State Board of Health – Nominating Committee
Agenda
June 15, 2012 – 8:30 a.m.
Perimeter Center – Training Room 1
9960 Mayland Drive
Richmond, Virginia 23233

Welcome and Introductions
Bhushan Pandya, MD, Chair

Officer Nominations - Discussion
Nominating Committee Members

Adjourn

State of Board of Health
Agenda
June 15, 2012 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233

Welcome and Introductions
Bruce Edwards, Chair

Review of Agenda
Karen Remley, MD, MBA, FAAP
State Health Commissioner

Approval of March 2011 Minutes
Mr. Edwards

Commissioner’s Report
Dr. Remley

Public Health Accreditation Update
Joshua Czarda
Performance Improvement Manager

Report of Nominating Committee
Bhushan Pandya, MD

Regulatory Action Update
Dr. Remley

Break

Public Comment

Lunch

Luncheon Speaker Jim Stewart, Commissioner
Virginia Department of Behavioral Health and Developmental Services
Regulatory Action Items

Sanitary Regulations for Marinas and Boat Moorings
12VAC5-570
(Proposed Amendments)

Regulations for Licensure of Abortion Facilities
12VAC5-412
(Proposed Regulations)

Board Action Items

Mammogram Report Guidelines (HB83/SB544 of 2012)

National Registry of Emergency Medical Technicians - Allocation Methodology for Payment of Initial Testing Expenses

Member Reports

Other Business

Adjourn
MEMORANDUM

DATE: May 4, 2012

TO: State Board of Health

THROUGH: Robert Hicks, Director, Office of Environmental Health Services

FROM: Allen L. Knapp, Director, Division of Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs

RE: Proposed Amendments to Sanitary Regulations for Marinas and Boat Moorings (12VAC5-570-10 et seq.)

ISSUE: Request to adopt proposed regulations

The text of the Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings (marina regulations) is attached. We are asking you to adopt the proposed amendments to the marina regulations. With your approval (and concurrence of the Office of the Attorney General) the Virginia Department of Health (VDH) will submit the proposed regulations to the Department of Planning and Budget (DPB) to begin the mandatory executive branch review. Once the executive branch review is complete and the Office of the Governor has approved, VDH will submit the proposed regulations to the Virginia Registrar for publication in the Virginia Register of Regulations and the proposed regulations will undergo a mandatory public comment period. After the mandatory public comment period, VDH will develop the final regulation and will present it to the Board of Health (Board) for its review and adoption.

DISCUSSION: The Board initially adopted the marina regulations circa 1968 and has not updated them since 1990. In the fall of 2010 VDH was required by § 2.2-4017 of the Code of Virginia and Executive Order 14 (2010) to conduct a periodic review of the marina regulations. The general purpose of the periodic review is to determine whether there is a need to retain the regulation as is, whether certain amendments are needed, or whether it should be repealed. VDH determined that the marina regulations were antiquated and should be amended in order to accommodate the changing environment of the marina industry and to incorporate changes in associated laws, regulations, and policies.

The Notice of Intended Regulatory Action (NOIRA) to amend the marina regulations was published in the Virginia Register of Regulations on February 28, 2011. The public comment
period closed March 30, 2011; the agency received no comments. In addition, VDH convened the marina regulations ad hoc advisory committee and we solicited input from members and technical experts as to how the marina regulations should be modified to reflect the current state of the industry. As a result of the ad hoc stakeholder meeting, a number of substantive changes to the marina regulations have been proposed in this regulatory action. Some salient changes include:

- Adding a requirement that boating access sites with 50 or more parking spaces for boat trailers have at least one portable toilet.

- Providing greater flexibility by ceasing to define slips as either seasonal or transient. The purpose of the old definitions was to assign wastewater design flows based on anticipated usage. VDH found that it was difficult to determine whether the slips were seasonal or transient. The proposed regulation counts all slips, except live-aboard slips, the same, and assigns a wastewater flow of 25 gallons per day per slip.

- Amending the regulations to include live-aboard slips based on its increasing popularity as a form of housing and the increased water usage associated with such arrangements.

- Amending the regulations to ensure that the number of sewerage fixtures required at marinas is based on the number of slips rather than the type of slip.

- Amending the regulations to require pump-out facilities at marinas and other place(s) where boats are moored that provide live-aboard slips or that serve boats with marine sanitation devices.

- Amending the regulations to provide an exemption from the requirement to install a sewage dump station for those marinas or other place(s) where boats are moored that have pump-out facilities capable of pumping portable sewage containers.

- Amending the regulation to allow smaller boating facilities to construct unisex bathrooms.

As mentioned above, the proposed amendments are necessary to reconcile the regulatory standards for marinas with the current state of the marina industry in the Commonwealth. 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 marina regulations.

Enclosures:
Regulations
Town Hall Form TH-02
This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

Brief summary

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

The Board of Health’s Sanitary Regulations for Marinas and Boat Moorings (“Marina Regulations”) establish minimum standards for sewage handling and disposal at regulated facilities. Sewerage facilities, sewerage systems, and treatment works that serve marinas, other places where boats are moored, and boating access facilities with 50 or more parking spaces for boat trailers should be sufficient to serve the number of boat slips or persons using such facilities. The proposed revisions to the marina regulations are designed to: (1) ensure that the number of sewerage fixtures required at marinas is based on the number of slips; (2) clarify existing requirements by combining sewerage fixture requirements into one table; (3) add a requirement that boating access sites with 50 or more parking spaces for boat trailers be equipped with appropriate sewerage facilities; (4) simplify procedures for assigning wastewater design flows by providing only one sewage design flow value per slip; (5) require pump-out systems at marinas and other place(s) where boats are moored that provide live-aboard slips or that serve boats with marine sanitary devices; and (6) provide an exemption from the requirement that regulated facilities install a dump station if such facilities have a pump-out system that is capable of pumping out portable sewerage containers.
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.

