.

In Section 170, the Board repealed subsection F, which had required the entire credentialing process to be completed before a provider could begin seeing covered persons or enter into a contractual relationship with the MCHIP licensee, because this subsection is in direct conflict with Ch. 703 (2018 Acts of Assembly). Language reflecting the provisions of Ch. 703 (2018) is added as subsections O through S.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The primary advantages will be to providers applying for credentialing by an MCHIP licensee, who may render services to covered persons and seek reimbursement for that care; and MCHIP-covered persons who will be able to be treated by those providers earlier in the credentialing process. The Code of Virginia and regulatory change protect patients from having to pay for services rendered by a new provider applicant if he is subsequently not approved to be credentialed as part of the MCHIP's network of participating providers.

As covered persons of an MCHIP will have expanded access to providers, the advantage to VDH for promulgating this regulatory change is the promotion of the public's access to health care. There are no known disadvantages to the public or the Commonwealth.

## Requirements More Restrictive than Federal

*Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.*

There are no requirements in this proposal that exceed federal requirements.

## Agencies, Localities, and Other Entities Particularly Affected

*Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

No other state agencies or localities will be particularly affected by this proposed regulatory action.

MCHIP licensees and the providers applying to be credentialed as part of the MCHIP's network will be particularly affected.

**Economic Impact**

*Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.*

**Impact on State Agencies**

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| <i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:<br>a) fund source / fund detail;<br>b) delineation of one-time versus on-going expenditures; and<br>c) whether any costs or revenue loss can be absorbed within existing resources | None |
| <i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.  | None |
| <i>For all agencies:</i> Benefits the regulatory change is designed to produce.  | None |

**Impact on Localities**

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| Projected costs, savings, fees or revenues resulting from the regulatory change. | None |
| Benefits the regulatory change is designed to produce.                           | None |

**Impact on Other Entities**

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.   | MCHIP licensees are subject to regulation in 12VAC5-408-10 <i>et seq.</i> , and thus will be required to establish protocols and procedures pursuant to § 38.2-3407.10:1 of the Code of Virginia. The providers included in or applying to be included in MCHIP licensees' networks are also affected by this change.  |
| Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million. | As of April, 2018, the Office of Licensure and Certification oversees 96 MCHIPs. None are considered small businesses. There is no method of estimating the number of providers or potential providers affected by this change, as no current provision in the Code of Virginia or regulations requires the reporting of the number of providers in each MCHIP licensee's network. |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:   | MCHIP licensees will now be required to provide for the reimbursement to a new provider applicant for covered health care services provided during the pendency of his credentialing   |

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| <p>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br/>                 b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br/>                 c) fees;<br/>                 d) purchases of equipment or services; and<br/>                 e) time required to comply with the requirements.</p> | <p>application. Additionally, there will likely be administrative costs associated with the processing of claims submitted by new provider applicants who are subsequently approved.</p> <p>New provider applicants or the entities that employ or engage them will be responsible for absorbing the cost of rendering health services to covered persons of an MCHIP if that new provider applicant's credentialing application is denied or the MCHIP is otherwise unwilling to enter into a contract with him.</p> |
| <p>Benefits the regulatory change is designed to produce.</p>  | <p>The provisions regarding the credentialing and reimbursement of physicians were mandated by legislation. The Board's inclusion of other provider types in the applicability of the provisions is designed to reduce administrative burden and confusion on the MCHIP licensees.</p>  |

### Alternatives

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

The changes to the credentialing processes as they apply to physicians were mandated by Ch. 703 (2018 Acts of Assembly) and as such, no viable alternative was considered. The inclusion of non-physician providers in the changes to the credentialing processes is discussed in the next section of this document.

### Regulatory Flexibility Analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.*

As mentioned above, MCHIP licensees currently engage with and credential other provider types. An alternative regulatory method to the application of the changes to the credentialing processes would be differentiating, in regulation, the credentialing processes for physicians and non-physician providers. This differentiation would create confusion and an administrative burden on MCHIP licensees to maintain separate credentialing processes and would create an administrative burden on VDH to inspect or examine the multiple processes for compliance with the regulations.

Additionally, health care continues to move towards the utilization of non-physician providers, particularly in the field of primary care. Legislative efforts to expand the scope of practice of nurse practitioners, such



as Ch. 776 (2018 Acts of Assembly), continue to move forward. The maintenance of separate credentialing processes may allow for disparities in access to certain services, such as primary care, as it relates to the credentialing of physician vs. non-physician providers. As such, and under the authority discussed elsewhere in this document, the Board decided to include non-physician providers in the changes to the credentialing requirements.

Due to the nature of the insurance industry, very few, if any, MCHIP licensees qualify as “small businesses.” Additionally, the requirements of the Certificate of Quality Assurance program act as a form of consumer protection for covered persons and ensure that licensees are providing or arranging for adequate and high quality health care.

### Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, VDH shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

### Detail of Changes

*Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.*

*If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.*

*If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.*

| Current section number     | New section number, if applicable | Current requirement   | Change, intent, rationale, and likely impact of new requirements   |
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| 12VAC5-408-10. Definitions | N/A                               | There is no existing definition for “health care provider” or “provider,” “managed care plan,” “new provider applicant,” or “participating provider.” | <p><b>CHANGE:</b> The following definitions have been added:</p> <p><u>“Health care provider” or “provider” means a physician or other health care practitioner licensed, accredited, or certified to perform specified health care services consistent with state law.</u></p> <p><u>“Managed care plan” means a health benefit plan, as defined in</u></p> |

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|  |  |  | <p><u>§ 38.2-3407.10:1 of the Code of Virginia, that requires a covered person to use, or creates incentives, including financial incentives, for a covered person to use health care providers managed, owned, under contract with, or employed by the MCHIP licensee.</u></p> <p><u>"New provider applicant" means a provider who has submitted a completed credentialing application to an MCHIP licensee.</u></p> <p><u>"Participating provider" means a provider who is managed, under contract with, or employed by an MCHIP licensee and who has agreed to provide health care services to covered persons with an expectation of receiving payments, other than coinsurance, copayments, or deductibles, directly or indirectly from the MCHIP licensee.</u></p> <p><b>INTENT:</b> The intent of these changes is to conform to § 38.2-3407.10:1, pursuant to Ch. 703 of the 2018 Acts of Assembly and to ensure the scope of definitions are in line with the Board's existing authority to regulation MCHIP licensees.</p> <p><b>RATIONALE:</b> Where Ch. 703 (2018 Acts of Assembly) uses the word "carrier," the Board is using the term "MCHIP licensee" as it is already defined in the regulations and refers to the same entity; additionally, the Board presently only has regulatory authority over MCHIPs and not all health insurance entities. Where Ch. 703 (2018 Acts of Assembly) uses the word "physician," the Board is using the word "provider" for consistency with the MCHIP licensees' current credential practice that covers all providers. Where Ch. 703</p> |
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|  |            |  | <p>(2018 Acts of Assembly) uses the term “health benefit plan,” the Board is using the term “managed care plan” as it is more specific to the regulated health benefit plans being offered by MCHIP licensees. As it relates to the Board’s regulation of MCHIP licensees, the Board confines the term “covered person” in the regulations to residents of the Commonwealth, as the Board has no enforcement mechanisms to regulate the coverage of out-of-state persons.</p> <p><b>LIKELY IMPACT:</b> These proposed changes will provide clarity as to whom and what is covered by the new credentialing changes in Section 170.</p>   |
| <p>12VAC5-408-170. Provider credentialing and recredentialing.</p> | <p>N/A</p> | <p>A. The MCHIP licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation for providers who have completed their residency or fellowship requirements for their specialty area more than 12 months prior to the credentialing decision shall include:</p> <ol style="list-style-type: none"> <li>1. Current valid license and history of licensure or certification;</li> <li>2. Status of hospital privileges, if applicable;</li> <li>3. Valid DEA certificate, if applicable;</li> <li>4. Information from the National Practitioner Data Bank, as available;</li> </ol> | <p><b>CHANGE:</b> The following subsections have been struck from the regulatory text and the remaining subsections have been re-lettered:</p> <p><del>F. The appropriate credentialing process shall be completed before the provider:</del></p> <ol style="list-style-type: none"> <li><del>1. Begins seeing covered persons;</del></li> <li><del>2. Enters into the employment or contractual relationship with the MCHIP licensee; and</del></li> <li><del>3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.</del></li> </ol> <p>The following subsections have been added to the regulatory text:</p> <p><u>O. The MCHIP licensee shall establish protocols and</u></p> |

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|  | <p>5. Education and training, including post graduate training, if applicable;</p> <p>6. Specialty board certification status, if applicable;</p> <p>7. Practice or work history covering at least the past five years; and</p> <p>8. Current, adequate malpractice insurance and malpractice history of at least the past five years.</p> <p>B. The MCHIP licensee may grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within 12 months prior to the credentialing decision. Written supporting documentation necessary to provisionally credential a practitioner shall include:</p> <p>1. Primary source verification of a current, valid license to practice prior to granting the provisional status;</p> <p>2. Written confirmation of the past five years of malpractice claims or settlements, or both, from the malpractice carrier or the results of the National Practitioner Data Bank query prior to granting provisional status; and</p> <p>3. A completed application and signed attestation.</p> <p>C. Providers provisionally credentialed may remain so for 60 calendar days.</p> <p>D. Policies for credentialing and recredentialing shall include:</p> <p>1. Criteria used to credential and recredential;</p> | <p><u>procedures for reimbursing new provider applicants, after being credentialed by the MCHIP licensee, for health care services provided to covered persons during the period in which the new provider applicant's completed credentialing application was pending. At a minimum, the protocols and procedures shall:</u></p> <p><u>1. Apply only if the new provider applicant's credentialing application is approved by the MCHIP licensee;</u></p> <p><u>2. Permit provider reimbursement for services rendered from the date the new provider applicant's completed credentialing application is received for consideration by the MCHIP licensee;</u></p> <p><u>3. Apply only if a contractual relationship exists between the MCHIP licensee and the new provider applicant or entity for whom the new provider applicant is employed or engaged; and</u></p> <p><u>4. Require that any reimbursement be paid at the in-network rate that the new provider applicant would have received had he been, at the time the covered health care services were provided, a credentialed participating provider in the network for the applicable managed care plan.</u></p> <p><u>P. Nothing in this section shall require:</u></p> <p><u>1. Reimbursement of provider-rendered services that are not benefits or services covered by the MCHIP licensee's managed care plan.</u></p> |
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|  | <p>2. Process used to make credentialing and recredentialing decisions;</p> <p>3. Type of providers, including network providers, covered under the credentialing and recredentialing policies;</p> <p>4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider;</p> <p>5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process; and</p> <p>6. A requirement that the MCHIP licensee notify the applicant within 60 calendar days of receipt of an application if information is missing or if there are other deficiencies in the application. The MCHIP licensee shall complete the credentialing process within 90 calendar days of the receipt of all such information requested by the MCHIP licensee or, if information is not requested from the applicant, within 120 calendar days of receipt of an application. The department may impose administrative sanctions upon an MCHIP licensee for failure to complete the credentialing process as provided herein if it finds that such failure occurs with such frequency as to constitute a general business practice.</p> <p>The policies shall be made available to participating providers and applicants upon written request.</p> <p>E. A provider fully credentialed by an MCHIP licensee, who</p> | <p><u>2. An MCHIP licensee to pay reimbursement at the contracted in-network rate for any covered health care services provided by the new provider applicant if the new provider applicant's credentialing application is not approved or the MCHIP licensee is otherwise not willing to contract with the new provider applicant.</u></p> <p><u>Q. Payments made or retroactive denials of payments made under this section shall be governed by § 38.2-3407.15.</u></p> <p><u>R. If a payment is made by the MCHIP licensee to a new provider applicant or any entity that employs or engages a new provider applicant under this section for a covered service, the patient shall only be responsible for any coinsurance, copayments, or deductibles permitted under the insurance contract with the MCHIP licensee or participating provider agreement with the provider.</u></p> <p><u>S. A new provider applicant, in order to submit claims to the MCHIP licensee pursuant to this section, shall provide written or electronic notice to covered persons in advance of treatment that:</u></p> <p><u>1. He has submitted a credentialing application to the MCHIP licensee of the covered person; and</u></p> <p><u>2. The MCHIP licensee is in the process of obtaining and verifying the written documentation from the new provider applicant, pursuant to 12VAC5-408-170 A.</u></p> <p><u>The written or electronic notice shall conform to the requirements in § 38.2-</u></p> |
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|  | <p>changes his place of employment or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon receipt by the MCHIP licensee of the following:</p> <ol style="list-style-type: none"> <li>1. The effective date of the change;</li> <li>2. The new tax ID number and copy of W-9, as applicable;</li> <li>3. The name of the new practice, contact person, address, telephone and fax numbers; and</li> <li>4. Other such information as may materially differ from the most recently completed credentialing application submitted by the provider to the MCHIP licensee.</li> </ol> <p>This provision shall not apply if the provider's prior place of employment or employer had been delegated credentialing responsibility by the MCHIP licensee.</p> <p>Nothing in this section shall be construed to require an MCHIP licensee to contract or recontract with a provider.</p> <p>F. The appropriate credentialing process shall be completed before the provider:</p> <ol style="list-style-type: none"> <li>1. Begins seeing covered persons;</li> <li>2. Enters into the employment or contractual relationship with the MCHIP licensee; and</li> <li>3. Is included in the listing of health care providers as a participating provider in any</li> </ol> | <p><u>3407.10:1 G of the Code of Virginia.</u></p> <p>Statutory Authority<br/> <del>§ 32.1-137.4</del> §§ <u>32.1-12</u> and <u>32.1-137.3</u> of the Code of Virginia.</p> <p><b>INTENT:</b> Subsection F of the existing regulation is inconsistent with the new § 38.2-3407.10:1 of the Code of Virginia. The intent is to allow physicians and non-physician providers to provide care to covered persons of an MCHIP during the pendency of their credentialing application and to receive reimbursement from the MCHIP carrier, provided that their application is approved</p> <p><b>RATIONALE:</b> MCHIP licensees presently credential and contract with physicians and other healthcare providers; to differentiate between physician and non-physicians for the purposes of credentialing would require MCHIP licensees to set up two separate credentialing protocols and procedures, including two different billing practices. Aside from being administratively burdensome for the MCHIP licensee, it would also complicate VDH's annual regulatory examination of the MCHIP licensees.</p> <p><b>LIKELY IMPACT:</b> It is expected that physicians and non-physician providers will exercise this new ability and begin to see MCHIP-covered persons while their completed credentialing application is pending. The MCHIP licensees will have to establish the protocols and procedures outlined by § 38.2-3407.10.1.</p> |
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|  |  | <p>marketing and covered person materials.</p> <p>G. The providers shall be recredentialed at least every three years. Recredentiaing documentation shall include:</p> <ol style="list-style-type: none"> <li>1. Current valid license or certification;</li> <li>2. Status of hospital privileges, if applicable;</li> <li>3. Current valid DEA registration, if applicable;</li> <li>4. Specialty board eligibility or certification status, if applicable;</li> <li>5. Data from covered person complaints and the results of quality reviews, utilization management reviews and covered persons satisfaction surveys, as applicable; and</li> <li>6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgments.</li> </ol> <p>H. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose to a provider, or any other person or party, information or documents: (i) that the MCHIP or the MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing process or (ii) that are privileged under applicable law. The department may require the MCHIP licensee to provide a copy of its credentialing policies.</p> |  |
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|  |  | <p>I. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in the status of any credentialing criteria.</p> <p>J. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the credentials of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.</p> <p>K. The MCHIP licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP licensee. The policies shall include actions to be taken to improve performance prior to termination and an appeals process for instances when the MCHIP licensee chooses to alter the condition of provider participation based on issues of quality of care or service, except in circumstances where an covered person's health has been jeopardized. Providers shall have complete and timely access to all data and information used by the licensee to identify or determine the need for altering the conditions of participation.</p> <p>L. The MCHIP licensee shall retain the right to approve new providers and sites based on quality issues, and to terminate or suspend individual providers. Termination or suspension of individual providers for quality of care considerations shall be supported by documented records of noncompliance with specific MCHIP expectations and requirements for providers. The provider shall have a prescribed system of appeal of this decision available to them as prescribed in the contract between the MCHIP or its</p> |  |
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|  |  | <p>delegated service entity and the provider.</p> <p>M. Providers shall be informed of the appeals process. Profession specific providers actively participating in the MCHIP plan shall be included in reviewing appeals and making recommendations for action.</p> <p>N. The MCHIP licensee shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.</p> <p>O. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.</p> |  |
|--|--|---|--|

1 **Project 5941 - none**

2

**DEPARTMENT OF HEALTH**

3

**Amend Regulations to Conform to Ch 703 of the 2018 Acts of Assembly**

4

5

**Part I**

6

**Definitions and General Information**

7

**12VAC5-408-10. Definitions.**

8

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

9

10

"Adverse decision" means a utilization review determination by the utilization review entity that a health service rendered or proposed to be rendered was not or is not medically necessary, when such determination may result in noncoverage of the health service or health services. When the policy, contract, plan, certificate, or evidence of coverage includes coverage for prescription drugs and the health service rendered or proposed to be rendered is a prescription for the alleviation of cancer pain, any adverse decision shall be made within 24 hours of the request for coverage.

17

"Appeal" means a formal request by a covered person or a provider on behalf of a covered person for reconsideration of a decision, such as a final adverse decision, a benefit payment, a denial of coverage, or a reimbursement for service.

20

"Basic health care services" means those health care services, as applicable to the type of managed care health insurance plan, described in § 38.2-5800 of the Code of Virginia which are required to be provided, arranged, paid for, or reimbursed by the managed care health insurance plan licensee for its covered persons.

24

"Board" means the Board of Health.

25

"Bureau of Insurance" means the State Corporation Commission acting pursuant to Title 38.2 of the Code of Virginia.

27

"Center" means the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health.

29

"Certificate" means a certificate of quality assurance.

30

"Complaint" means a written communication from a covered person primarily expressing a grievance. A complaint may pertain to the availability, delivery, or quality of health care services including claims payments, the handling or reimbursement for such services, or any other matter pertaining to the covered person's contractual relationship with the MCHIP.

34

"Covered person" means an individual residing in the Commonwealth, whether a subscriber, policyholder, enrollee, or member, of a managed care health insurance plan (MCHIP), who is entitled to health services or benefits provided, arranged for, paid for, or reimbursed pursuant to an MCHIP.

38

"Delegated service entity" means the entity with which an MCHIP licensee contracts to provide one or more of the services listed in 12VAC5-408-320 A for one or more of its MCHIPs, pursuant to and in accordance with the provisions of Part VI (12VAC5-408-320 et seq.) of this chapter, inclusive.

42

"Department" means the Virginia Department of Health.

43

"Emergency services" means those health care services as defined in § 38.2-3438 of the Code of Virginia.

45

"Evidence of coverage" means any certificate, individual or group agreement or contract, or identification card or related document issued in conjunction with the certificate, agreement or

46

47 contract, issued to a covered person setting out the coverage and other rights to which a covered  
48 person is entitled.

49 "Final adverse decision" means a utilization review determination made by a physician advisor  
50 or peer of the treating health care provider in a reconsideration of an adverse decision, and upon  
51 which a provider or patient may base an appeal.

52 "Health care data reporting system" means the state contracted integrated system for the  
53 collection and analysis of data used by consumers, employers, providers, and purchasers of  
54 health care to continuously assess and improve the quality of health care in the Commonwealth.

55 "Health care provider" or "provider" means a physician or other health care practitioner  
56 licensed, accredited, or certified to perform specified health care services consistent with state  
57 law.

58 "Health care services" means services as defined in § 38.2-3438 of the Code of Virginia.

59 "Health carrier" means an entity as defined in § 38.2-3438 of the Code of Virginia.

60 "Managed care health insurance plan" or "MCHIP" means an arrangement for the delivery of  
61 health care in which a health carrier, as defined in § 38.2-5800 of the Code of Virginia, undertakes  
62 to provide, arrange for, pay for, or reimburse any of the costs of health care services for a covered  
63 person on a prepaid or insured basis which (i) contains one or more incentive arrangements,  
64 including any credentialing requirements intended to influence the cost or level of health care  
65 services between the health carrier and one or more providers with respect to the delivery of  
66 health care services and (ii) requires or creates benefit payment differential incentives for covered  
67 persons to use providers that are directly or indirectly managed, owned, under contract with or  
68 employed by the health carrier. Any health maintenance organization as defined in § 38.2-4300  
69 of the Code of Virginia or health carrier that offers preferred provider contracts or policies as  
70 defined in § 38.2-3407 of the Code of Virginia or preferred provider subscription contracts as  
71 defined in § 38.2-4209 of the Code of Virginia shall be deemed to be offering one or more  
72 managed care health insurance plans. For the purposes of this definition, the prohibition of  
73 balance billing by a provider shall not be deemed a benefit payment differential incentive for  
74 covered persons to use providers who are directly or indirectly managed, owned, under contract  
75 with or employed by the health carrier. A single managed care health insurance plan may  
76 encompass multiple products and multiple types of benefit payment differentials; however, a  
77 single managed care health insurance plan shall encompass only one provider network or set of  
78 provider networks.

79 "Managed care health insurance plan licensee" or "MCHIP licensee" means a health carrier  
80 subject to licensure by the Bureau of Insurance and to quality assurance certification by the  
81 department under Title 38.2 of the Code of Virginia who is responsible for a managed care health  
82 insurance plan in accordance with Chapter 58 (§ 38.2-5800 et seq.) of Title 38.2 of the Code of  
83 Virginia.

84 "Managed care plan" means a health benefit plan, as defined in § 38.2-3407.10:1 of the Code  
85 of Virginia, that requires a covered person to use, or creates incentives, including financial  
86 incentives, for a covered person to use health care providers managed, owned, under contract  
87 with, or employed by the MCHIP licensee.

88 "Material" means that which has an effective influence or bearing on, or is pertinent to, the  
89 issue in question.

90 "Medical necessity" or "medically necessary" means appropriate and necessary health care  
91 services which are rendered for any condition which, according to generally accepted principles  
92 of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury,  
93 or pregnancy-related condition, and are not provided only as a convenience.

94 "Nationally recognized accrediting body" means an organization that sets national standards  
95 specifically governing healthcare quality assurance processes, utilization review, provider  
96 credentialing, as well as other areas covered by this chapter and provides accreditation to  
97 managed care health insurance plans pursuant to national standards. The following entities shall  
98 be considered nationally recognized accrediting bodies:

- 99 1. The American Accreditation HealthCare Commission/URAC;
- 100 2. The National Committee for Quality Assurance (NCQA);
- 101 3. The Joint Commission on Accreditation of Healthcare Organizations, (JCAHO); and
- 102 4. Other nationally recognized accrediting bodies with national standards as described  
103 above that are accepted by the department.

104 "Network" means a group of providers as defined in § 38.2-3438 of the Code of Virginia.

105 "New provider applicant" means a provider who has submitted a completed credentialing  
106 application to an MCHIP licensee.

107 "Participating provider" means a provider who is managed, under contract with, or employed  
108 by an MCHIP licensee and who has agreed to provide health care services to covered persons  
109 with an expectation of receiving payments, other than coinsurance, copayments, or deductibles,  
110 directly or indirectly from the MCHIP licensee.

111 "Person" means any individual, aggregate of individuals, association, business, company,  
112 corporation, joint-stock company, Lloyds type of organization, other organization, partnership,  
113 receiver, reciprocal or inter-insurance exchange, trustee or society.

114 "Plan of correction" means an MCHIP'S written plan that outlines the action the MCHIP will  
115 take to address compliance issues identified during an administrative review or on-site  
116 examination conducted by the department.

117 "Preferred provider organization" or "PPO" means an arrangement in which a health carrier,  
118 as defined in § 38.2-5800 of the Code of Virginia, undertakes to provide, arrange for, pay for, or  
119 reimburse any of the costs of health care services, on an insured basis, which creates incentives,  
120 including financial incentives, for a covered person to use health care providers directly or  
121 indirectly managed, owned, under contract with, or employed by the health carrier, but shall not  
122 include a health maintenance organization as defined in § 38.2-4300 of the Code of Virginia.

123 "Quality assurance program" means the systems, standards and processes including, but not  
124 limited to, reasonable and adequate systems to assess, measure, and improve the health status  
125 of covered persons, necessary to obtain a certificate of quality assurance from the department in  
126 accordance with this chapter and in accordance with § 32.1-137.2 C of the Code of Virginia.

127 "Service area" means a geographic area as defined in § 38.2-5800 of the Code of Virginia.

128 "Timely" means the provision of services so as not to impair or jeopardize the integrity of the  
129 covered persons' diagnosis or outcomes of illness.

130 "Treating health care provider" means a licensed health care provider who renders or  
131 proposes to render health care services to a covered person.

132 "Utilization review" means a system for reviewing the necessity, appropriateness, and  
133 efficiency of hospital, medical or other health care services rendered or proposed to be rendered  
134 to a patient or group of patients for the purpose of determining whether such services should be  
135 covered or provided by an insurer, health services plan, managed care health insurance plan  
136 licensee, or other entity or person. For purposes of this chapter, "utilization review" shall include,  
137 but not be limited to, preadmission, concurrent and retrospective medical necessity determination,  
138 and review related to the appropriateness of the site at which services were or are to be delivered.  
139 "Utilization review" shall not include (i) review of issues concerning insurance contract coverage  
140 or contractual restrictions on facilities to be used for the provision of services, (ii) any review of

141 patient information by an employee of or consultant to any licensed hospital for patients of such  
142 hospital, or (iii) any determination by an insurer as to the reasonableness and necessity of  
143 services for the treatment and care of an injury suffered by an insured for which reimbursement  
144 is claimed under a contract of insurance covering any classes of insurance defined in §§ 38.2-  
145 117 through 38.2-119, 38.2-124 through 38.2-126, 38.2-130 through 38.2-132 and 38.2-134 of  
146 the Code of Virginia.

147 "Utilization review entity" means a person or entity performing utilization review.

148 "Utilization review plan" means a written procedure for performing a utilization review.

149 Statutory Authority

150 § 32.1-137.3 of the Code of Virginia.

151 Historical Notes

152 Derived from Virginia Register Volume 16, Issue 7, eff. January 20, 2000; amended, Virginia  
153 Register Volume 18, Issue 8, eff. January 30, 2002; Volume 28, Issue 4, eff. November 23, 2011.

154 **12VAC5-408-170. Provider credentialing and recredentialing.**

155 A. The MCHIP licensee shall establish and maintain a comprehensive credentialing  
156 verification program to ensure its providers meet the minimum standards of professional licensure  
157 or certification. Written supporting documentation for providers who have completed their  
158 residency or fellowship requirements for their specialty area more than 12 months prior to the  
159 credentialing decision shall include:

- 160 1. Current valid license and history of licensure or certification;
- 161 2. Status of hospital privileges, if applicable;
- 162 3. Valid DEA certificate, if applicable;
- 163 4. Information from the National Practitioner Data Bank, as available;
- 164 5. Education and training, including post graduate training, if applicable;
- 165 6. Specialty board certification status, if applicable;
- 166 7. Practice or work history covering at least the past five years; and
- 167 8. Current, adequate malpractice insurance and malpractice history of at least the past  
168 five years.

169 B. The MCHIP licensee may grant provisional credentialing for providers who have completed  
170 their residency or fellowship requirements for their specialty area within 12 months prior to the  
171 credentialing decision. Written supporting documentation necessary to provisionally credential a  
172 practitioner shall include:

- 173 1. Primary source verification of a current, valid license to practice prior to granting the  
174 provisional status;
- 175 2. Written confirmation of the past five years of malpractice claims or settlements, or both,  
176 from the malpractice carrier or the results of the National Practitioner Data Bank query  
177 prior to granting provisional status; and
- 178 3. A completed application and signed attestation.

179 C. Providers provisionally credentialed may remain so for 60 calendar days.

180 D. Policies for credentialing and recredentialing shall include:

- 181 1. Criteria used to credential and recredential;
- 182 2. Process used to make credentialing and recredentialing decisions;
- 183 3. Type of providers, including network providers, covered under the credentialing and  
184 recredentialing policies;

- 185 4. Process for notifying providers of information obtained that varies substantially from the  
186 information provided by the provider;
- 187 5. Process for receiving input from participating providers to make recommendations  
188 regarding the credentialing and recredentialing process; and
- 189 6. A requirement that the MCHIP licensee notify the applicant within 60 calendar days of  
190 receipt of an application if information is missing or if there are other deficiencies in the  
191 application. The MCHIP licensee shall complete the credentialing process within 90  
192 calendar days of the receipt of all such information requested by the MCHIP licensee or,  
193 if information is not requested from the applicant, within 120 calendar days of receipt of  
194 an application. The department may impose administrative sanctions upon an MCHIP  
195 licensee for failure to complete the credentialing process as provided herein if it finds that  
196 such failure occurs with such frequency as to constitute a general business practice.

197 The policies shall be made available to participating providers and applicants upon written  
198 request.

199 E. A provider fully credentialed by an MCHIP licensee, who changes his place of employment  
200 or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if  
201 practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon  
202 receipt by the MCHIP licensee of the following:

- 203 1. The effective date of the change;
- 204 2. The new tax ID number and copy of W-9, as applicable;
- 205 3. The name of the new practice, contact person, address, telephone and fax numbers;  
206 and
- 207 4. Other such information as may materially differ from the most recently completed  
208 credentialing application submitted by the provider to the MCHIP licensee.

209 This provision shall not apply if the provider's prior place of employment or employer had been  
210 delegated credentialing responsibility by the MCHIP licensee.

211 Nothing in this section shall be construed to require an MCHIP licensee to contract or  
212 recontract with a provider.

213 ~~F. The appropriate credentialing process shall be completed before the provider:~~

- 214 ~~1. Begins seeing covered persons;~~
- 215 ~~2. Enters into the employment or contractual relationship with the MCHIP licensee; and~~
- 216 ~~3. Is included in the listing of health care providers as a participating provider in any~~  
217 ~~marketing and covered person materials.~~

218 G.F. The providers shall be recertified at least every three years. Recredentialing  
219 documentation shall include:

- 220 1. Current valid license or certification;
- 221 2. Status of hospital privileges, if applicable;
- 222 3. Current valid DEA registration, if applicable;
- 223 4. Specialty board eligibility or certification status, if applicable;
- 224 5. Data from covered person complaints and the results of quality reviews, utilization  
225 management reviews and covered persons satisfaction surveys, as applicable; and
- 226 6. Current, adequate malpractice insurance and history of malpractice claims and  
227 professional liability claims resulting in settlements or judgments.

228 H.G. All information obtained in the credentialing process shall be subject to review and  
229 correction of any erroneous information by the health care provider whose credentials are being  
230 reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose

231 to a provider, or any other person or party, information or documents: (i) that the MCHIP or the  
232 MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing  
233 process or (ii) that are privileged under applicable law. The department may require the MCHIP  
234 licensee to provide a copy of its credentialing policies.

235 I.H. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in  
236 the status of any credentialing criteria.

237 J.I. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the  
238 credentials of a health care provider solely because the provider treats a substantial number of  
239 patients who require expensive or uncompensated care.

240 K.J. The MCHIP licensee shall have policies and procedures for altering the conditions of the  
241 provider's participation with the MCHIP licensee. The policies shall include actions to be taken to  
242 improve performance prior to termination and an appeals process for instances when the MCHIP  
243 licensee chooses to alter the condition of provider participation based on issues of quality of care  
244 or service, except in circumstances where an covered person's health has been jeopardized.  
245 Providers shall have complete and timely access to all data and information used by the licensee  
246 to identify or determine the need for altering the conditions of participation.

247 L.K. The MCHIP licensee shall retain the right to approve new providers and sites based on  
248 quality issues, and to terminate or suspend individual providers. Termination or suspension of  
249 individual providers for quality of care considerations shall be supported by documented records  
250 of noncompliance with specific MCHIP expectations and requirements for providers. The provider  
251 shall have a prescribed system of appeal of this decision available to them as prescribed in the  
252 contract between the MCHIP or its delegated service entity and the provider.

253 M.L. Providers shall be informed of the appeals process. Profession specific providers actively  
254 participating in the MCHIP plan shall be included in reviewing appeals and making  
255 recommendations for action.

256 N.M. The MCHIP licensee shall notify appropriate authorities when a provider's application or  
257 contract is suspended or terminated because of quality deficiencies by the health care provider  
258 whose credentials are being reviewed.

259 O.N. There shall be an organized system to manage and protect the confidentiality of  
260 personnel files and records. Records and documents relating to a provider's credentialing  
261 application shall be retained for at least seven years.

262 Statutory Authority

263 O. The MCHIP licensee shall establish protocols and procedures for reimbursing new provider  
264 applicants, after being credentialed by the MCHIP licensee, for health care services provided to  
265 covered persons during the period in which the new provider applicant's completed credentialing  
266 application was pending. At a minimum, the protocols and procedures shall:

267 1. Apply only if the new provider applicant's credentialing application is approved by the  
268 MCHIP licensee;

269 2. Permit provider reimbursement for services rendered from the date the new provider  
270 applicant's completed credentialing application is received for consideration by the MCHIP  
271 licensee;

272 3. Apply only if a contractual relationship exists between the MCHIP licensee and the new  
273 provider applicant or entity for whom the new provider applicant is employed or engaged;  
274 and

275 4. Require that any reimbursement be paid at the in-network rate that the new provider  
276 applicant would have received had he been, at the time the covered health care services  
277 were provided, a credentialed participating provider in the network for the applicable  
278 managed care plan.

279 P. Nothing in this section shall require:  
280 1. Reimbursement of provider-rendered services that are not benefits or services covered  
281 by the MCHIP licensee's managed care plan.  
282 2. An MCHIP licensee to pay reimbursement at the contracted in-network rate for any  
283 covered health care services provided by the new provider applicant if the new provider  
284 applicant's credentialing application is not approved or the MCHIP licensee is otherwise  
285 not willing to contract with the new provider applicant.  
286 Q. Payments made or retroactive denials of payments made under this section shall be  
287 governed by § 38.2-3407.15.  
288 R. If a payment is made by the MCHIP licensee to a new provider applicant or any entity that  
289 employs or engages a new provider applicant under this section for a covered service, the patient  
290 shall only be responsible for any coinsurance, copayments, or deductibles permitted under the  
291 insurance contract with the MCHIP licensee or participating provider agreement with the provider.  
292 S. A new provider applicant, in order to submit claims to the MCHIP licensee pursuant to this  
293 section, shall provide written or electronic notice to covered persons in advance of treatment that:  
294 1. He has submitted a credentialing application to the MCHIP licensee of the covered  
295 person; and  
296 2. The MCHIP licensee is in the process of obtaining and verifying the written  
297 documentation from the new provider applicant, pursuant to 12VAC5-408-170 A.  
298 The written or electronic notice shall conform to the requirements in § 38.2-3407.10:1 G of the  
299 Code of Virginia.  
300 Statutory Authority  
301 § 32.1-137.4 §§ 32.1-12 and 32.1-137.3 of the Code of Virginia.  
302 Historical Notes  
303 Derived from Virginia Register Volume 16, Issue 7, eff. January 20, 2000; amended, Virginia  
304 Register Volume 18, Issue 8, eff. January 30, 2002.





# COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA  
STATE HEALTH COMMISSIONER

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

## MEMORANDUM

DATE: July 18, 2019

TO: State Board of Health

FROM: Allen L. Knapp, Director, Office of Environmental Health Services  
Julie Henderson, Director, Division of Food and General Environmental Services

SUBJECT: Proposed Amendments – Rules and Regulations Governing Bedding and Upholstered Furniture Inspection Program (12VAC5-125)

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Proposed amendments to the Commonwealth of Virginia Board of Health Regulations for Bedding and Upholstered Furniture Inspection Program (bedding regulations) are attached. The Virginia Department of Health (VDH) recommends that the Board adopt the proposed amendments to these regulations.

The Board of Health adopted the current bedding regulations on September 1, 2007. The intent of this regulatory action is to: i) reduce conflicts with other states' bedding and upholstered furniture regulations; ii) transparently outline existing requirements for use of animal hair, feathers, or down; iii) establish consumer notifications on law labels for the use of reclaimed and reprocessed materials; iv) clarify licensing and permitting requirements and operating standards; and v) address concerns expressed by the General Assembly and Office of the Attorney General regarding certain items in the regulation.

VDH completed a periodic review of the Regulations for Bedding and Upholstered Furniture Inspection Program on May 17, 2017, and concluded that the regulations needed to be amended. This regulatory action flows from that determination. VDH began regulatory action by publishing a Notice of Intended Regulatory Action (NOIRA) on January 21, 2019, and received no public comments on Virginia Town Hall regarding the proposed changes. Following the end of the public comment period of the NOIRA, a stakeholder group was formed that consisted of manufacturers and importers of bedding and upholstered furniture, representatives of the law label printing and registration industry, secondhand furniture resellers, re-upholsterers, and members of the national bedding and upholstered furniture regulatory community. Stakeholder webinars were held on April 17, 2019; April 25, 2019; and May 13, 2019; and these events were publicized on VDH's website and open for any attendee. Five hundred Virginia antique dealers received a letter notifying them of the

antiques-focused webinar and providing instructions on how to attend. All attendee groups delivered positive feedback on the proposed amendments, with the exception of an antique dealer who does not wish to fall under VDH regulation due to the proposed changes.

The following is a brief summary of the substantive changes:

1. Establishment of standards for reclaimed and reprocessed filling material.
2. Removal of unauthorized exemption for antique items (re: Office of the Attorney General, 2017 Periodic Review).
3. Re-naming re-upholsterer and renovator authorizations from license to permit (semantic only; in consideration of request made by 2018 General Assembly).
4. Removal of requirement for importers and distributors to obtain multiple licenses when they contract with multiple manufacturers.
5. Moving law label templates into cohesive tables and removing provisions contradictory to national standards, creation of law label template for reclaimed and reprocessed products
6. Clarification of existing sanitization procedures for secondhand bedding and combining two sections of sanitization requirements into one section (repealing and relocating)
7. Establishment of new general methods for sanitization (heat and steam) and pathway for new specific products and processes to be approved through policy
8. Transparently outlining existing standards for sterilized animal hair, feathers, and down and complying with national standards
9. Repealing unnecessary descriptions of agency authority and obsolete administrative and enforcement procedures and replacing with enforcement procedures compliant with the Virginia Administrative Process Act; and
10. Adjusting fee schedules to ensure importer and distributor license revenue remains budget neutral and the program's operating revenue will not change; exempting single-employee renovators and re-upholsterers from permit fees (in consideration of request made by 2018 General Assembly)

If the Board approves the proposed amendments, the regulation will be published on [www.townhall.virginia.gov](http://www.townhall.virginia.gov) where it will be available for public comment for 60 days. VDH then will consider comments in the preparation of final regulatory text. The proposed amendments are necessary to update the Regulations for Bedding and Upholstered Furniture Inspection Program. As such, VDH recommends that the Board act pursuant to its authority provided in § 32.1-12 of the Code of Virginia and adopt the proposed amendments to the regulations.



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

## Proposed Regulation Agency Background Document

|   |  |
|---|--|
| <b>Agency name</b>                                    | Virginia Department of Health  |
| <b>Virginia Administrative Code (VAC) citation(s)</b> | 12VAC5-125   |
| <b>Regulation title(s)</b>                            | Regulations for Bedding and Upholstered Furniture Inspection Program |
| <b>Action title</b>                                   | Amend regulations following Periodic Review                          |
| <b>Date this document prepared</b>                    | July 29, 2019  |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

### Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

The Regulations for Bedding and Upholstered Furniture Inspection Program (12VAC5-125) outline health, safety, and licensure requirements for mattresses, box-springs, pillows, comforters, cushions, and all upholstered furniture, including products designed for infants and small children. Licensure and inspection activities are performed in order to protect and promote public health through ensuring that all new bedding and upholstered furniture is properly labeled with the type of concealed filling materials found in the item. This law also ensures that consumers are informed about any animal hair, feathers, and down used as filling material, and the presence of any concealed material that may be an allergen to the members of the consumer's household. The regulations also protect Virginia consumers from diseases and insect pests spread through unsanitary secondhand bedding and upholstered furniture through permitting and inspection of secondhand dealers (Sanitizers), Reupholsterers, and Renovators.

The intent of this action is to: i) update the regulation by reducing conflicts with other states' bedding and upholstered furniture regulations, ii) transparently outline existing requirements for use of animal hair, feathers, or down, iii) establish consumer notifications on law labels for the use of reclaimed and reprocessed materials, iv) clarify licensing and permitting requirements and operating standards, and v) address concerns expressed by the General Assembly and Office of the Attorney General regarding certain items in the regulation.

The overarching goal of this regulatory action will be to protect the health and safety of consumers of new and secondhand bedding and upholstered furniture in the Commonwealth with a minimally intrusive regulation that is clear and easy to understand and implement.

### 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.*

None

### Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*

This regulatory action derives from two impetuses for change:

1. A 2017 periodic review of this chapter determined amendments were necessary to improve the legality, implementation, and clarity of the regulation; and
2. during the 2018 legislative session, the General Assembly requested the agency consider specific amendments to the regulation (see *Purpose* section for details).

### Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.*

The Virginia Department of Health has general authority to promulgate regulations pursuant to § 32.1-12 of the Code of Virginia, which states the Board shall make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of the title to protect the public health and safety. Sections 32.1-212 through 32.1-226 of the Code of Virginia require every entity importing, manufacturing, renovating, or reupholstering any bedding or upholstered furniture, or processing or selling any filling material to be used in articles of bedding or upholstered furniture, must obtain a license from the Commissioner of the Virginia Department of Health. Every entity renting, selling, or bartering a secondhand item of bedding and upholstered furniture must sanitize the item before commercial disposal, and must obtain a permit to do so from the Commissioner of the Virginia Department of Health (with no

exemptions for antiques established in Code). Section 32.1-218 of the Code of Virginia authorizes the Board of Health to establish fees for licensing and permitting. Additionally, every item of bedding or upholstered furniture sold, rented, or otherwise commercially distributed in the Commonwealth must be tagged with a law label accurately describing the item.

## Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.*

Nationwide, one independent locality and 32 other states regulate bedding and upholstered furniture. These localities use the Uniform Registry Number (URN) system, in which all localities recognize registration numbers issued by other localities, and allow Manufacturers and Importers to use these numbers in the licensing and registration of their products across the country. These numbers are used on the law labels required on bedding and upholstered furniture. However, law label requirements in Virginia contain conflicts with other states' standards, which creates an unnecessary burden on industry. Eliminating the conflicts between Virginia regulations and national standards will reduce the burden on the regulated industry, bring Virginia in line to national standards, and still be protective of public health.

Additionally, during development of the proposed amendments, the regulated industry and representatives from other state's bedding and upholstered furniture regulatory programs requested Virginia address standards for reclaimed and reprocessed filling materials in the amendments. Public demand for products made with post-consumer materials has increased in recent years, and is only expected to further increase in the future. New technologies have allowed reclaimed and reprocessed materials, such as polyester generated from recycled plastic and post-consumer reclaimed down, to be processed with methods that produce products with equal or better quality and cleanliness than those made with virgin materials. The language of the regulation must be updated to reflect these modern practices in industry.

The text of the regulation is currently vague about certain licensing requirements, implying multiple licenses must be held by Importers and Distributors working with multiple Manufacturers. Additionally, permitting requirements for Reupholsterers and Renovators who also need to sanitize secondhand bedding and upholstered furniture are not clear, and the implications of exemptions for individuals who sell their household goods through consignment are not well set out. Overall, the language of all licensing, permitting, inspection, and enforcement sections require revision and streamlining to make administrative procedures more clear to the regulated public.

During the 2018 legislative session, the General Assembly requested that the Virginia Department of Health consider amending 12VAC5-125. Specifically, it was requested that the department issue Reupholsterers an operating permit instead of a license (this is a semantic change only), and consider reducing the fee associated with this permit. Both of these requests were addressed in the proposed amendments.

Additionally, the Office of the Attorney General stated in the 2017 Periodic Review of this regulation that the Board of Health does not have the authority to exempt antiques from this regulation. As this regulation currently has an exemption for antiques, this language must be removed to align with the Board's statutory authority.

## Substance

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

The proposed amendments reorganize the way information is presented, add a new sections to outline variance procedures, repeal sections to remove obsolete information and duplication, and improve grammar and ease of understanding by the general public and regulated industry.

Substantive changes include:

1. Revision, addition, and deletion of definitions as required to support other amendments;
2. Establishment of standards for reclaimed and reprocessed new materials;
3. Removal of unauthorized exemption for antique items;
4. Revision and clarification of license and permit application procedures;
5. Re-designating Reupholsterer and Renovator authorizations as permits (currently licenses, semantic only);
6. Removal of requirement for Importers and Distributors to obtain multiple licenses when they contract with multiple Manufacturers;
7. Reorganization and clarification of the agency's rights to inspect under this chapter;
8. Moving law label templates into cohesive tables and removal of provisions contradictory to national standards;
9. Creation of law label template for reclaimed and reprocessed products;
10. Clarification of existing sanitization procedures for secondhand bedding, combining two sections of sanitization requirements into one section (repealing and relocating);
11. Establishment of new general methods for sanitization (heat and steam) and pathway for new specific products and processes to be approved through policy;
12. Transparently outlining existing standards for sterilized animal hair, feathers, and down; complying with national standards;
13. Establishment of enforcement procedures compliant with the Virginia Administrative Process Act;
14. Repealing unnecessary descriptions of agency authority and obsolete administrative and enforcement procedures;
15. Adjusting fee schedules to ensure Importer and Distributor license revenue remains budget neutral and the program's operating revenue will not change; exempting single-employee Renovators and Reupholsterers from permit fees;
15. Repealing an obsolete "Documents Included By Reference" terminology manual no longer in use; and
16. Revision of the regulation title for improved grammar when the chapter is referenced in text.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The primary advantage of the proposed amendments is that they will provide organization and clarity to the existing text, which will better facilitate the public's and regulated industry's understanding of the regulation.

Under the amendments, Importers and Distributors will maintain one license. These license holders will save significant time and effort in comparison to their current administrative burden of maintaining multiple licenses (when they contract with multiple Manufacturers; in some cases, up to 86 fewer licenses will be required for an importing entity). Fee adjustments will ensure no overall revenue change associated with this amendment.

The amendments will also provide industry a compliant pathway for the use and labeling of products with reclaimed and reprocessed filling materials, which are not currently addressed in the regulation. These new provisions will respond to and address a growing sector in the industry, and better meet public demand for safe and healthy eco-friendly products.

Antique dealers will experience some disadvantage through the elimination of the current exemption for antiques. Businesses that are not currently regulated by the agency (because they do not sell non-antique bedding or upholstered furniture) will be required to sanitize regulated items and retain a Sanitizer permit. However, there is no option for this change, as it is required to bring the chapter under

the limits of its statutory authority. Multiple changes to sanitizing requirements, most notably the addition of steam as a sanitizing method, are designed to mitigate these disadvantages for businesses that do not want to use the currently approved method of spraying items with isopropyl-alcohol based chemicals.

The agency will benefit from the clarity of the revisions, as they may reduce the time and effort staff spend on explaining procedures that are not well outlined in the current text. The agency also expects to observe a slight reduction in licensing administrative procedures (e.g. returned, incomplete license applications).

### Requirements More Restrictive than Federal

*Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.*

There are no requirements that exceed applicable federal requirements; there are no federal requirements that directly overlap with the scope of this regulation.

### Agencies, Localities, and Other Entities Particularly Affected

*Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

There are no state agencies, localities, or other entities which bear any identified disproportionate material impacts.

### Economic Impact

*Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.*

#### Impact on State Agencies

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| <p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> <li>a) fund source / fund detail;</li> <li>b) delineation of one-time versus on-going expenditures; and</li> <li>c) whether any costs or revenue loss can be absorbed within existing resources</li> </ul> | <p>a) Per § 32.1-218, all fee revenue is held in a separate fund for the expenditures of administering the bedding program (Agency cost code 102P). To construct the proposed fee schedule, current (2018) Importer and Distributor accounts were analyzed for distributions of the number of licenses held by each discrete entity; various fee schedules were modeled on this distribution until an ideal schedule was selected.</p> |
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|  | <p>This schedule has the least total fee change for entities, results in neutral revenue, and reflects the cost to the agency of administering each account. Currently, these entities pay \$100 per license; one license corresponds to one Manufacturer Uniform Registry Number (URN) from which they import or distribute. In the new schedule, all URNs from which they import or distribute from will be tied to a singular Importer or Distributor license with one fee. A sliding scale was selected to reduce mid-year administrative burden to industry when Importers and Distributors add new Manufacturer URNs to their license. The proposed fee schedule will allow this flexibility and will result in negligible income difference compared to the current fee schedule (modeled outcome with 2018 licenses: \$212,600 under current schedule vs. \$216,180 for new schedule).</p> <p>Creation of a fee exemption for single-employee Renovators and Reupholsterers is not expected to have a significant fiscal impact to the agency. The agency has no estimate of how many permit holders will qualify for this exemption, but total revenue for these permit types is less than 1% of all fee revenues (\$4,500 of \$695,865 for active accounts at time of analysis).</p> <p>b) The one-time costs to administrative and data-keeping systems associated with fee changes are expected to be approximately \$8,000. Bringing antique dealers under regulation will require one-time costs for outreach, inspector travel to seek out and communicate with unpermitted entities, and initial permitting costs. These costs are estimated at \$50,000.</p> <p>c) One-time costs associated with permitting for antique dealers will exceed the revenues from those permits by approximately \$20,000; however, these costs are expected to be able to be absorbed by the existing total revenues of the program.</p> |
| <p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p> | <p>There are no impacts to any other state agency.</p>  |
| <p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>   | <p>Fee adjustments are designed to be revenue neutral. Text changes will result in greater clarity to the regulated industry, which is anticipated to slightly reduce the administrative burden of the program (in returned, incomplete license applications).</p>  |

**Impact on Localities**



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| Projected costs, savings, fees or revenues resulting from the regulatory change. | There are no impacts on localities.   |
| Benefits the regulatory change is designed to produce.                           | There are no impacts on localities other than a general increase in clarity for regulated entities and members of the public. |

**Impact on Other Entities**

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.  | Three sectors will be most affected by this regulatory change:<br>1. Antique dealers currently not regulated under this chapter that will require a Sanitizers permit (\$60) and must sanitize secondhand bedding and upholstered furniture before sale.<br>2. Importers and Distributors who will no longer have to maintain a separate license for each URN from which they import or distribute.<br>3. Companies that wish to make, sell, and label products with reclaimed and reprocessed filling materials.   |
| Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.  | As antiques are not currently regulated, the agency has no internal data source for the number of entities operating in the Commonwealth. There is no Virginia chapter of any antique dealer’s trade or professional organization. Antiques.com lists approximately 500 vendors in the Commonwealth. The agency expects all of these entities qualify as small businesses.<br>For the 2018 license year, there were 690 discrete entities with Importer or Distributor licenses. The majority of these entities may be small businesses with less than 500 employees, but the agency does not collect information on the size of these businesses.  |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:<br>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br>c) fees;<br>d) purchases of equipment or services; and<br>e) time required to comply with the requirements. | a) Importers and Distributors will see significant costs savings from only having to maintain one license, but these costs cannot be generalized, as they will vary on the individual business’s size and internal structure. Currently, these entities pay \$100 per license, and entities maintain 1-84 licenses each.<br>There will be little to no (<\$5) cost associated with the new requirement for keeping a record of sanitization events in a delivery vehicle; this sanitization was already required, and only the logging of the event is a new provision.<br>Newly regulated antique dealers will require an annual Sanitizer permit (\$60).<br>b) There are no real estate development implications for this regulatory action.<br>c) The majority of the fees are unchanged, with implementation of a sliding fee scale, Importers and Distributors will pay a slightly higher license fee. Contacted stakeholders with the largest |

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|   | <p>increased fees report satisfaction with this proposal, as administrative savings associated with only having one license to maintain more than offset the fee increase. The agency presented these fees to industry at a national conference and in a public webinar, and have received no objections to the slight increases. Reupholsterers and Renovators with no additional employees (one-individual business) will be exempt from the \$25 fee; this action was taken in response to a request for fee reductions for this permit category from the General Assembly in 2018.</p> <p>d) Newly regulated antique dealers will incur the cost of purchasing sanitizing equipment, such as the spray chemical SteriFab (~\$40 for 48 oz.) or a hand-operated steamer (\$50-\$100, depending on type purchased).</p> <p>e) There is no anticipated time required to comply with new requirements, with the exception of newly-regulated antique dealers establishing proper sanitizing procedures in their businesses.</p> |
| <p>Benefits the regulatory change is designed to produce.</p> | <p>The major benefits of these changes are:</p> <ol style="list-style-type: none"> <li>1. Reduction in labeling conflicts for bedding and upholstered furniture industry,</li> <li>2. Pathway for use of reclaimed and reprocessed materials in manufactured products,</li> <li>3. Significantly reduced administrative burden on Importers and Distributors,</li> <li>4. More options for approved methods of sanitization, and</li> <li>5. Increased clarity in existing standards.</li> </ol>  |

## Alternatives

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

Alternatives to amending this regulation would be to leave the regulation in place without any revision. However, this will result in maintaining a regulation with burdensome and unneeded standards for law labels that conflict with requirements in other states, and a lack of overall clarity in administrative and licensing/permitting requirements. Leaving the exemption for antique dealers in place is not a viable option; the regulation must lie within its designated statutory authority. The proposed revisions should eliminate nationwide conflicts, streamline administrative processes, and increase the clarity of health and safety standards for facilities that sell used bedding and upholstered furniture.

## Regulatory Flexibility Analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.*

1. There are minimal reporting requirements associated with the proposed regulation. The proposed amendments streamline the licensing process for Importers and Distributors, reducing the administrative burden borne by industry. The compliance requirements of the proposed regulation should not be reduced or simplified, as the agency believes they establish the minimum standards required to protect public health and safety.
2. No deadlines have been modified in the proposed amendments.
3. As noted above, reporting (licensing application) requirements in the proposed amendments have been simplified and consolidated.
4. Design and operational standards cannot be further simplified or replaced; the requirements of the regulations are minimal and already partially performance-based. The proposed amendments do not place any significant additional procedural requirements in place. Clarifications and new provisions establish allowances for use of reclaimed and reprocessed materials, such as polyester made from reprocessed plastic water bottles. Additionally, provisions for different methods of sanitizing have been created to allow maximum flexibility for businesses, including the newly-regulated antiques sector.
5. Small businesses can readily comply with the requirements of the proposed amendments. In consideration of the request of the General Assembly (see *Mandate and Impetus*), self-employed Renovators and Reupholsterers with no employees have been given an exemption to permit fees.

**Periodic Review and Small Business Impact Review Report of Findings**

*If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.*

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

Not applicable.

**Public Comment**

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

| Commenter | Comment   | Agency response |
|-----------|---|-----------------|
|           | There were no comments received on Town Hall or directly by the agency during the public comment period of the Notice of Intended Regulatory Action (NOIRA) from 1/21/2019 – 2/20/2019. |                 |
|           |   |                 |

### Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Virginia Department of Health 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 for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Olivia McCormick, [Olivia.Mccormick@vdh.virginia.gov](mailto:Olivia.Mccormick@vdh.virginia.gov), 804-864-7475(fax). In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<https://townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://commonwealthcalendar.virginia.gov/>). Both oral and written comments may be submitted at that time.

### Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

For changes to existing regulation(s), please use the following chart:

| Current section number | New section number, if applicable | Current requirement  | Change, intent, rationale, and likely impact of new requirements                           |
|------------------------|-----------------------------------|--|--|
| CHAPTER<br>TITLE       |                                   | Regulations for Bedding and Upholstered Furniture Inspection Program | <b>Intent-</b> Changes title to <u>Regulations for Bedding and Upholstered Furniture</u> . |

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|  |  |   | <p><b>Rationale-</b> Updated to sound grammatically correct in sentences referencing the chapter.</p> <p><b>Impact-</b> None.</p>  |
| <p>12VAC5-125-10</p> <p>Row 1 of 3 for this section</p> <p>DELETIONS</p> |  | <p><b>Definitions.</b><br/>                 "Antique"<br/>                 "As is"<br/>                 "Board"<br/>                 "Commissioner"<br/>                 "Department"<br/>                 "Designee or designated officer or agent"<br/>                 "Inspector"<br/>                 "Soiled or torn"<br/>                 "Used"<br/>                 "Wholesaler"</p> <p>"Filling material definitions will be in accordance with definitions published in the 2004 Edition of the International Sleep Products Association Handbook."</p>  | <p><b>Intent-</b> The definitions and statement listed in column 3 will be deleted.</p> <p><b>Rationale-</b> The terms are no longer used in the regulations, or are changed to other definitions (Commissioner to Health Commissioner). The referenced handbook is no longer in use by the Bedding Program or industry.</p> <p><b>Impact-</b> Streamlined regulation with no erroneous or unnecessary references.</p> |
| <p>12VAC5-125-10</p> <p>Row 2 of 3 for this section</p> <p>EDITS</p>     |  | <p><b>Definitions.</b><br/>                 "Bedding"<br/>                 "Bedding Program"<br/>                 "Distributor/wholesaler"<br/>                 "Filling material"<br/>                 "Importer"<br/>                 "Law label"<br/>                 "License"<br/>                 "Licensing state"<br/>                 "Manufacturer"<br/>                 "New"<br/>                 "Permit"<br/>                 "Person"<br/>                 "Renovator"<br/>                 "Retailer"<br/>                 "Reupholsterer"<br/>                 "Secondhand"<br/>                 "Sell"<br/>                 "Shoddy"<br/>                 "Shoddy pad"<br/>                 "Supply dealer"<br/>                 "Uniform registry number"<br/>                 "Upholstered furniture"</p> | <p><b>Intent-</b>The definitions for the terms listed in column three will be amended.</p> <p><b>Rationale-</b>The changes reflect current use of the terms, grammar improvements, changes in terminology, and/or using easier to understand word choices.</p> <p><b>Impact-</b> Improved understanding and application of the regulations.</p>  |
| <p>12VAC5-125-10</p> <p>Row 3 of 3 for this section</p> <p>ADDITIONS</p> |  | <p><b>Definitions.</b><br/>                 N/A</p>   | <p><b>Intent-</b> Adds new definitions for: "Health Commissioner" "Reclaimed and reprocessed".</p> <p><b>Rationale-</b> Relocation for stricken definition "Commissioner".</p> <p>New definition for "reclaimed and reprocessed" adapted from Global</p>   |

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|               |          |   | <p>Recycling Standard. The term “recycled” is currently prohibited in several states that regulate bedding and upholstered furniture, so “reclaimed and reprocessed” was chosen to avoid national conflicts.</p> <p><b>Impact-</b>Introduces concept of reclaimed and reprocessed into the chapter.</p>  |
| 12VAC5-125-20 | Repealed | <p><b>Administration.</b><br/>Describes rights of the Board to enact the regulations.</p>   | <p><b>Intent</b> - Removes language unnecessary to the regulation.</p> <p><b>Rationale-</b> These authorities are established in §§32.1- 212 through 226; Statements are not integral to the chapter.</p> <p><b>Impact-</b> None. Removal of the language streamlines the chapter, but does not affect any of the described authorities.</p>   |
| 12VAC5-125-30 |          | <p><b>Powers and procedures of chapter not exclusive.</b><br/>The Board may pursue enforcement options not listed in the chapter.</p>                           | <p><b>Intent-</b> Changes title to <u>Compliance with the Virginia Administrative Process Act</u> and outlines the chapter will be enforced in accordance with this act.</p> <p><b>Rationale-</b> All enforcement procedures must be compliant with the Administrative Process Act.</p> <p><b>Impact-</b>None.</p>   |
| 12VAC5-125-40 |          | <p><b>Exemptions.</b><br/>Establishes list of exemptions from chapter, includes exemption for antiques, and an individual selling personal household goods.</p> | <p><b>Intent-</b>Removes exemption for antiques.<br/>Includes reference to consignment in exemption for an individual selling personal household goods.<br/>Adds two exemption types relocated from section 100.</p> <p><b>Rationale-</b>The regulations may not exempt antiques; this exemption is not provided for in the Code of Virginia, which directs the Board to regulate secondhand items (thereby including antiques).<br/>Consignment is the sale of an item by an individual, through a broker, and is equivalent to sale through a yard or garage sale, or listing on online self-sell platforms (examples exempt through the provision for individual sale). The exemption for individuals selling household items currently</p> |

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|                      |  |   | <p>applies to consignment; inclusion of the new language is for clarity. Relocated exemptions logically belong in this exemptions section.</p> <p><b>Impact-</b> Antique dealers selling bedding and upholstered furniture will have to sanitize articles and obtain a Sanitizer permit. Requirements for consignment will be more transparent; no change in regulation results from the amendment.</p>  |
| <p>12VAC5-125-50</p> |  | <p><b>Licenses, permits, and registration numbers.</b><br/>Establishes requirement for licenses and permits. Outlines transferability, application procedures, and issuance procedures for licenses and permits. Establishes that Importers and Distributors must obtain a separate license for each branch factory they contract with (i.e. each Manufacturer/URN they import or distribute from).</p> | <p><b>Intent-</b> Revises section title to <u>Licenses, permits, and uniform registry numbers</u>. Reorganizes and reorders subsections. Changes terminology for Reupholsterer and Renovator authorizations from <u>license</u> to <u>permit</u>. Clarifies that the processes used by Sanitization and Sterilizer permit applicants must comply with the regulations. Outlines use of uniform registry numbers. Removes requirement for Importers and Distributors to obtain a separate license for each branch factory they contract with (i.e. each Manufacturer/URN they import or distribute from).</p> <p><b>Rationale-</b> The terminology change of license to permit was requested by the 2018 General Assembly; the agency agrees permit better suits the operations of a facility; license carries the connotation of an authorized entity, rather than an operating facility. Permit application requirements (processes must comply) are currently implied in regulation; amendments will ensure this provision is more clearly stated. Uniform registry number assignment and use varies between licensee types (existing national practice), and this should be clearly stated in the chapter.</p> <p>The requirement for Importers and Distributors to obtain a separate license for each branch factory they contract with is a significant administrative burden to industry. This requirement is not reflected in the</p> |

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|               |          |  | <p>Code language requiring licensure (§32.1-217).</p> <p><b>Impact-</b> Regulation is clearer, more transparent, and easier to understand. Terminology for Reupholsterers and Renovators is aligned to other regulated counterparts (operating facilities v. licensed entities). Revising Importer and Distributor licensure requirements lifts a significant administrative burden to industry. There is no revenue impact associated with this change (see section 180).</p>   |
| 12VAC5-125-60 |          | <p><b>Revocation of a license or permit.</b><br/>                 Outlines revocation of licenses and permits.</p>   | <p><b>Intent-</b> Revises section title to <u>Enforcement, Notices, Informal Conferences</u> (second and third term capitalized because they are proper nouns); content updates with modern language on revocations, suspensions, and informal conferences.</p> <p><b>Rationale-</b>Revised procedures are more reflective of current practice and are more inclusive of options and procedures provided by the Administrative Process Act; added language is adapted from other Environmental Health Regulations.</p> <p><b>Impact-</b> None.</p> |
| 12VAC5-125-70 | Repealed | <p><b>Application after revocation.</b><br/>                 Describes permit or license application after revocation</p>  | <p><b>Intent-</b> Content addressed in section 60.</p> <p><b>Rationale-</b>Content more applicable in section 60.</p> <p><b>Impact-</b>None.</p>   |
| 12VAC5-125-80 |          | <p><b>Inspections.</b><br/>                 Outlines six types of complaints that may result in an inspection.</p> <p>Late or nonrenewal of permit may result in an inspection.</p> <p>Permit holders must self-report any infestations at their place of business to the Bedding Program.</p> | <p><b>Intent-</b>Revises and restructures entire section. Complaint types will be consolidated to one item. Inspection types will be organized in new structure: inspections of unlicensed/unpermitted entities, and inspections of licensed/permitted entities. Infestation reporting will be relocated to section 100. Adds inspection documentation requirements.</p> <p><b>Rationale-</b> Listing six types of complaints was unnecessary; all types</p>   |



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|   |  |  | <p>are more effectively described once, simply as complaints.<br/>                 Restructuring the presentation of inspection types does not reflect change from the current regulation; the edit is for clarity only.<br/>                 Infestation reporting is more logically located in section 100 with other operating standards for secondhand businesses.<br/>                 Statement on documentation added to improve transparency on public expectations of the enforcement of this chapter.</p> <p><b>Impact-</b> Increase in organization, simplicity, and clarity.</p>  |
| <p>12VAC5-125-90</p> <p>Row 1 of 2 for this section</p> <p>TEXT</p> |  | <p><b>Law labels conforming to the Virginia law.</b><br/>                 Description of general provisions for law labels, when they must be attached; includes both new and secondhand law labels.</p> | <p><b>Intent-</b> Changes section title to <u>Law label requirements</u>.<br/>                 All content will be reorganized and rephrased; all requirements remain the same, except:<br/>                 Reference to requirements for bold font will be removed.<br/>                 Adds three choices for declaring a percentage of new filling materials as “reclaimed and reprocessed” (all are optional):</p> <ol style="list-style-type: none"> <li>1. Statement in ‘Other Information’ section of standard new product law label (table 1; see next row for label table changes),</li> <li>2. Use of new ‘Reclaimed and Reprocessed’ law label (table 2), or</li> <li>3. Both.</li> </ol> <p><b>Rationale-</b> Reorganization of content and renaming of section was necessary to update and modernize language, and to improve clarity and sentence structure.<br/>                 Bold font is not a clearly evaluated standard (non-bold font on one tag may be printed with same intensity as bold on a different tag). This change will not mean bold is not allowed, only that Virginia will not regulate bold font.</p> <p>Standards for declaring reclaimed and reprocessed materials have been requested by industry; however, restrictions in place in other states require these standards be introduced thoughtfully, in a manner allowing a tiered approach:</p> |

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|   |  |  | <p>1. All language on reclaimed and reprocessed is optional. Reclaimed and reprocessed materials are new materials, and use of the new materials law label with no other addition is legal.</p> <p>2. Where a product will be sold in Virginia <i>and</i> states that allow the reference to reclaimed and reprocessed in the ‘Other Information’ section, this statement can be added to the new materials law label.</p> <p>3. Where the product will be sold only in Virginia, or in Virginia and in other states without a bedding law or law label standards, (and in the future, in any state adopting the green font reclaimed and reprocessed label), the product can use the green font reclaimed and reprocessed law labels.</p> <p>4. To ease burden on manufacturing, both may be used on products sold in Virginia (Manufacturers may attach both and remove one for sale in other states, or other states may allow the reclaimed and reprocessed label only if the standard national new label is also present).</p> <p><b>Impact-</b> Virginia better responds to public demand, industry requests, and a key component of bedding and upholstered furniture law: consumer notification.</p> <p>These standards pave the way for national acceptance of reclaimed and reprocessed materials in bedding and upholstered furniture products. Green-font labels will draw consumer attention and increase the relevancy of law labels to the public.</p> <p>Several states have expressed interest in adopting the reclaimed and reprocessed standards and templates established in this regulatory action.</p> |
| <p>12VAC5-125-90</p> <p>Row 2 of 2 for this section</p> <p>TABLES</p> |  | <p><b>Law labels conforming to the Virginia law.</b></p> <p>Seven “Attachments”, each with a table demonstrating a law label template, footnotes, and margin notes. Each attachment has identical margin notes.</p> <p>Template types/names:</p> <p>1. All new material,</p> | <p><b>Intent-</b> Removes all seven existing law label template tables (referred to as “Attachments” in text, and all footnotes associated with them.</p> <p>Adds three new tables compiling templates for law labels</p> <p>Table 1- New (not secondhand) bedding and upholstered furniture labels</p> <p>Table 2- New (not secondhand) OPTIONAL bedding and upholstered</p>  |

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|  |  | <p>2. All new material articles with extra cushions as an integral part of unit,<br/>         3. Animal hair, feathers, or down and other materials requiring sterilization,<br/>         4. Secondhand items remade or renovated for a consumer,<br/>         5. Secondhand items,<br/>         6. Secondhand items remade or renovated for resale, and<br/>         7. Filling materials (in bulk).</p> | <p>furniture labels for entities that choose to declare a percentage of new materials are reclaimed and reprocessed.<br/>         Table 3- Secondhand bedding and upholstered furniture labels.</p> <p>All individual law label templates are identical to pre-amendment versions, except:<br/>         “Date of Delivery” and font size requirement for certification statement will be removed.<br/>         Items will be re-ordered on secondhand product law labels, and a combination Sanitizer and Renovator/Reupholsterer law label will be established.</p> <p><b>Rationale-</b> The existing seven tables are difficult for regulated industry to review and compare. The repetition of footnotes gives the illusion of varying requirements for each tag. The consolidation into three tables will make it easier to find the pertinent label for each product.<br/>         Removed items (date of delivery and font size for certification statement) are not required elsewhere in the country, have no impact to public health, and represent a burden to industry; law label printing is a significant cost to industry, and there is no reason Virginia should require a different law label template than other states.</p> <p>Creating an optional label, with “reclaimed and reprocessed” at the top of the label, provides maximum notification to the consumer about the type of concealed filling materials in the item. This label may not yet be legal in several states (although they have expressed interest in changing their laws to model new tags established in this regulatory change), so it is deemed optional.<br/>         Manufacturers may attach it when the product will not be sold in a state where it is not a legal law label (also see above row on section 90 text changes for context on this label change).<br/>         Reordering items on secondhand labels and creating a combination</p> |
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|                       |  |   | <p>Sanitizer and Renovator/Reupholsterer label in column 3 of table 3, will make the labels easier to compare and use.</p> <p><b>Impact-</b> Industry will not have to maintain compliance with certain law label requirements that are not required elsewhere in the country, and that do not impact public health. Industry will have multiple legal options to declare that a percentage of the new materials are reclaimed and reprocessed, with built in flexibility for adapting to national standards, and the continuing evolution of bedding and upholstered furniture laws in America. No impact for secondhand label changes.</p>   |
| <p>12VAC5-125-100</p> |  | <p><b>Sanitization of Used Bedding and Upholstered Furniture.</b></p> <ol style="list-style-type: none"> <li>1. Secondhand products must be sanitized, tagged, and logged,</li> <li>2. Use of two spray products, named by brand (SteriFab and Microban), are approved sanitizing methods, and</li> <li>3. Description of two exemption types.</li> </ol> | <p><b>Intent-</b>Changes section title to <u>Secondhand bedding and upholstered furniture</u>.</p> <p>Adds language to clarify when reupholstered and renovated items must be sanitized.</p> <p>Removes brand names, outlines general process by which a person may apply for approval of sanitizing product (specific brand name or specific methodology), and outlines two categories of approved methods: isopropyl alcohol-based spray, and thermal (heat or steam).</p> <p>Relocates requirement for delivery vehicle sanitization from section 110, adds requirement for vehicle sanitizing events to be logged, and removes date sold tracking requirements for all sanitizing logs.</p> <p>Relocates requirement that premises must be clean from section 110.</p> <p>Strikes exemptions (moved to section 40).</p> <p><b>Rationale-</b> Name change reflects true scope of section (all secondhand industries: Sanitizers, Reupholsterers, and Renovators).</p> <p>Distinction of when remade items require sanitization is existing, but was previously only outlined in the titles of law label templates, and thus was not immediately obvious.</p> <p>Brand names should not be included in regulation; the currently listed products (SteriFab and Microban) will still be approved for use, and are described</p> |

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|                       |  |  | <p>by the isopropyl alcohol spray category. Heat and steam are two established methods for pathogen destruction (and killing bedbugs and their eggs; serious concerns for secondhand furniture). Heat is already in use by the secondhand rental industry (on a case by case basis), and steam is added for consideration of antique dealers working with older fabrics where conservation is a concern.</p> <p>Relocated secondhand industry items create one section for secondhand item provisions (previously two, separated by a section on animal-derived filling materials).</p> <p>The requirement for vehicle sanitization logging was added to ensure there is a method to check compliance for the existing requirement to sanitize the vehicle; this will create little to no burden for industry.</p> <p>The prescriptive log requirement (date sold), used by inspectors to cross-check current inventory and logged sanitization events, was replaced with a performance measure (easily identifiable connection between log and inventory) to decrease burden on regulants. The stricken provision (date sold) is a common complaint of the regulated industry.</p> <p>Exemptions relocated, as they belong in exemptions section.</p> <p><b>Impact-</b> All item relocations will result in a regulation more easily understood by the public.</p> <p>Creation of a pathway for new sanitizing product approvals in policy will allow flexibility for industry without requiring a regulatory amendment (when brand names were listed in regulation).</p> <p>New sanitizing methods of heat and steam will allow flexibility while still being protective of public health and safety.</p> |
| <p>12VAC5-125-110</p> |  | <p><b>Sterilization of new animal hair, feathers and down.</b><br/>Animal-derived filling materials must be sterilized before use.</p> | <p><b>Intent-</b>Revises existing provision for grammar.<br/>Adds subsection on approved processes for sterilization; including pressurized steam, streaming steam, heat, and washing.</p>  |

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|                |          |  | <p><b>Rationale-</b> The methods added to this section are taken from sterilization laws in Utah and Pennsylvania. Without standards in place, past Virginia practice has been to send applicants for Sterilizer permits to Pennsylvania to obtain a permit before issuing one in Virginia. This practice evolved from Pennsylvania refusing reciprocity for Virginia-issued sterilization permit URNs, as Virginia had no standards for Sterilizers. This practice is common in other states as well. Utah has recently added Pennsylvania standards to their law to initiate reciprocity for Sterilizer URNs with Pennsylvania. Adding these standards, which are already national practice, will lead to transparency of current practice, and opportunity for future reciprocity of Sterilizer URNs with Pennsylvania and other states.</p> <p><b>Impact-</b> Standards for sterilization will be transparent to regulated industry. Virginia will no longer have to advise applicants that they should seek permitting in Pennsylvania prior to obtaining a permit in Virginia. There will be no process impact on regulants, as the described methods are already standard practice in industry.</p> |
| 12VAC5-125-120 | Repealed | <p><b>Separation and storage of new and sanitized items.</b><br/> 1. Separation of sanitized and unsanitized goods,<br/> 2. Delivery vehicle sanitization, and<br/> 3. Mattresses must be stored six inches or the height of one standard pallet off the floor.</p>  | <p><b>Intent-</b> Items 1 and 2 will move to section 100.</p> <p><b>Rationale-</b> (Items 1-2) All sanitization provisions should be in one section of the regulation for ease of access.</p> <p><b>Impact-</b> None.</p>  |
| 12VAC5-125-130 |          | <p><b>Violation of regulations.</b><br/> Establishes (in different order in section):<br/> 1. Retailer responsibility for compliance,<br/> 2. Authority to order Sanitizers with significant violations to cease selling secondhand merchandise until violations are corrected (placarding),<br/> 3. Violations of this chapter are also violations of the</p> | <p><b>Intent-</b>Provides grammar and word choice updates for items 1- 3. Removes reference to items 4-6.</p> <p><b>Rationale-</b> Increases clarity and simplicity of items 1- 3. Items 4- 6 are not integral to the chapter. All three enforcement outcomes are appropriate for the most flagrant, continued violations with serious threat to health; they have not been sought in any bedding regulation violation since the creation of this</p>  |

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|                |                | <p>Virginia Consumer Protection Act,<br/>                 4. Authority to order a violating product to be returned to a Manufacturer,<br/>                 5. Authority to refuse to issue a permit or license to persons who fail to appear in court to answer a charge of violation, and<br/>                 6. Violations of this chapter are Class 2 misdemeanors.</p> | <p>chapter. Inclusion is misleading to the regulated public.</p> <p><b>Impact-</b> No impact for revision to items 1- 3.<br/>                 The removal of items 4-6 does not impede the Board or Commonwealth’s authority to pursue these actions.</p>   |
| 12VAC5-125-140 | Repealed       | <p><b>Enforcement of regulation.</b><br/>                 Contains explanations on nature of Commissioner-issued enforcement orders, other enforcement options available to the Commissioner, and outlines differences between informal hearings and adjudicatory hearings.</p>   | <p><b>Intent-</b> Removes language unnecessary to the regulation.</p> <p><b>Rationale-</b> The described enforcement outcomes are possible for any violation of Title 32.1; inclusion in a bedding-specific chapter is unnecessary. The outcomes are appropriate for the most flagrant, continued violations with serious threat to health; they have not been sought in any bedding regulation violation since the creation of this chapter. Inclusion is misleading to the regulated public.<br/>                 Statements on hearings are not integral to the chapter, and provide unnecessary detail.</p> <p><b>Impact-</b>None. The removal of enforcement option references does not impede the Board or Commonwealth’s authority to pursue these enforcement avenues.<br/>                 Hearing rights are established in the Administrative Process Act, referenced in section 20 of this chapter.</p> |
|                | 12VAC5-125-145 | N/A; new section  | <p><b>Intent-</b> Establishes procedures for applications for variances to the regulations, and agency dispensation requirements for variances.</p> <p><b>Rationale-</b>Persons may request variances to the regulations; these may be granted by the authority of §32.1-12. The regulated public should be informed about how to apply for variances, how the agency must to respond to the request, and applicant’s rights under the Administrative Process Act.</p> <p><b>Impact-</b> Regulated public understands these procedures; there is no effect to the agency, as these practices are</p>  |

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|                |          |   | already in place, and the language is taken from other Environmental Health regulations.  |
| 12VAC5-125-150 | Repealed | <b>Request for hearing.</b><br>Procedures for requesting a hearing; hearing must be requested within 15 days of the decision to be challenged.  | <b>Intent-</b> Removes language and deadline unnecessary to the regulation.<br><br><b>Rationale-</b> Statement is not integral to the chapter, and establishes an unrealistic deadline for requests (regulated industry has significant presence in Southeast Asia; mail service can take a month).<br><br><b>Impact-</b> None, other than the removal of the deadline. These rights are established in the Administrative Process Act, referenced in section 20 of this chapter.   |
| 12VAC5-125-160 | Repealed | <b>Hearing as a matter of right.</b><br>Permit and license holders may request adjudicatory or informal hearings to contest any decision made subject to the chapter. Those not holding these authorizations may only request hearings if they can prove they have been harmed by a decision made subject to the chapter. | <b>Intent-</b> Removes language unnecessary to the regulation.<br><br><b>Rationale-</b> Statement is not integral to the chapter, and provides unnecessary and undesired detail about who has a right to a hearing.<br><br><b>Impact-</b> None. These rights are established in the Administrative Process Act, referenced in section 20 of this chapter.   |
| 12VAC5-125-170 | Repealed | <b>Penalties, injunctions, civil penalties and charges for violations.</b><br>Entities violating this chapter may be subject to civil penalties (fines, or charges imposed by the Board of Health) and criminal penalties (up to a class 2 misdemeanor).  | <b>Intent-</b> Removes references to enforcement outcomes extremely unlikely to be employed for violations of this chapter.<br><br><b>Rationale-</b> The described outcomes are possible for any violation of Title 32.1; inclusion in a bedding-specific chapter is unnecessary. The outcomes are appropriate for the most flagrant, continued violations with serious threat to health; they have not been sought in any bedding regulation violation since the creation of this chapter. Inclusion in is misleading to the regulated public<br><br><b>Impact-</b> None. The removal of these references does not impede the Board or Commonwealth's authority to pursue these enforcement avenues. |
| 12VAC5-125-180 |          | <b>Fees.</b>  | <b>Intent-</b> Importers' and Distributors' fees will be changed to a sliding scale; the more Manufacturers/URNs they   |



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|      |          | <p>Manufacturers, Importers, and Distributors pay \$100 per license.</p> <p>Sanitizers pay a \$60 fee.</p> <p>Supply Dealers, Renovators, and Reupholsterers pay \$25.</p> | <p>import or distribute from, the higher the fee.</p> <p>Very small Renovators and Reupholsterers (sole individual, no additional employees) will be exempt from permit fee.</p> <p>Sterilizers pay a \$60 fee.</p> <p><b>Rationale-</b> Importer and Distributor fees must be adjusted to maintain current operating revenue while allowing the amendment to section 50 removing the requirement for these entities to maintain multiple licenses. A sliding scale allows some mid-year URN additions without mid-year fees. The reduction in the Renovator and Reupholster fee was requested by the General Assembly in 2018. Sterilizers were traditionally charged the Sanitizer permit fee, as these items have been grouped together in Code and Regulation, but there has not been a specific line item for the Sterilizer permit in the fee scale.</p> <p><b>Impact-</b> No impact, fee scale is designed to <u>maintain revenue that is budget neutral</u> from Importer and Distributor licenses (see Economic Impact table in this document). Permit fees from Renovator and Reupholsterer permits are a negligible part of the chapter's revenues (%1), and can be absorbed by the program, even if all permit holders are eligible for the fee exemption. No change for Sterilizer permit fees.</p> |
| DIBR | Repealed | 2004 Manual of Labeling Laws, Registration Requirements, International Sleep Products Association.   | <p><b>Intent-</b> Removes Document Incorporated by Reference.</p> <p><b>Rationale-</b> Manual is no longer in use. Rapid technological development of filling materials call for flexibility. Honesty in labeling and use of generic trade names has been a practiced requirement in Virginia for the recent history of the administration of this chapter. Virginia does not test filling materials in a laboratory setting, and cannot enforce specific and technical aspects as may be established by third-party</p>   |

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|  |  |  | <p>documents such as the repealed document.</p> <p><b>Impact-</b> None. Manual of filling material definitions has not been in use. Filling materials are listed by generic trade name (section 90).</p> |
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1 Project 5745 - none

2 DEPARTMENT OF HEALTH  
3 Amend Bedding Regulations following Periodic Review

4  
5 CHAPTER 125  
6 REGULATIONS FOR BEDDING AND UPHOLSTERED FURNITURE INSPECTION PROGRAM  
7 12VAC5-125-10. Definitions.

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

10 "Antique" ~~means any product that is at least 75 years old.~~

11 "As is" ~~means a sales term to describe bedding and upholstered furniture products as any~~  
12 ~~condition other than in new or undamaged condition.~~

13 "Bedding" means any mattress, mattress pad, box spring, upholstered bed, davenport, futon,  
14 upholstered sofa bed, quilted pad, packing pads, hammock pad, comforter, quilt, bolster, cushion,  
15 pillow, featherbed, sleeping bag, studio couch, or any other bag, case, pillow, cushion, or cover  
16 made of leather, textile, or other material, that is stuffed or filled in whole or in part with concealed  
17 substance filling material, that and can be used by any a human being for sleeping or reclining  
18 purposes.

19 "Bedding Program" means the Bedding and Upholstered Furniture Inspection Program, a unit  
20 of the Virginia Department of Health authorized by the ~~commissioner~~ State Health Commissioner  
21 to carry out the duties and responsibilities of this chapter.

22 "~~Board~~" ~~means the State Board of Health.~~

23 "~~Commissioner~~" ~~means the State Health Commissioner, his duly designated officer or agent.~~

24 "~~Department~~" ~~means the State Department of Health.~~

25 "~~Designee~~" or "~~designated officer or agent~~" ~~means any person or group of persons designated~~  
26 ~~by the commissioner to act on his behalf.~~

27 "~~Distributor/wholesaler~~" "Distributor" means any person who receives bedding, upholstered  
28 furniture, or filling materials from another company inside the United States for the purpose of  
29 resale.

30 "Filling material" means cotton, wool, feathers, kapok, down, hair, liquid, plant or vegetable  
31 fibers, or any other material or substance or combination thereof, loose or in batting, pads, or in  
32 any prefabricated form, concealed or not concealed, that is used or that may be potentially used  
33 in articles of bedding or upholstered furniture.

34 "Health Commissioner" means the chief executive officer of the Board of Health or authorized  
35 agent.

36 "Importer" means any person who ~~for the purpose of manufacture or resale~~ receives from  
37 another company bedding, upholstered furniture, or filling material from any country other than  
38 the United States for the purpose of resale.

39 "~~Inspector~~" ~~means department employees designated by the commissioner to inspect,~~  
40 ~~examine, investigate, evaluate and conduct tests, review documentation, interview witnesses,~~  
41 ~~take samples and provide testimony in the enforcement of Title 32.1 of the Code of Virginia and~~  
42 ~~§ 59.1-200 of the Virginia Consumer Protection Act.~~

43 "Law label" means the tag bearing legal notice and information concerning the contents and  
44 manufacturing location as required by 12VAC5-125-90 ~~§ 32.1-219~~ of the Code of Virginia. A white  
45 tag certifies all new materials. A yellow label indicates used materials.

46 "License" means ~~permission authorization granted in accordance with § 32.1-217 of the Code~~  
47 ~~of Virginia by the Health Commissioner for every that allows a person manufacturing, importing,~~  
48 ~~distributing/wholesaling, processing or selling to manufacture, distribute, or import bedding and~~  
49 ~~upholstered furniture, or any filling materials to be used in new bedding and upholstered furniture,~~  
50 ~~and reupholstering or renovating bedding or upholstered furniture being returned to its original~~  
51 ~~owner.~~

52 "Licensing state" means any of the United States that require a manufacturer, importer,  
53 ~~distributor/wholesaler distributor,~~ supply dealer, sanitizer, reupholsterer, or renovator to apply for  
54 a license or permit in order to sell bedding and upholstered furniture products in that state.

55 "Manufacturer" means a person who, using new materials, makes or ~~has employees or~~  
56 employs agents who make any article of bedding or upholstered furniture in whole or in part, or  
57 who covers or upholsters any unit thereof.

58 "New" means not previously used for any purpose. Uncovered floor models and customer  
59 returns ~~shall not be~~ are not considered new. Manufacturing process, including manufacturing of  
60 reclaimed and reprocessed materials, shall not be considered prior use.

61 "Permit" means ~~consent authorization granted in accordance with § 32.1-216 of the Code of~~  
62 ~~Virginia to approve a process by the Health Commissioner that allows a person to sanitize or~~  
63 ~~sterilize filling material, or to sanitize, reupholster, or renovate secondhand bedding or~~  
64 ~~upholstered furniture by a person treating used products for resale.~~

65 "Person" means ~~an individual, corporation, partnership, association~~ any individual or group of  
66 individuals, named party, partnership, firm, private or public association or corporation, state,  
67 county, city, town, or anyone who by covenant, restriction, or agreement has care, control,  
68 custody, ownership, or management of property or parts thereof, or any combination of the above,  
69 or any other legal entity.

70 "Reclaimed and reprocessed" means filling materials recovered from sources that would have  
71 otherwise been disposed of as waste or used for energy recovery, and have been recovered as  
72 material input in lieu of virgin material, and reprocessed using a manufacturing process identical  
73 to the processing of like virgin material to quality and cleanliness standards comparable to non-  
74 reclaimed material. Reclaimed and reprocessed filling materials are considered new.

75 "Renovator" means a person who, either solely or through agents, rebuilds, repairs, makes  
76 ~~over, re-covers, recovers,~~ restores, renovates, or renews used secondhand bedding mattresses,  
77 and box springs.

78 "Retailer" means any person engaged in commerce who sells any article of bedding,  
79 upholstered furniture, or filling materials to a consumer ~~of the article as purchased.~~

80 "Reupholsterer" means a person who, ~~either by himself solely or through employees or~~  
81 agents, rebuilds, repairs, reupholsters, recovers, restores, or renews bedding (except mattresses  
82 and box springs) and upholstered furniture; or who makes to order and specification of the user  
83 any article of bedding (except mattresses and box springs) and upholstered furniture, using either  
84 new or secondhand materials, or the owner's materials.

85 "Sanitize" means to reduce the level of microbiological agents to a level not injurious to health.

86 "Sanitizer" means a person who, either solely or through agents, sanitizes articles of bedding  
87 or upholstered furniture.

88 "Secondhand" means ~~having been previously owned,~~ made prior use of, or containing any  
89 previously used filling material ~~of which prior use has been made,~~ or that has having been in a  
90 customer's possession outside of the place of purchase. Reclaimed materials or customer-  
91 purchased items in the uninterrupted possession of a retailer are not secondhand.

92 "Sell" or any of its variants tenses, includes means and includes any of, or any combination  
93 of; the following: to possess with an intent to sell, to sell, offer or expose for sale, barter, trade,

94 ~~deliver, delivery, give away, rent, rental, consign, lease, possess with an intent to sell or to dispose~~  
95 ~~of in any other commercial manner.~~

96 "Shoddy" means any material ~~that has been~~ spun into yarn, knit, or woven into fabric and  
97 subsequently, cut up, torn up, broken, or ground up.

98 "Shoddy pad" (also called "insulator pad") means a nonwoven material made from byproducts  
99 of textile or manufacturing processes ~~and is free from dirt, insects, and other contamination.~~

100 ~~"Soiled or torn" means articles of new or used bedding or upholstered furniture that contain~~  
101 ~~stains, dirt, ripped edges or covers, or damaged frames.~~

102 "Sterilize" means to render free of viable microbiological agents.

103 "Supply dealer" means a person who manufactures, processes, or sells any felt, batting, pads,  
104 woven or plastic fabrics, or loose material in bags or containers, concealed or not concealed, to  
105 be used ~~or that could be used~~ in articles of upholstered furniture or bedding.

106 "Uniform registry number" (also called "registration number", URN, and "REG. NO.") means  
107 a unique number assigned ~~to a licensee~~ by a licensing state to identify the name and ~~each~~ location  
108 of a manufacturer, reupholsterer, sanitizer, sterilizer, or renovator, or importer of bedding and  
109 upholstered ~~products~~ furniture. The Uniform Registry Number begins with the initials of the  
110 licensing state, followed by the assigned number, ~~then~~ and ends with the initials of the state or  
111 country where the manufacturer, reupholsterer, sanitizer, sterilizer, or renovator, or importer is  
112 physically located. Each location of a manufacturer, reupholsterer, sanitizer, sterilizer, or  
113 renovator, ~~or importer~~ uses only one Uniform Registry Number.

114 "Upholstered furniture" means any ~~article of furniture designed to be~~ item used for sitting,  
115 resting, or reclining by a human, including limbs, ~~that is~~ wholly or partly stuffed ~~or filled with any~~  
116 concealed filling material. Upholstered furniture may include, ~~but is not limited to~~, children's  
117 furniture, fitness and exercise equipment, ~~furniture used exclusively for the purpose of physical~~  
118 fitness and exercise, and medical equipment, ~~or furniture or seats in RVs, boats or automobiles.~~  
119 Upholstered furniture may be movable or stationary, ~~made or~~ and may be sold with loose or  
120 attached cushions or pillows, ~~loose or attached, or is itself stuffed or filled in whole or in part with~~  
121 ~~any substance or material, hidden or concealed by fabric or any other covering, including cushions~~  
122 ~~or pillows belonging to or forming a part thereof, together with the structural units, the filling~~  
123 ~~material and its container and its covering that can be used as a support for the body of a human~~  
124 ~~being, or his limbs and feet.~~

125 "Used" means bedding or upholstered furniture that has been previously owned or used by  
126 another person.

127 "Wholesaler" means ~~a person who, on his own account, sells any article of upholstered~~  
128 ~~furniture or bedding or filling materials to another for the purpose of resale.~~

129 ~~Filling material definitions will be in accordance with definitions published in the 2004 Edition~~  
130 ~~of the International Sleep Products Association Handbook.~~

### 131 **12VAC5-125-20. Administration. (Repealed.)**

132 A. ~~The board has the responsibility to promulgate, amend and repeal regulations necessary~~  
133 ~~to protect the public health and the environment.~~

134 B. ~~The State Health Commissioner is the chief executive officer of the State Department of~~  
135 ~~Health. In accordance with §§ 32.1-20 and 32.1-22 of the Code of Virginia, the commissioner has~~  
136 ~~the authority to act for the board when it is not in session, subject to such rules and regulations~~  
137 ~~as may be prescribed by the board, and may employ such personnel as are necessary for the~~  
138 ~~proper performance of his duties as executive officer of the board.~~

139 C. ~~In addition to other authority granted by law, the commissioner has the authority to do the~~  
140 ~~following:~~

- 141 1. Approve the process of sanitizing or sterilizing filling materials, bedding, or upholstered  
142 furniture.
- 143 2. Issue licenses/permits and assign a uniform registry number to importers,  
144 manufacturers, renovators, reupholsterers, or sanitizers.
- 145 3. Order the return of any item of bedding or upholstered furniture or any filling material  
146 made, remade, renovated, reupholstered, prepared, processed, labeled or not labeled in  
147 violation of the provisions of this chapter to the manufacturer or importer thereof.
- 148 4. Inspect the premises of a holder of a license or permit issued by the commissioner,  
149 subject to the requirements set forth at 12VAC5-125-80.
- 150 5. Refuse to issue, suspend or revoke the license or permit of any person (i) who violates  
151 any provision of this chapter, any regulation of the board pursuant to this chapter or any  
152 order of the board or commissioner or (ii) who is not a resident of the Commonwealth and  
153 fails or refuses to enter an appearance in any circuit court in the Commonwealth to answer  
154 a charge or charges of violation of any provision of this chapter, regulation of the board or  
155 order of the board or commissioner.

156 **12VAC5-125-30. Powers and procedures of chapter not exclusive. Compliance with the**  
157 **Virginia Administrative Process Act**

158 The board reserves the right to authorize a procedure for enforcement of this chapter that is  
159 not inconsistent with the provisions set forth herein and the provisions of Chapter 1 (§ 32.1-1 et  
160 seq.) of Title 32.1 of the Code of Virginia. The provisions of the Virginia Administrative Process  
161 Act (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the promulgation and administration  
162 of this chapter, including the procedures for rendering and appealing any case decision.

163 **12VAC5-125-40. Exemptions.**

164 The provisions of this chapter shall not apply to:

- 165 1. Any item of bedding or upholstered furniture sold under the order of any court, in  
166 enforcement of lien or pursuant to § 55-419 of the Code of Virginia, or any sale settlement  
167 of a decedent's estate or any sale by any individual of his household effects.
- 168 2. Upholstered furniture and bedding products that are antiques as defined in 12VAC5-  
169 125-10. Any sale by any individual of their household effects, either directly to another  
170 individual, or through consignment.
- 171 3. Any interstate public carrier.
- 172 4. Any state institution, agency, or department, unless such institution, agency, or  
173 department manufactures, reupholsters, or renovates bedding or upholstered furniture  
174 and offers items for sale to the public items of bedding or upholstered furniture  
175 manufactured, reupholstered or renovated by it.
- 176 5. Any retailer who sells, gives away, or rents used upholstered furniture that has been  
177 purchased by the retailer as new furniture and has been used in the course of business,  
178 when such used furniture ~~has been~~ is (i) conspicuously identified as used furniture and (ii)  
179 reduced in price, sold at auction, donated to charity, or made available for a rental fee,  
180 and so tagged.
- 181 6. Any person who sells at retail, exclusively on a consignment basis, articles of bedding  
182 ~~that are~~ handmade by individuals and whose gross annual receipts from the sale of such  
183 articles are not in excess of do not exceed \$2,000 shall be deemed to be the manufacturer  
184 of such articles and shall not be required to obtain a license to make such articles. Each  
185 such- However, each handmade article of bedding article shall have a securely attached  
186 label affixed stating the kind of filling materials used in such the article but shall be exempt  
187 from any other requirement as to tags set forth in this chapter.

188 Persons engaged in commerce, not otherwise exempt from this chapter as provided by this  
189 section, who donate secondhand articles of bedding and upholstered furniture are not required to  
190 sanitize those articles if the donation is to a holder of a valid sanitizing permit, and the articles are  
191 not represented as sanitized.

192

193 **12VAC5-125-50. Licenses, permits, and ~~registration~~uniform registry numbers.**

194 A. ~~Licenses for manufacturers, importers, distributors, wholesalers, renovators,~~  
195 ~~reupholsterers, supply dealers.~~ General Provisions.

196 1. ~~Every importer and every person manufacturing, renovating or reupholstering any~~  
197 ~~bedding or upholstered furniture or processing or selling any filling material to be used in~~  
198 ~~articles of bedding or upholstered furniture, such as a distributor/wholesaler or supply~~  
199 ~~dealer, shall first obtain a license from the commissioner for each place of business,~~  
200 ~~subsidiary, branch or branch factory operated or contracted by him for such purpose. Only~~  
201 ~~persons complying with the requirements of this chapter and §§ 32.1-212 through 32.1-~~  
202 ~~226 of the Code of Virginia shall receive or retain a license or permit.~~

203 2. ~~Such license shall be numbered; shall, unless sooner revoked, All licenses and permits~~  
204 ~~shall expire one year from the date of issue; shall be renewable annually through receipt~~  
205 ~~of a fee; and shall not be transferable. The commissioner shall assign a uniform registry~~  
206 ~~number to each licensee.~~

207 3. ~~Each branch, branch factory and subsidiary shall be responsible for the contents and~~  
208 ~~for the tagging, as provided in this chapter, of items of bedding and upholstered furniture~~  
209 ~~made, remade, renovated, reupholstered, or imported by it and offered for sale or use in~~  
210 ~~the Commonwealth. Licenses and permits are nontransferable and void upon change of~~  
211 ~~ownership or Federal Taxpayer Identification Number.~~

212 4. ~~Every person who, on his own account or for others, sells or distributes either directly~~  
213 ~~or indirectly to any person either at wholesale or retail any bedding, filling material, shoddy~~  
214 ~~pad, or upholstered furniture by means of a permanent location, car, truck, catalog, office,~~  
215 ~~Internet sales or in any other manner, shall obtain from the commissioner a license for~~  
216 ~~each such method of sale or distribution. A new license or permit is not required for a~~  
217 ~~change of company name or address; however, licenses and permits are void if a license~~  
218 ~~or permit holder fails to notify the Bedding Program of any address change within 30 days.~~  
219 ~~Reapplication for the purposes of having a new permit issued shall be the responsibility of~~  
220 ~~the former license or permit holder, and such reapplication shall be handled as an initial~~  
221 ~~application.~~

222 5. ~~Any person subject to this section doing business at the same address under more than~~  
223 ~~one firm name shall obtain a license or permit for each firm name.~~

224 B. Procedure for obtaining a license or permit.

225 1. ~~A person applying to obtain a license or permit shall submit an application on a form~~  
226 ~~provided by the Bedding Program. The required fee, as provided in 12VAC5-125-180,~~  
227 ~~shall be submitted together with the application.~~

228 2. ~~Before license or permit issuance, the Bedding Program must conduct one or more~~  
229 ~~preoperational inspections of all manufacturers, supply dealers, sterilizers, sanitizers,~~  
230 ~~reupholsterers, and renovators, located in the Commonwealth of Virginia, not licensed or~~  
231 ~~permitted in the previous year. This preoperational inspection must demonstrate the~~  
232 ~~manufacturer, supply dealer, sterilizer, sanitizer, reupholsterer, or renovator complies with~~  
233 ~~the requirements of this chapter.~~

234 C. Licenses.

235 Every manufacturer, importer, distributor, and supply dealer shall obtain a license for each  
236 business, subsidiary, or branch where bedding and upholstered furniture products are  
237 manufactured, imported, or distributed, before offering those products for sale in or delivery to the  
238 Commonwealth of Virginia. Each location of a manufacturer must obtain a separate license for  
239 each place of manufacture.

240 1. Importers and distributors shall be licensed to import or distribute only from  
241 manufacturers listed on the license application. To add a manufacturer to this list during  
242 the license year, the importer or distributor shall notify the Bedding Program in writing on  
243 an approved form, and ensure the license fees paid during that license year are current  
244 with the new total number of manufacturers (as provided by the fee schedule at 12VAC5-  
245 125-180).

246 2. A manufacturer must be licensed as required under this chapter prior to an importer or  
247 distributor obtaining a license to import or distribute from that manufacturer.

#### 248 D. Permits.

249 ~~Every Permits for sterilizers and sanitizers. Every person who, on his own account or for~~  
250 ~~others, is a sterilizer or a sanitizer sterilizer, sanitizer, reupholsterer, and renovator shall obtain~~  
251 ~~from the commissioner a permit for each location place of business where bedding and~~  
252 ~~upholstered furniture are sterilized, sanitized, reupholstered, or renovated, before offering those~~  
253 ~~products for sale in or delivery to the Commonwealth of Virginia, at which sterilizing or sanitizing~~  
254 ~~operations occur. Any person applying for approval of a process by which filling materials,~~  
255 ~~bedding, or upholstered furniture are sanitized or sterilized shall submit to the commissioner a~~  
256 ~~description of the process, test results and any apparatus and method to be used in such process.~~  
257 ~~Upon approval of such process by the commissioner and payment of the current annual permit~~  
258 ~~fee by the applicant, a numbered permit for use of such process shall be issued. Such permit~~  
259 ~~shall expire one year from the date of issue. Nothing herein shall prevent any person from having~~  
260 ~~any sanitizing or sterilization required by this chapter performed by any person who has a valid~~  
261 ~~permit for such purposes, provided the number of such permit appears on the tag attached to~~  
262 ~~each article as required by § 32.1-219 of the Code of Virginia.~~

263 1. Any person applying for a sanitizer or sterilizer permit must submit a description of the  
264 process by which filling materials, bedding, or upholstered furniture will be sanitized or  
265 sterilized.

266 2. All processes used to sanitize bedding and upholstered furniture shall comply with the  
267 requirements of 12VAC5-125-100.

268 3. All processes used to sterilize animal feathers, hair, or down shall comply with the  
269 requirements of 12VAC5-125-110.

#### 270 G. General provisions.

271 ~~1. Any person subject to this section must obtain a new license or permit when there is~~  
272 ~~change of ownership or a change of Federal Taxpayer Identification Number (TIN). A new~~  
273 ~~license or permit is not required for a change of company name or address if the ownership~~  
274 ~~remains the same, but the person must notify the commissioner of such change within 30~~  
275 ~~days after such change. Licenses and permits are nontransferable.~~

276 ~~2. Every person subject to this section doing business at the same address under more~~  
277 ~~than one firm name shall obtain a license for each firm name.~~

#### 278 D. Procedure for obtaining a license or permit.

279 ~~1. Submit a written application for license or permit to the Bedding Program on a form~~  
280 ~~provided by the Bedding Program prior to selling in the Commonwealth.~~

281 ~~2. With the application, submit the required application fee, in accordance with the fee~~  
282 ~~schedule, in the form of a check in U.S. dollars.~~



283 E. Uniform Registry Numbers.

284 Licensed or permitted manufacturers, supply dealers, sterilizers, sanitizers, reupholsterers,  
285 and renovators will be assigned a uniform registry number (URN). The Bedding Program will  
286 recognize a URN issued by another state and assign the URN if the applicant has a currently  
287 valid license for that URN from the issuing state at the time of application, and the URN and copy  
288 of the valid license are supplied together with the license or permit application.

289 1. Manufacturers, supply dealers, sterilizers, sanitizers, reupholsterers, and renovators  
290 shall use their assigned URN on all law labels as provided in 12VAC5-125-90.

291 2. Importers and distributors shall use the URNs assigned to the licensed manufacturers  
292 of the imported or distributed product on all law labels as provided in 12VAC5-125-90.

293 ~~Issuance of license or permit. The Bedding Program shall issue the appropriate license or~~  
294 ~~permit to the applicant after:~~

295 ~~1. A properly completed application is submitted;~~

296 ~~2. The appropriate fee, if required, is submitted;~~

297 ~~3. A preoperational inspection shows that the manufacturer, importer, distributor,~~  
298 ~~wholesaler, renovator, reupholsterer, or supply dealer is in compliance with the~~  
299 ~~requirements of this chapter.~~

300  
301 **12VAC5-125-60. Revocation of a license or permit. Enforcement, Notices, Informal**  
302 **Conferences**

303 A. The commissioner ~~Health Commissioner~~ may, after providing an opportunity for a hearing,  
304 revoke a license or permit for flagrant or continuing violation of any of the requirements of this  
305 chapter.

306 Prior to revocation, the commissioner shall notify in writing the holder of the license or permit  
307 of the specific reason for which the license or permit is to be revoked. The license or permit shall  
308 be revoked at the end of the 15 days following service of such notice unless a written request for  
309 a hearing is filed before then with the commissioner. If no request for a hearing is filed within the  
310 15-day period, the revocation of the license or permit shall be final. a notice of intent to revoke a  
311 license or permit, and after providing an opportunity for an informal conference in accordance with  
312 § 2.2-4019 of the Code of Virginia, revoke a license or permit for flagrant or continuing violation  
313 of this chapter. Any person to whom a notice of revocation is directed shall immediately comply  
314 with the notice. Upon revocation, the former license or permit holder shall be given an opportunity  
315 for appeal of the revocation in accordance with the Administrative Process Act (§ 2.2-4000 et seq.  
316 of the Code of Virginia). Any person whose license or permit has been revoked may apply for a  
317 new license or permit by following the procedures outlined in 12VAC5-125-50.

318 B. The Health Commissioner may summarily suspend a sanitizer, reupholsterer, or renovator  
319 permit if continued operation constitutes a substantial and imminent threat to public health. Upon  
320 receipt of such notice that a permit is suspended, the permit holder shall cease permitted  
321 operations immediately. Whenever a permit is suspended, the holder of the permit shall be  
322 notified in writing by certified mail or by hand delivery. Upon service of notice that the permit is  
323 immediately suspended, the former permit holder shall be given an opportunity for an informal  
324 conference in accordance with § 2.2-4019 of the Code of Virginia. The request for an informal  
325 conference shall be in writing and shall be filed with the Bedding Program by the former holder of  
326 the permit. If written request for an informal conference is not filed within 10 working days after  
327 the service of notice, the suspension is sustained. Each holder of a suspended permit shall be  
328 afforded an opportunity for an informal conference within three working days of receipt of a  
329 request for the informal conference. The Health Commissioner may end the suspension at any  
330 time if the reasons for the suspension no longer exist. Working days means days on which the

331 central office of the Virginia Department of Health is open for business and does not include  
332 holidays and closures.

333 C. Any person affected by a determination issued in connection with the enforcement of this  
334 chapter may challenge such determination in accordance with the provisions of the Administrative  
335 Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

336 D. The Health Commissioner may enforce this chapter through any means lawfully available  
337 pursuant to § 32.1-27 of the Code of Virginia, and nothing in this chapter shall be construed as  
338 preventing the Health Commissioner from making efforts to obtain compliance through warning,  
339 conference, or any other appropriate enforcement means.

340 **12VAC5-125-70. Application after revocation. (Repealed.)**

341 Any person whose license or permit has been revoked, may apply for a new license or permit  
342 by following the procedures outlined in 12VAC5-125-50.

343 **12VAC5-125-80. Bedding and upholstered furniture inspections Inspections.**

344 A. Inspections of license and permit holders.

345 Inspection of the premises of a holder of a license or license or permit holders issued under  
346 this chapter ~~will~~ may be initiated ~~upon~~ in the following circumstances: ~~complaints when they relate~~  
347 ~~to a violation of this chapter:~~

348 ~~1. Upon complaints received by the commissioner. Upon receipt of a complaint relating to~~  
349 ~~a violation of law, including a complaint of insect infestation required by 12VAC5-125-~~  
350 ~~100G; and~~

351 ~~2. Upon complaints received by the Bedding Program. Pursuant to alleged violations of~~  
352 ~~this chapter observed during a previous inspection and any subsequent steps taken by~~  
353 ~~the permit holder to comply with this chapter, or as necessary to verify compliance.~~

354 ~~3. Upon complaints received by the Department of Agriculture and Consumer Services~~  
355 ~~and reported to the commissioner or Bedding Program. 4. Upon complaints made to an~~  
356 ~~inspector in the course of a routine inspection and reported to the Bedding Program.~~

357 ~~5. Upon complaints against a licensee made by an inspector when noted in the course of~~  
358 ~~a routine inspection of an ancillary operation (such as a sanitizer, distributor/wholesaler or~~  
359 ~~retailer) and reported to the Bedding Program.~~

360 ~~6. Upon complaints (or findings of violations) against a licensee by the authorities of a~~  
361 ~~government jurisdiction outside the Commonwealth that the licensee has sold bedding in~~  
362 ~~violation of laws, regulations or standards of that jurisdiction dealing with tagging,~~  
363 ~~sanitization, or consumer protection requirements.~~

364 ~~7. Upon late or nonrenewal of permit or license by a licensee or permit holder or upon late~~  
365 ~~notification of a change of location. Renewal application and payment not received by the~~  
366 ~~due date contained in the renewal notice and a failure to timely notify the commissioner of~~  
367 ~~a change of address shall result in the licensee being moved to an unlicensed status and~~  
368 ~~may result in an inspection by the Bedding Program to determine if the licensee continues~~  
369 ~~in business. If the licensee continues to operate, a license or permit shall not be issued~~  
370 ~~until a program inspection occurs and the requirements of the law are satisfied.~~

371 ~~Inspections will be carried out and completed as required under the law.~~

372 ~~B. Request for information, documents; verifications.~~

373 ~~1. Upon complaint, the commissioner may request that a licensee provide information and~~  
374 ~~documentation to substantiate its compliance with the requirements of this chapter. The~~  
375 ~~commissioner may also require that the accuracy and completeness of such information~~  
376 ~~and documentation be verified.~~

377 ~~2. Upon a finding that a licensee has failed to timely and fully comply with a request for~~  
378 ~~information and documents issued by the commissioner, or failed to substantiate the~~  
379 ~~accuracy and completeness of such information and documentation, a review may be~~  
380 ~~conducted by the Bedding Program.~~

381 ~~3. Any holder of a license or permit is required to report to the Bedding Program any~~  
382 ~~occurrences of insect infestation at the licensee's or permit holder's place of business or~~  
383 ~~in any article of new or used bedding or upholstered furniture offered for sale, rent, or use.~~

384 ~~CB. Inspections of unlicensed entities.~~

385 ~~Inspections of unlicensed entities and of retailers of bedding and upholstered furniture may~~  
386 ~~be conducted in accordance with § 32.1-25 of the Code of Virginia. the following circumstances:~~

387 1. Upon receipt of an application for a license or permit;

388 2. Upon nonrenewal of a sanitizer, reupholsterer, or renovator permit, or upon failure by a  
389 permit holder to notify the Health Commissioner of a change of address within timelines  
390 established by 12VAC5-125-50.A, resulting in a former permit holder being moved to an  
391 unlicensed status;

392 3. To verify retailer compliance with this chapter; and

393 4. Pursuant to alleged violations of this chapter observed during inspections resulting from  
394 circumstances in subdivisions 1, 2, or 3 and of this subsection, any subsequent steps  
395 taken by the permit holder to comply with this chapter, or as necessary to verify  
396 compliance.

397 ~~Inspections shall be conducted upon receipt of application for a permit or license by an~~  
398 ~~unlicensed entity.~~

399 C. All inspections shall be conducted in accordance with § 32.1-25 of the Code of Virginia.  
400 Whenever an inspection is conducted, a completed inspection report shall be provided to the  
401 license or permit holder or inspected retailer. The inspection report shall contain descriptions of  
402 observations made and citations to the alleged violations of this chapter. The report shall provide  
403 an opportunity for due process in accordance with the Administrative Process Act (§ 2.2-4000 et  
404 seq. of the Code of Virginia).

405 **12VAC5-125-90. Law labels conforming to the Virginia law label requirements.**

406 A. General provisions.

407 No law label required by this chapter shall contain false or misleading statements, terms, or  
408 designations. Filling materials shall be listed by generic textile names in order of descending  
409 predominance. The removal, defacement, or alteration of any law label prior to retail sale is  
410 prohibited. Law labels shall contain no advertising matter, nor anything that detracts from the  
411 required statements. No person shall place a mark, tag, sticker, or any other device on a law label  
412 that covers the required statements indicated in Figures 1-3 unless the Bedding Program provides  
413 written approval. No person shall use any law label unless licensed or permitted under this  
414 chapter.

415 All stamp or print on law labels required by this section shall be legible and at least 1/8<sup>th</sup> inch  
416 in height and capitalized, unless otherwise indicated in Figures 1-3.

417 B. New bedding and upholstered furniture, filling material.

418 Every importer of and every person manufacturing a new item of bedding or upholstered  
419 furniture shall attach securely thereto a substantial A white cloth tag (law label) or equivalent law  
420 label shall be securely attached, in a position where it can be conveniently examined, visible on  
421 the outside covering of such every item of new bedding or upholstered furniture, or any filling  
422 material, however contained, and not less than Law labels shall be made of durable, tear-  
423 resistant white cloth or equivalent, and shall be at least six square inches in size, All label printing

424 shall be resistant to fading, bleeding, and abrasion, and all text upon which shall be plainly  
425 stamped or printed, in English, and clearly legible, the name and address of the manufacturer,  
426 importer, or distributor, the registration number of the manufacturer or importer, the kind of filling  
427 material used therein, a statement that the filling materials are new, and the number of the permit  
428 issued to the person sterilizing any new feathers, hair, or down in such item. New bedding,  
429 upholstered furniture, and filling material shall use the appropriate law label from either Figure 1,  
430 Figure 2, or both; use of a Figure 2 law label in addition to the corresponding Figure 1 law label  
431 is not a violation of this chapter. Law label contents shall conform to the layout and requirements  
432 indicated by Figures 1 and 2, as appropriate. If the filling materials are reclaimed and reprocessed  
433 as defined in 12VAC5-125-1, law labels from Figure 1 may contain this statement in the Other  
434 Information section: "New filling material is composed of (entirely, partially, or %) reclaimed and  
435 reprocessed materials". Law labels for new bedding and upholstered furniture shall be securely  
436 attached to the article at the point of manufacture; law labels for filling material shall be securely  
437 attached to shipment packaging, or printed directly on retail packaging, prior to delivery or  
438 shipment.

439 B. ~~Law labels for new bedding and upholstered furniture shall be securely attached to the~~  
440 ~~article or filling material at the point of manufacture, in a position where they can be conveniently~~  
441 ~~examined. Law labels shall contain no advertising matter, nor anything that detracts or is likely to~~  
442 ~~detract from the required statements. No mark, tag, sticker, or any other device shall be placed~~  
443 ~~upon law labels by any dealer or any other person in such a way as to cover the required~~  
444 ~~statements. No one may possess such law labels outside that facility unless by prior approval of~~  
445 ~~the commissioner for correction purposes.~~

446 C. Secondhand, reupholstered, or renovated articles.

447 ~~Any person sanitizing, remaking, renovating, or reupholstering any A yellow law label shall be~~  
448 ~~securely attached, in a position where it can be conveniently examined, to every secondhand item~~  
449 ~~of bedding or upholstered furniture, or manufacturing any item of bedding or upholstered furniture~~  
450 ~~containing any shoddy or secondhand filling material, shall attach securely to it a substantial~~  
451 ~~yellow cloth tag or equivalent (law label), visible on the outside of such item. The law label shall~~  
452 ~~be made of durable yellow cardstock paper, cloth, or equivalent, and shall be at least and not less~~  
453 ~~than six square inches in size, All writing on the law label shall be resistant to fading, bleeding,~~  
454 ~~and abrasion, and all text shall be plainly upon which shall be stamped or printed, in English, The~~  
455 ~~label contents shall be composed according to the layout and requirements indicated by Figure~~  
456 ~~3, as appropriate. the kind of filling materials used therein, a statement that the item or filling~~  
457 ~~materials are secondhand, and the number of the permit issued to the person who sanitized such~~  
458 ~~item or filling material. This requirement shall not apply to mattresses that contain a shoddy pad~~  
459 ~~unless it otherwise contains secondhand filling materials.~~

460 D. ~~Any person shipping or delivering filling material, however contained, shall have~~  
461 ~~conspicuously attached thereto a law label upon which shall be stamped or printed, as provided~~  
462 ~~in § 32.1-219 of the Code of Virginia or as provided in this chapter, the kind of material, whether~~  
463 ~~the material is new or secondhand, the name, address, and registration number of the~~  
464 ~~manufacturer or importer, and the permit number of the person who sterilized or sanitized such~~  
465 ~~material.~~

466 E. ~~The stamp or print on law labels required by this section shall be in type not less than three~~  
467 ~~millimeters in height.~~

468 F. ~~It shall be unlawful to use any false or misleading statement, term or designation on any~~  
469 ~~tag required by this chapter or to remove, deface or alter, or to attempt to remove, deface or alter~~  
470 ~~any such tag or the statement of filling materials made thereon, prior to retail sale.~~

471 G. ~~No person shall use or have in his possession with intent to use any tag provided for in this~~  
472 ~~chapter unless such person holds a license or permit issued to him pursuant to this chapter. No~~

473 ~~person shall sell, give or in any way provide such law labels to anyone who does not have a~~  
474 ~~license, or permit issued to him pursuant to this chapter, or is not allowed to use such a tag~~  
475 ~~pursuant to this provision.~~

476 ~~(Specific law label requirements contained in Attachments 1 through 7)~~

477 ATTACHMENT 1

478 THE FOLLOWING LABELS COMPLY WITH THE VIRGINIA LAW

479 NO. 1

480 WHITE LABEL FOR ALL NEW MATERIAL

481 For Filling Material NOT Requiring Sterilization

SPACE TO ATTACH →

-  
-

In bold, black ink, minimum type size 3mm  
in height

→

Space for description of filling material.

Printing to be in English using capital  
letters

not less than 3mm in height

→

-  
-  
-

See NOTE (3) at bottom of page. →

-

Required in Virginia →

-  
-  
-

"Date of Delivery" line of Manufacturer's  
stock information, etc., here.

→

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>ALL NEW MATERIAL<br/>CONSISTING OF</b>   |
| -   |
| -   |
| _____   |
| REG. NO.  |
| _____   |
| <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with law.</b> |
| -   |
| -   |
| _____   |
| MADE BY<br>(NAME OF MANUFACTURER OR VENDOR)<br>(ADDRESS OF MANUFACTURER OR<br>VENDOR)   |
| <b>Date of Delivery</b>   |
| _____   |
| -   |
| (Additional Information)  |

482 Note:

483 (1) ~~All above printing in black ink on white vellum cloth or a material of comparable quality, which~~  
484 ~~shall not flake out when abraded.~~

485 (2) ~~Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size~~

486 ~~of the tag shall be not less than (six) square inches, but may be greater as the need demands.~~

487 ~~(3) Virginia approves and recognizes the uniform registry number and will accept the registration~~  
488 ~~number issued by another state, if registrant so desires, providing such registration follows the~~  
489 ~~policy of uniform registration. This policy is intended to benefit the registrant by requiring but one~~  
490 ~~registration to be imprinted on the law label used, regardless of where merchandise may be~~  
491 ~~shipped. The registration number shall be preceded by name of state (may be abbreviated)~~  
492 ~~issuing REG. NO. and if factory is located in another state than that issuing REG. NO., then name~~  
493 ~~of state in which factory is located shall follow the registration number in parenthesis.~~

494 ATTACHMENT 2

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499

NO. 2

~~WHITE LABEL FOR ALL NEW MATERIAL  
ARTICLES WITH EXTRA CUSHIONS AS AN  
INTEGRAL PART OF UNIT~~

~~For Filling Material NOT Requiring Sterilization~~

SPACE TO ATTACH →

-  
-

In bold, black ink, minimum type size 3mm  
in height

→

Space for description of filling material.

Printing to be in English using capital  
letters

not less than 3mm in height

→

-  
-  
-  
-

See NOTE (3) at bottom of page. →

-

Required in Virginia →

-  
-  
-

"Date of Delivery" line of Manufacturer's  
stock information, etc., here.

→

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>ALL NEW MATERIAL</b>   |
| CONSISTING OF   |
| BODY  |
| CUSHIONS  |
| -   |
| _____   |
| REG. NO.  |
| _____   |
| <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with law.</b> |
| -   |
| -   |
| _____   |
| MADE BY   |
| (NAME OF MANUFACTURER OR VENDOR)  |
| (ADDRESS OF MANUFACTURER OR<br>VENDOR)  |
| <b>Date of Delivery</b>   |
| _____   |
| (Additional Information)  |

500  
501  
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507

Note:

(1) All above printing in black ink on white vellum cloth or a material of comparable quality, which shall not flake out when abraded.

(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than (six) square inches, but may be greater as the need demands.

(3) Virginia approves and recognizes the uniform registry number and will accept the registration number issued by another state, if registrant so desires, providing such registration follows the policy of uniform registration. This policy is intended to benefit the registrant by requiring but one

508 registration to be imprinted on the law label used, regardless of where merchandise may be  
509 shipped. The registration number shall be preceded by name of state (may be abbreviated)  
510 issuing REG. NO. and if factory is located in another state than that issuing REG. NO., then name  
511 of state in which factory is located shall follow the registration number in parenthesis.

512 ATTACHMENT 3

NO. 3

WHITE LABEL FOR ALL NEW MATERIAL

For Animal and Fowl and Any Other Filling Material Requiring Sterilization

SPACE TO ATTACH →

-  
-

In bold, black ink, minimum type size 3mm  
in height

→

Space for description of filling material.

Printing to be in English using capital  
letters

not less than 3mm in height

→

-  
-

See NOTE (3) at bottom of page. →

-  
-

Required in Virginia →

-  
-

"Date of Delivery" line of Manufacturer's  
stock information, etc., here.

→

|  |
|--|
| <hr/> <hr/> <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b> <hr/> <hr/> <b>ALL NEW MATERIAL<br/>CONSISTING OF</b><br>-<br>-<br>- <hr/> <hr/> <b>REG. NO. PERMIT NO.</b> <hr/> <hr/> <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with law.</b> <hr/> <hr/> <b>CONTENTS<br/>STERILIZED</b> <hr/> <hr/> <b>MADE BY</b><br>(NAME OF MANUFACTURER OR VENDOR)<br>(ADDRESS OF MANUFACTURER OR<br>VENDOR)<br><b>Date of Delivery</b> <hr/> <hr/> <p>(Additional Information)</p> |
|--|

516 Note:

517 (1) All above printing in black ink on white vellum cloth or a material of comparable quality, which  
518 shall not flake out when abraded.



519 ~~(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size~~  
520 ~~of the tag shall be not less than (six) square inches, but may be greater as the need demands.~~

521 ~~(3) Virginia approves and recognizes the uniform registry number and will accept the registration~~  
522 ~~number issued by another state, if registrant so desires, providing such registration follows the~~  
523 ~~policy of uniform registration. This policy is intended to benefit the registrant by requiring but one~~  
524 ~~registration to be imprinted on the law label used, regardless of where merchandise may be~~  
525 ~~shipped. The registration number shall be preceded by name of state (may be abbreviated)~~  
526 ~~issuing REG. NO. and if factory is located in another state than that issuing REG. NO., then name~~  
527 ~~of state in which factory is located shall follow the registration number in parenthesis.~~

528 ~~(4) Virginia will accept the PERMIT NO. issued by another state if applicant so desires providing~~  
529 ~~approval is granted and a Virginia Sterilization Permit is issued to applicant bearing such number.~~

530 ATTACHMENT 4

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NO. 4

~~YELLOW LABEL FOR ARTICLES THAT HAVE BEEN REMADE AND  
RENOVATED FOR CONSUMER AND THAT CONTAIN  
SECONDHAND MATERIAL IN WHOLE OR IN PART~~

~~If new filling material has been added, state type in space provided~~

~~SPACE TO ATTACH →~~

~~-  
-~~

~~In bold, black ink, minimum type size 3mm  
in height~~

~~→~~

~~Space for description of filling material.~~

~~Printing to be in English using capital  
letters~~

~~not less than 3mm in height~~

~~→~~

~~-  
-  
-~~

~~Registration number or name of person or  
firm that renovated article →~~

~~-~~

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>This article contains the same material<br/>received from the owner, to which has been<br/>added the following New material.</b> |
| -   |
| -   |
| _____   |
| <b>The following work has been done:</b>  |
| <b>YES — NO</b>   |
| <input type="checkbox"/> <input type="checkbox"/> <del>Old covering completely removed</del>  |
| <input type="checkbox"/> <input type="checkbox"/> <del>Frame repaired</del>   |
| <input type="checkbox"/> <input type="checkbox"/> <del>Spring retied and/or repaired</del>  |
| <b>OTHER:</b> _____   |
| _____   |
| <del>REG. NO. VA.</del>   |
| _____   |
| <b>This article must not be sold, it is the property<br/>of and must be returned to:</b>  |
| <b>Name</b> _____   |
| <b>Address</b> _____  |
| _____   |
| <b>REMADE AND RENOVATED BY</b>  |
| -   |
| -   |
| Date _____  |
| -   |
| (Additional Information)  |

536 Note:

537 (1) All above printing in black ink on yellow vellum cloth or a material of comparable quality, which  
538 shall not flake out when abraded.

539 ~~(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size~~  
540 ~~of the tag shall be not less than (six) square inches, but may be greater as the need demands.~~

541 ~~(3) If secondhand filling material is added instead of new, article is required to be sanitized and~~  
542 ~~Law Label No. 6 shall be used stating Permit No. of person or firm doing the sanitizing.~~

543 ATTACHMENT 5

544 NO. 5  
545 YELLOW LABEL FOR ARTICLES CONTAINING  
546 ALL SECONDHAND MATERIAL OFFERED  
547 FOR SALE OR RENT "AS IS"  
548 REQUIRED TO BE SANITIZED

SPACE TO ATTACH →  
-  
-  
In bold, black ink, minimum type size 3mm  
in height  
→  
Space for description of filling material.  
Printing to be in English using capital  
letters  
not less than 3mm in height  
→  
-  
-  
Permit number of person or firm who  
sanitized  
article →  
-  
Required in Virginia →  
-

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>THIS ARTICLE CONTAINS</b>  |
| ALL SECOND-HAND MATERIAL  |
| CONTENTS UNKNOWN  |
| -   |
| _____   |
| -PERMIT NO.   |
| _____   |
| <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with law.</b> |
| _____   |
| SANITIZED   |
| _____   |
| SANITIZED BY  |
| -   |
| -   |
| <b>Date Sanitized</b>   |
| _____   |
| -   |
| (Additional Information)  |

549 Note:  
550 (1) All above printing in black ink on yellow vellum cloth or a material of comparable quality, which  
551 shall not flake out when abraded.

552 (2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size  
553 of the tag shall be not less than (six) square inches, but may be greater as the need demands.

554 ATTACHMENT 6

555 NO. 6

556 YELLOW LABEL FOR ARTICLES THAT HAVE BEEN RENOVATED

557 FOR RESALE AND THAT CONTAIN

558 SECONDHAND MATERIAL IN WHOLE OR IN PART

559 REQUIRED TO BE SANITIZED

SPACE TO ATTACH →

-

-

In bold, black ink, minimum type size 3mm  
in height

→

Space for description of filling material.

Printing to be in English using capital  
letters

not less than 3mm in height

→

-

-

Registration number of person or firm who  
renovated article. Permit number of  
person or firm who sanitized article

→

-

Required in Virginia →

-

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>THIS ARTICLE CONTAINS<br/>SECOND HAND MATERIAL<br/>TO WHICH HAS BEEN ADDED</b>   |
| -   |
| -   |
| -   |
| _____   |
| REG. NO. _____ PERMIT NO. _____   |
| _____   |
| <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with the law.</b> |
| _____   |
| CONTENTS<br>SANITIZED   |
| _____   |
| REMADE AND RENOVATED BY   |
| -   |
| -   |
| <b>RENOVATOR NAME</b> _____   |
| <b>RENOVATOR ADDRESS</b> _____  |
| -   |
| <b>Date Sanitized</b>   |
| _____   |
| -   |
| (Additional Information)  |

560 Note:

561 (1) All above printing in black ink on white vellum cloth or a material of comparable quality, which  
562 shall not flake out when abraded.

563 (2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size  
564 of the tag shall be not less than (six) square inches, but may be greater as the need demands.

565 ATTACHMENT 7

566 NO. 7  
567 WHITE LABEL FOR ALL NEW MATERIAL  
568 ARTICLES IMPORTED INTO THE UNITED STATES  
569 For Filling Material NOT Requiring Sterilization

SPACE TO ATTACH →

-  
-

In bold, black ink, minimum type size 3mm  
in height

→

Space for description of filling material.

Printing to be in English using capital  
letters

not less than 3mm in height

→

-  
-  
-

See NOTE (3) at bottom of page. →

-

Required in Virginia →

-  
-  
-

"Date of Delivery" line of Manufacturer's  
stock information, etc., here.

→

Name of country where factory is located

→

-

|   |
|---|
| -   |
| -   |
| -   |
| _____   |
| <b>UNDER PENALTY OF LAW THIS TAG NOT TO<br/>BE REMOVED EXCEPT BY CONSUMER</b>   |
| _____   |
| <b>ALL NEW MATERIAL<br/>CONSISTING OF</b>   |
| -   |
| -   |
| _____   |
| REG. NO.  |
| _____   |
| <b>Certification is made by the manufacturer<br/>that the materials in this article are<br/>described in accordance with law.</b> |
| -   |
| -   |
| _____   |
| <b>IMPORTED BY</b>  |
| -   |
| -   |
| <b>Date of Delivery</b>   |
| _____   |
| -   |
| <b>MADE IN</b>  |
| -   |

570 Note:

571 (1) All above printing in black ink on white vellum cloth or a material of comparable quality, which  
572 shall not flake out when abraded.

Figure 1. White tags with black ink for new materials, with or without a % of reclaimed and reprocessed materials.

| BEDDING, SINGLE-COMPONENT ARTICLES, FILLING MATERIAL  | FURNITURE, MULTIPLE-COMPONENT ARTICLES WHERE EACH COMPONENT IS AN INTEGRAL PIECE OF THE ITEM                              | ITEMS CONTAINING MATERIALS REQUIRING STERILIZATION  |   |
|---|---|---|---|
| <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>                                      | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>                                      | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>                                      |   |
| <p><b>ALL NEW MATERIAL</b><br/>consisting of</p>  | <p><b>ALL NEW MATERIAL</b><br/>consisting of<br/>(BODY)<br/>(CUSHIONS)</p>  | <p><b>ALL NEW MATERIAL</b><br/>consisting of<br/>(FEATHERS)<br/>(DOWN)<br/>(SPECIFIC TYPE ANIMAL HAIR)</p>                | <p>Uppercase text in these rows shall be at least 1/8th inch.</p>   |
| <p><b>REG NO.</b></p>   | <p><b>REG NO.</b></p>   | <p><b>REG NO.      PER NO.</b></p>  |   |
| <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> | <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> | <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> | <p>-----<br/>The 1/8th inch font size requirement does not apply to this section.<br/>-----</p>   |
| <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>         | <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>         | <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>         | <p>-----<br/>Uppercase text in these rows shall be at least 1/8th inch.<br/>-----</p>   |
| <p>(Other Information section)</p>  | <p>(Other Information section)</p>  | <p>(Other Information section)</p>  | <p>-----<br/>This section may contain dimensions, FTC, RN#, or other information. No advertising material is allowed. The 1/8th inch font size requirement does not apply to this section.<br/><br/>If filling materials are reclaimed and reprocessed as defined in 12VAC5-125-10, this section may contain the statement "New filling material is composed of (entirely, partially, or %) reclaimed and reprocessed materials".</p> |
| <p><b>MADE IN (COUNTRY)</b></p>   | <p><b>MADE IN (COUNTRY)</b></p>   | <p><b>MADE IN (COUNTRY)</b></p>   |   |

Figure 2. White tags with green ink, for use only if new materials contain a % of reclaimed and reprocessed materials as defined in 12VAC5-125-10.

| <b>BEDDING, SINGLE-COMPONENT ARTICLES, FILLING MATERIAL</b>   | <b>FURNITURE, MULTIPLE-COMPONENT ARTICLES WHERE EACH COMPONENT IS AN INTEGRAL PIECE OF THE ITEM</b>                       | <b>ITEMS CONTAINING MATERIALS REQUIRING STERILIZATION</b>   |  |
|---|---|---|--|
| <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>                                      | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>                                      | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>  |  |
| <p>ALL NEW MATERIAL (% RECLAIMED AND REPROCESSED MATERIAL) consisting of</p>  | <p>ALL NEW MATERIAL (% RECLAIMED AND REPROCESSED MATERIAL) consisting of<br/>(BODY)<br/>(CUSHIONS)</p>                    | <p>ALL NEW MATERIAL (% RECLAIMED AND REPROCESSED MATERIAL) consisting of<br/>(FEATHERS)<br/>(DOWN)<br/>(SPECIFIC TYPE ANIMAL HAIR)<br/><br/>CONTENTS STERILIZED</p> | <p>Uppercase text in these rows shall be at least 1/8th inch.</p>  |
| <p><b>REG NO.</b></p>   | <p><b>REG NO.</b></p>   | <p><b>REG NO. PER NO.</b></p>   |  |
| <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> | <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> | <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p>   | <p>-----<br/>The 1/8th inch font size requirement does not apply to this section.<br/>-----</p>  |
| <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>         | <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>         | <p><b>MADE BY (or MADE FOR)</b><br/>Name and address of manufacturer, importer, or distributor as appropriate</p>   | <p>-----<br/>Uppercase text in these rows shall be at least 1/8th inch.<br/>-----</p>  |
| <p>(Other Information section)</p>  | <p>(Other Information section)</p>  | <p>(Other Information section)</p>  | <p>-----<br/>This section may contain dimensions, FTC, RN#, or other information. No advertising material is allowed. The 1/8th inch font size requirement does not apply to this section.<br/>-----</p> |
| <p><b>MADE IN (COUNTRY)</b></p>   | <p><b>MADE IN (COUNTRY)</b></p>   | <p><b>MADE IN (COUNTRY)</b></p>   |  |

Figure 3. Yellow tags with black ink for secondhand materials.

| SECONDHAND BEDDING OR UPHOLSTERED FURITURE REQUIRING SANITIZATION   | REUPHOLSTERED OR RENOVATED ARTICLES TO BE RETURNED TO ORIGINAL OWNER, NOT REQUIRING SANITIZATION   | ITEMS CONTAINING MATERIALS REQUIRING STERILIZATION  |  |
|---|--|---|--|
| <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>  | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>   | <p><b>UNDER PENALTY OF LAW THIS TAG NOT BE BE REMOVED EXCEPT BY THE CONSUMER</b></p>  |  |
| <p><b>THIS ARTICLE CONTAINS ALL SECOND-HAND MATERIAL CONTENTS UNKNOWN</b></p> <p>CONTENTS SANITIZED<br/>Date Sanitized: _____</p> | <p><b>THIS ARTICLE CONTAINS THE SAME MATERIAL RECEIVED BY THE OWNER, TO WHICH HAS BEEN ADDED THE FOLLOWING NEW MATERIAL:</b><br/>(LIST)</p>  | <p><b>THIS ARTICLE CONTAINS SECONDHAND MATERIAL, TO WHICH HAS BEEN ADDED THE FOLLOWING NEW MATERIAL:</b><br/>(LIST)</p> <p>CONTENTS SANITIZED<br/>Date Sanitized: _____</p> | <p>Uppercase text in these rows shall be at least 1/8th inch.</p>  |
| <p>PERMIT NO.</p>   | <p>PERMIT NO.</p>  | <p>SAN. PERMIT NO.<br/>RE. PERMIT NO.</p>   |  |
| <p>Certification is made by the manufacturer that the materials in this article are sanitized in accordance with law.</p>         | <p>Certification is made by the manufacturer that the materials in this article are described in accordance with law.</p> <p>The following work has been done:<br/>YES NO</p> <p style="padding-left: 100px;">Old covering removed<br/>Frame repaired<br/>Spring retied and/or repaired<br/>Other: _____</p> | <p>Certification is made by the manufacturer that the materials in this article are described and sanitized in accordance with law.</p>                                     | <p>The 1/8th inch font size requirement does not apply to this section.</p>  |
| <p>SANITIZED BY:<br/>Name and address of Sanitizer</p>  | <p>This article must not be sold, it is the property of &amp; must be returned to: Name and address of owner</p>   | <p>SANITIZED BY:<br/>Name and address of Sanitizer</p>  | <p>Uppercase text in these rows shall be at least 1/8th inch.</p>  |
| <p>(Other Information section)</p>  | <p>REUPHOLSTERED (or RENOVATED) BY:<br/>Name and address of Reupholsterer or Renovator</p>   | <p>REUPHOLSTERED (or RENOVATED) BY:<br/>Name and address of Reupholsterer or Renovator</p>  | <p>These rows may be combined in Tag 3 if Sanitizer and (Reupholserer or Renovator) Permits are held by the same person.</p> |
| <p>(Other Information section)</p>  | <p>(Other Information section)</p>   | <p>(Other Information section)</p>  | <p>The 1/8th inch font size requirement does not apply to this section.</p>  |



573 (2) ~~Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size~~  
574 ~~of the tag shall be not less than (six) square inches, but may be greater as the need demands.~~

575 (3) ~~Virginia approves and recognizes the uniform registry number and will accept the registration~~  
576 ~~number issued by another state, if registrant so desires, providing such registration follows the~~  
577 ~~policy of uniform registration. This policy is intended to benefit the registrant by requiring but one~~  
578 ~~registration to be imprinted on the law label used, regardless of where merchandise may be~~  
579 ~~shipped. The registration number shall be preceded by name of state (may be abbreviated)~~  
580 ~~issuing REG. NO. and the two letter abbreviation of the country in which factory is located shall~~  
581 ~~follow the registration number in parenthesis.~~

582 **12VAC5-125-100. Sanitization of used Secondhand bedding and upholstered furniture.**

583 A. ~~No article of secondhand bedding or upholstered furniture person engaged in commerce~~  
584 ~~shall be sold, rent, offer or expose for sale, barter, give away, or dispose of in any other~~  
585 ~~commercial manner any article of bedding or upholstered furniture made, remade, reupholstered~~  
586 ~~or renovated in violation of § 32.1-213 or 32.1-214 of the Code of Virginia or any secondhand~~  
587 ~~article of bedding or upholstered furniture unless since last used use such secondhand article has~~  
588 ~~been sanitized by a reasonable process approved by the commissioner permitted sanitizer in~~  
589 ~~accordance with this chapter.~~

590 ~~However, a retailer may sell, give away, or rent used upholstered furniture when the used~~  
591 ~~upholstered furniture has been purchased by the retailer as new furniture and has been used in~~  
592 ~~the course of business. Such used furniture shall be (i) conspicuously identified as used furniture,~~  
593 ~~and (ii) reduced in price, sold at auction, donated to charity, or made available for a rental fee,~~  
594 ~~and so tagged.~~

595 B. ~~No person shall use in the making, remaking, reupholstering, or renovating of any bedding~~  
596 ~~or upholstered furniture any shoddy, or any fabric from which shoddy is made or any secondhand~~  
597 ~~filling material, or any secondhand feathers, animal hair, or down, in the manufacture,~~  
598 ~~reupholstery, or renovation of bedding and upholstered furniture unless such shoddy, secondhand~~  
599 ~~filling material, feathers, animal hair, or down has been sanitized by a reasonable process~~  
600 ~~approved by the commissioner permitted sanitizer in accordance with this chapter.~~

601 ~~Any reupholstered or renovated bedding or upholstered furniture, sold to a customer who was~~  
602 ~~not the original owner of the item, must be sanitized by a permitted sanitizer in accordance with~~  
603 ~~this chapter.~~

604 ~~CB. Steri-Fab or Microban, or a comparable product approved by the commissioner meeting~~  
605 ~~all the qualities and specifications of these chemicals, are the industry recognized chemicals for~~  
606 ~~sanitizing and disinfecting mattresses, bedding or upholstered furniture. This process is required~~  
607 ~~for any business sanitizing used, secondhand or renovated mattresses, box springs, or similar~~  
608 ~~articles of bedding or upholstered furniture offered for resale or rent in Virginia. The use of these~~  
609 ~~chemicals Persons applying for approval of a process by which filling materials, bedding, or~~  
610 ~~upholstered furniture are sanitized shall submit to the Bedding Program a description of the~~  
611 ~~process, test results, apparatus, and method to be used in such process. The following general~~  
612 ~~processes are considered approved methods of sanitization; a list of specific approved products~~  
613 ~~and methods shall be maintained by the Bedding Program:~~

614 ~~1. The application of an approved isopropyl-alcohol solution via direct spray onto the filling~~  
615 ~~materials, bedding, or upholstered furniture item. Application shall reach and treat all~~  
616 ~~surfaces, seams, piping, and other design features of the item. Application, storage, and~~  
617 ~~disposal of the isopropyl-alcohol solution shall be performed according to in compliance~~  
618 ~~with the specific instructions from the product manufacturers is deemed a reasonable~~  
619 ~~sanitization process approved by the commissioner. All licensees are required to follow all~~  
620 ~~product application, safety, storage, and disposal instructions provided by the product~~  
621 ~~manufacturers. It is a violation of federal law to use Steri-Fab or Microban disinfectant in~~

622 a manner inconsistent with its labeling. Diluting or mixing with other chemicals is  
623 prohibited.

624 2. Heat treatment, via containment in a heat chamber, or direct application of steam. All  
625 submersion heat treatment methods shall exceed the temperature and time duration  
626 necessary to reach the thermal death point for bedbugs (113 degrees F for 90 minutes).  
627 All steam applications shall be designed to reach and treat all surfaces, seams, piping,  
628 and other design features of the article to be sanitized, and shall be conducted at a pace  
629 of 12" of article per 30 seconds, unless otherwise approved as provided in subsection B  
630 of this section.

631 C. Unsanitized, secondhand bedding and upholstered furniture shall be separated from new  
632 or sanitized, secondhand bedding or upholstered furniture by a dividing wall or a distance of at  
633 least 20 feet.

634 D. Yellow law labels in compliance with 12VAC5-125-90 must shall be attached to all sanitized  
635 articles and dated as soon as the approved sanitizing process is completed.

636 E. Persons donating (no monetary exchange) secondhand articles of bedding and  
637 upholstered furniture are not required to sanitize those articles if the donation is to a holder of a  
638 valid sanitizing permit. Any items sold (monetary exchange) must be sanitized first. A delivery  
639 vehicle used to transport secondhand, unsanitized bedding and upholstered furniture must be  
640 sanitized by a process approved by subsection B of this section before it is used to transport new  
641 or secondhand, sanitized products. Such sanitization shall include the entirety of the inside of the  
642 transport portion of the vehicle; however, any area not used for transport separated from the  
643 storage portion of the vehicle by a wall or partition shall not require sanitization.

644 F. Persons selling dealing in used secondhand bedding and upholstered furniture, unless  
645 otherwise exempt from this chapter as considered in 12VAC5-125-40, shall maintain a log of  
646 sanitized items, bedding and upholstered furniture, indicating the identification of each sanitized  
647 item, and the date the item was sanitized, and date rented or sold. Identification shall be by visual  
648 description, of sufficient detail to allow identification of any sanitized item offered for sale, or by a  
649 unique number also printed in the Other Information section of the yellow law label. A separate  
650 log shall be maintained in each vehicle sanitized as required by subsection E of this section; this  
651 log shall indicate the dates of all sanitization events for that vehicle within the previous 12 months.

652 G. To ensure effective sanitization is maintained, mattresses shall be stored at least six inches  
653 or the height of one standard pallet off the floor in a dry room, and so spaced to allow a four inch  
654 separation around the four sides of the mattresses. All areas where secondhand bedding or  
655 upholstered furniture are stored, rebuilt, recovered, or presented for sale shall be kept clean and  
656 free of trash, hazardous waste, insects, rodents, pets, or other animals. Permit holders shall report  
657 to the Bedding Program any infestations of insects or rodents at the permit holder's place of  
658 business, or in any bedding or upholstered furniture offered for sale by the permit holder.

659 **12VAC5-125-110. Sterilization of new animal hair, feathers and down.**

660 A. No article of new bedding or upholstered furniture using animal hair, feathers, or down for  
661 filling material shall be sold or offered for sale person shall use in the making, remaking,  
662 reupholstering or renovating of any bedding or upholstered furniture any new animal hair, new  
663 feathers, or new down unless such new animal hair, new feathers, or new down shall have has  
664 been sterilized by a permitted sterilizer in accordance with this chapter reasonable process  
665 approved by the commissioner.

666 B. Persons applying for approval of a process by which animal hair, feathers, or down are  
667 sterilized shall submit to the Bedding Program a description of the process, test results and any  
668 apparatus and method to be used in such process. The following general processes are  
669 considered approved methods of sterilization; a list of specific methods and products shall be  
670 maintained by the Bedding Program.

- 671 1. Treatment by steam under pressure, at 15 pounds maintained for 30 minutes or at 20  
672 pounds maintained for 20 minutes. A gauge for registering steam pressure, visible from  
673 the outside of the room, shall be provided.
- 674 2. Treatment by two applications of streaming steam, maintained for a period of one hour  
675 each, applied at intervals of not less than six, nor more than 24 hours. Valved outlets shall  
676 be provided near the top and bottom of the room.
- 677 3. Containment in a closed container held at a temperature of 235°F(113°C) for 2 hours.
- 678 4. Washing at a temperature of at least 140°F (60°C), followed by complete drying at a  
679 temperature of at least 158°F (70°C).

680 ~~12VAC5-125-120. Separation and storage of new and sanitized items.~~

681 ~~A. New and sanitized upholstered furniture, bedding and filling materials shall be kept~~  
682 ~~separate from any secondhand upholstered furniture, bedding and filling materials that have not~~  
683 ~~been sanitized. To prevent contamination, a distance of at least 20 feet or a dividing wall must be~~  
684 ~~kept between new and sanitized articles, and unsanitized used articles of bedding and~~  
685 ~~upholstered furniture.~~

686 ~~B. Delivery vehicles shall be disinfected before delivering new or sanitized items if that vehicle~~  
687 ~~has been used to previously transport unsanitized used merchandise, not limited to bedding and~~  
688 ~~upholstered furniture.~~

689 ~~C. Mattresses shall be stored at least six inches from the floor or the height of one standard~~  
690 ~~pallet (whatever is greater) in a dry room preferably above ground, and so spaced to allow a four~~  
691 ~~inch separation around the four sides of the mattresses. The storage as well as workroom areas~~  
692 ~~for sanitized items shall be clean and free from trash, vermin, insects, filth and any hazardous~~  
693 ~~waste. Pets and other animals shall be prohibited in storage and workroom areas.~~

694 ~~12VAC5-125-130. Violation of regulations.~~

695 ~~A. It is the responsibility of the retailer to make certain~~ ensure ~~that any article of bedding or~~  
696 ~~upholstered furniture that he offers~~ offered ~~for sale in the Commonwealth of Virginia, regardless~~  
697 ~~of where manufactured, is properly labeled and is in compliance with all provisions of the law~~ this  
698 chapter.

699 ~~B. Upon a complaint made to the commissioner as provided in § 32.1-224 of the Code of~~  
700 ~~Virginia, the commissioner may order the return of any item of bedding or upholstered furniture~~  
701 ~~or any filling material made, remade, renovated, reupholstered, prepared, processed, labeled, or~~  
702 ~~not labeled in violation of the provisions of this chapter to the manufacturer or importer thereof.~~  
703 ~~The manufacturer or importer shall be liable to the person returning such item for the costs of~~  
704 ~~crating, shipping and the invoice price to the purchaser. Failure of a manufacturer or importer to~~  
705 ~~pay such costs to the person returning such item shall be grounds for revocation or suspension~~  
706 ~~of a license issued pursuant to this chapter.~~

707 ~~CB.~~ The commissioner ~~Health Commissioner~~ or his designee ~~may order "off sale" all any~~  
708 ~~improperly sanitized or unsanitized articles of secondhand bedding or upholstered furniture~~ "off  
709 sale". ~~A significant number of violations in any one business location will~~ may ~~result in a sign being~~  
710 ~~placed on the business door taking off sale all used bedding and upholstered items in the store.~~  
711 ~~These items may not be bartered, given away, rented, or disposed of in any manner inconsistent~~  
712 ~~with this chapter until properly sanitized.~~

713 ~~D. The commissioner may refuse to issue, may suspend or may revoke the license or permit~~  
714 ~~of any person who violates any provision of this chapter, or who is not a resident of the~~  
715 ~~Commonwealth and fails or refuses to enter an appearance in any circuit court in the~~  
716 ~~Commonwealth to answer a charge or charges of violation of any provision of this chapter, or~~  
717 ~~order of the board or commissioner within 25 days after service upon him of a notice by certified~~  
718 ~~mail.~~

719 ~~EC. Any violation of the provisions of this chapter shall constitute a prohibited practice in~~  
720 ~~accordance with § 59.1-200 of the Code of Virginia and shall be subject to any and all of the~~  
721 ~~enforcement provisions of the Virginia Consumer Protection Act (§ 59.1-196 et seq. of the Code~~  
722 ~~of Virginia). Any person who violates this chapter may be subject to enforcement provisions of~~  
723 ~~the Virginia Consumer Protection Act (§ 59.1-196 et seq. of the Code of Virginia), and penalties~~  
724 ~~provided by § 32.1-27 of the Code of Virginia.~~

725 ~~F. Any person violating any provision of this chapter shall be guilty of a Class 2 misdemeanor~~  
726 ~~pursuant to § 32.1-226 of the Code of Virginia.~~

727 **12VAC5-125-140. Enforcement of regulation. (Repealed.)**

728 ~~A. This chapter shall be enforced by the board and the commissioner, as executive officer of~~  
729 ~~the board.~~

730 ~~B. All persons shall operate in compliance with the requirements set forth in this chapter and~~  
731 ~~shall not operate without a valid license or permit.~~

732 ~~C. Pursuant to the authority granted in § 32.1-224 of the Code of Virginia, the commissioner~~  
733 ~~may issue orders to require any license or permit holder or other person to comply with the~~  
734 ~~provisions of this chapter. The order may require the following:~~

- 735 ~~1. The immediate cessation and correction of the violation;~~  
736 ~~2. Appropriate remedial action to ensure that the violation does not continue or recur;~~  
737 ~~3. The submission of a plan to prevent future violations;~~  
738 ~~4. Any other corrective action deemed necessary for proper compliance with the~~  
739 ~~regulations, and safety and health of the consumers of the Commonwealth.~~

740 ~~D. Before the issuance of an order, the commissioner must comply with the requirements of~~  
741 ~~§ 32.1-26 of the Code of Virginia.~~

742 ~~E. All orders issued pursuant to subsection C of this section shall become effective not less~~  
743 ~~than 15 days after mailing a copy thereof by certified mail to the last known address of the license~~  
744 ~~or permit holder or person violating this chapter.~~

745 ~~F. The commissioner may act as the agent of the board to enforce all effective orders and~~  
746 ~~these regulations. Should any license or permit holder fail to comply with any effective order or~~  
747 ~~these regulations, the commissioner may:~~

- 748 ~~1. Institute a proceeding to revoke the license or permit in accordance with 12VAC5-125-~~  
749 ~~60;~~  
750 ~~2. Request the attorney for the Commonwealth to bring a criminal action;~~  
751 ~~3. Request the Attorney General to bring an action for civil penalty, injunction, or other~~  
752 ~~appropriate remedy; or~~  
753 ~~4. Do any combination of the above.~~

754 ~~G. Not exclusive means of enforcement. Nothing contained in this section shall be interpreted~~  
755 ~~to require the commissioner to issue an order prior to seeking enforcement of any regulations or~~  
756 ~~statute through an injunction, mandamus or criminal prosecution.~~

757 ~~H. Hearings before the commissioner or his designee shall include any of the following forms~~  
758 ~~depending on the nature of the controversy and the interests of the parties involved:~~

- 759 ~~1. Informal hearings. An informal hearing is a meeting with the Bedding Program~~  
760 ~~Supervisor presiding and held in conformance with § 2.2-4019 of the Code of Virginia.~~  
761 ~~2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory~~  
762 ~~proceeding before the commissioner, or his designated hearing officer, and held in~~  
763 ~~conformance with § 2.2-4020 of the Code of Virginia.~~

764 **12VAC5-125-145. Variances.**

765 A. One or more of the regulations in this chapter may be waived in whole or in part when, as  
766 determined by the Health Commissioner, the hardship imposed by the regulations, which may be  
767 economic, outweighs the benefits that may be received by the public, and that granting such a  
768 variance does not subject the public to unreasonable health risks. Variances shall be issued in  
769 writing by the Health Commissioner.

770 B. Any person who seeks a variance shall apply in writing to the Bedding Program. The  
771 application shall include:

772 1. A citation to the regulation from which a variance is requested;

773 2. The nature and duration of the variance requested;

774 3. Evidence that establishes that the public health and welfare would not be adversely  
775 affected if the variance were granted;

776 4. Suggested conditions that might be imposed on the granting of a variance that would  
777 limit the detrimental impact on the public health and welfare;

778 5. Other information believed pertinent by the applicant; and

779 6. Such other information as the Bedding Program or Health Commissioner may require.

780 C. If the Health Commissioner proposes to grant the variance request, the applicant shall be  
781 notified in writing of this decision within 90 days of receipt of the variance request. If the Health  
782 Commissioner proposes to deny the variance request, the Health Commissioner shall notify the  
783 applicant of the proposed denial within 90 days of receipt of the variance request and provide an  
784 opportunity for an informal fact-finding conference as provided in § 2.2-4019 of the Code of  
785 Virginia.

786 **12VAC5-125-150. Request for hearing. (Repealed.)**

787 ~~A request for an informal hearing shall be made by sending the request in writing to the~~  
788 ~~Bedding Program. Requests for hearings shall cite the reasons for the hearing request and shall~~  
789 ~~cite the section(s) of these regulations involved and must be received within 15 days of the~~  
790 ~~decision by the department that lead to the hearing request.~~

791 **12VAC5-125-160. Hearing as a matter of right. (Repealed.)**

792 ~~Any person holding a license or permit or named party whose rights, duties, or privileges have~~  
793 ~~been, or may be affected by any case decision of the board or its subordinates in the~~  
794 ~~administration of these regulations, shall have a right to both informal and adjudicatory hearings.~~  
795 ~~The commissioner may require participation in an informal hearing before granting the request for~~  
796 ~~a full adjudicatory hearing. Exception: No person other than an owner shall have the right to an~~  
797 ~~adjudicatory hearing to challenge the issuance of a license or permit unless the person can~~  
798 ~~demonstrate at an informal hearing that the minimum standards contained in these regulations~~  
799 ~~have not been applied and that he will be injured in some manner by the issuance of the license~~  
800 ~~or permit.~~

801 **12VAC5-125-170. Penalties, injunctions, civil penalties and charges for violations.**  
802 **(Repealed)**

803 ~~A. Any person willfully violating, or refusing, failing, or neglecting to comply with any~~  
804 ~~regulations or order of the board or commissioner, or any provision of this chapter, shall be guilty~~  
805 ~~of a Class 2 misdemeanor unless a different penalty is specified. Each day of violation shall~~  
806 ~~constitute a separate offense.~~

807 ~~B. Any person violating, or failing, neglecting, or refusing to obey any order of the board or~~  
808 ~~commissioner, or any provision of this chapter may be compelled, in a proceeding instituted in an~~  
809 ~~appropriate court by the board or commissioner, to obey and comply with such regulations, order,~~

810 or any applicable provision of Title 32.1 of the Code of Virginia. The proceeding may be by  
811 injunction, mandamus, or other appropriate remedy.

812 C. Without limiting the remedies that may be obtained pursuant to subsection B of this section,  
813 any person violating or failing, neglecting, or refusing to obey any injunction, mandamus, or other  
814 remedy obtained pursuant to subsection B of this section shall be subject, in the discretion of the  
815 court, to a civil penalty not to exceed \$25,000 for each violation. Each day of violation shall  
816 constitute a separate offense.

817 D. With the consent of any person who has violated or failed, neglected or refused to obey  
818 any regulation or order of the board or commissioner or any applicable provision of Title 32.1 of  
819 the Code of Virginia, the board may provide, in an order issued by the board against such person,  
820 for the payment of civil charges for past violations in specific sums not to exceed the limit set forth  
821 in subsection C of this section. Such civil charges shall be in place of any appropriate civil penalty  
822 that could be imposed under subsection C of this section.

823 **12VAC5-125-180. Fees.**

824 The board Board of Health shall set the annual fees imposed for licenses and permits issued  
825 pursuant to this chapter. All fees collected shall be deposited and held by the department in a  
826 separate fund, from which shall be paid all expenditures necessary in carrying out the provisions  
827 of this chapter.

828 The board shall review the fees being charged for the services delivered by the department  
829 pursuant to Article 7 (§ 32.1-212 et seq.) of Chapter 6 of Title 32.1 as such services and fees  
830 were in effect prior to July 1, 2003, and shall revise such fees, as appropriate, consistent with the  
831 level of services required by this chapter.

832 Table 1. The fee schedule established by the board is as follows:

| <u>Vendor Description: License or Permit Type</u> | <u>Annual Fee: (US Dollars)</u> |
|---|---------------------------------|
| Manufacturer of bedding                           | \$100                           |
| Manufacturer of upholstered furniture             | \$100                           |
| Renovator (bedding)*                              | \$25                            |
| Reupholsterer*                                    | \$25                            |
| Supply dealer                                     | \$25                            |
| Importer  | \$100 <u>see Table 2</u>        |
| Sanitizer   | \$60                            |
| <u>Sterilizer</u>                                 | <u>\$60</u>                     |
| <u>Distributor/wholesaler-Distributor</u>         | <u>\$100-see Table 2</u>        |

833 \*Self-employed Renovators and Reupholsterers with no employees are exempt from this fee.

834 Table 2. Importer and Distributor license fees

| <u># of Associated URNs</u> | <u>Importer Annual Fee (US Dollars)</u> |
|-----------------------------|---|
|-----------------------------|---|

|   |                  |
|---|------------------|
| <u>1</u>  | <u>100</u>       |
| <u>2</u>  | <u>100</u>       |
| <u>3</u>  | <u>300</u>       |
| <u>4</u>  | <u>400</u>       |
| <u>5-9</u>  | <u>805</u>       |
| <u>10-14</u>  | <u>1,380.00</u>  |
| <u>15-19</u>  | <u>1,995.00</u>  |
| <u>20-24</u>  | <u>2,530.00</u>  |
| <u>25-29</u>  | <u>3,105.00</u>  |
| <u>30-34</u>  | <u>3,680.00</u>  |
| <u>35-39</u>  | <u>4,255.00</u>  |
| <u>40-44</u>  | <u>4,830.00</u>  |
| <u>45-49</u>  | <u>5,405.00</u>  |
| <u>50-54</u>  | <u>5,980.00</u>  |
| <u>55-59</u>  | <u>6,555.00</u>  |
| <u>60-64</u>  | <u>7,130.00</u>  |
| <u>65-69</u>  | <u>7,705.00</u>  |
| <u>70-74</u>  | <u>8,280.00</u>  |
| <u>75-79</u>  | <u>8,855.00</u>  |
| <u>80-84</u>  | <u>9,430.00</u>  |
| <u>85-89</u>  | <u>10,005.00</u> |
| <u>90-94</u>  | <u>10,580.00</u> |
| <u>95-99</u>  | <u>11,155.00</u> |
| For 100 or more licenses, the additional fee for each increment of 5 licenses is \$575. |                  |

**835** DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-125)

**836** 2004 Manual of Labeling Laws, Registration Requirements, International Sleep Products  
**837** Association.