“VMRC” means the Virginia Marine Resources Commission.
“VDH” or “agency” means the Virginia Department of Health.

Legal basis

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

Statutory Authority:
Va. Code §§ 32.1-12 and 32.1-246 require the Board of Health (Board) to promulgate regulations establishing minimum requirements for sewerage facilities at marinas and other places where boats are moored. Va. Code § 32.1-164 provides that the Board's regulations may require that "residences, buildings, structures and other places designed for human occupancy as the Board may prescribe be provided with a sewerage system or treatment works."

Purpose

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

The Board’s Marina Regulations are intended to protect public health and the environment by ensuring that sewage generated from boats and onshore boating facilities is treated and disposed of properly. The Marina Regulations have not been revised since the Board adopted amendments in 1990. Since that time, development has increased dramatically in the Chesapeake Bay watershed and other tributaries and around Virginia’s inland lakes. At the same time the public’s awareness of and susceptibility to impaired water quality has increased. Boating has increased in popularity with more than 12 million boats in use nationwide. While the number of large commercial marinas has steadily grown, Virginia has also seen an increase in the number of smaller facilities, such as neighborhood marinas and public boat ramps. The proposed amendments simplify and clarify many regulatory requirements and address the need to modify the regulatory requirements for two facilities in particular: a. marinas that serve owners who live aboard their boats and b. public boating access facilities (boat ramps) that receive heavy use (i.e. that have parking spaces for 50 or more boat trailers). In addition, the proposed amendments reflect the evolution in the methods of conveying and disposing human waste aboard boats; in particular, the proposed amendments address the advent of waste disposal via a “marine sanitation device” or a portable toilet. In addition to these methods, the Marina Regulations also require pump-outs to safely and properly handle waste disposal. Some of the changes, particularly those that simplify the method for determining sewage flow as a function of the number of slips, are intended to provide marinas and other...
place(s) where boats are moored with the flexibility to redefine business models regarding the types of boats and boating activities they will service.

**Substance**

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

The amendments cover five main areas: (1) definitions of terms; (2) requirements for sanitary fixtures based on the number of slips and dry storage spaces; (3) sewerage facility requirements at boating access facilities (boat ramps); (4) sewage design flows based on the number of slips rather than the type of slip with a specific flow assigned to all slips used as “live-aboard” slips; (5) a new section for onshore facility requirements; and, (6) an exemption from the requirement for a sewage dump station for any facility that has a sewage pump-out and the correct appurtenance for pumping out portable toilets.

The agency amended 12VAC5-570-10 to define boating access facility as a location consisting of a boat ramp. The agency expanded the definition for dry storage to include different ways boats are stored between uses. The agency added a definition for “live-aboard slip”. The agency defined regulated facilities as marinas, other places where boats are moored, and boating access facilities with 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-150 to provide an allowance for smaller boating facilities to construct unisex bathrooms.

The agency amended 12VAC5-570-160 to require sewerage facilities at boating access facilities that have 50 or more parking spaces for boat trailers.

The agency amended 12VAC5-570-180 to prohibit marinas or other places that provide live-aboard slips or boats with a marine sanitation device to invoke an exemption to provide a pump-out service.

The agency amended 12VAC5-570-190 to allow marinas with a pump-out facility equipped with a specialized device (i.e. porta-potty wand) to use the device to excavate sewage from portable sewage containers instead of installing a dump station.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.*

The primary advantage to the public of these amendments is improved sewage handling in sensitive waterfront areas and the assurance that when they visit a regulated facility there will be adequate sewerage fixtures to meet their needs. Having sewerage facilities available in such locations reduces the potential that human wastes will be improperly dumped into the waters of the Commonwealth. The requirement for smaller-sized marinas to install shower facilities poses an additional economic burden on
smaller marina owners. This burden is offset somewhat, however, by the change that allows these smaller facilities to install a unisex bathroom instead of having to construct separate facilities for men and women. The proposed amendments create advantages to the public and VDH by simplifying the regulatory program; specifically, the number of sewerage fixtures required at regulated facilities is no longer driven by the type of slip (seasonal or transient) but rather by the total number of slips and dry storage spaces. This proposed amendment allows owners the freedom to accommodate both short-term and long-term boaters without impacting any future growth. The amendments propose a higher sewage flow for live-aboard slips to reflect the higher water usage associated with these residences. While this change may pose economic impacts to owners, this change provides public health protection from raw sewage discharge by helping to ensure that sewerage systems and treatment works are sized adequately to handle the wastewater load.

VDH worked with an ad hoc group of stakeholders in developing the proposed amendments. While that group was not able to review all of the proposed amendments, it supported the need to update the regulations and generally supported the substantive changes proposed.

**Requirements more restrictive than federal**

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

The proposed amendments to the regulations do not conflict with nor exceed applicable federal requirements.

**Localities particularly affected**

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

Localities that own (or propose to own) regulated facilities are regulated under the current regulations and will be affected by the proposed amendments. These include the Cities of Alexandria, Hampton, Newport News, Norfolk, Portsmouth, Virginia Beach, Suffolk and the counties of Fairfax, Prince William, Stafford, Spotsylvania, James City, and the Northern Neck, Middle Peninsula, and Eastern Shore regions.

**Public participation**

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

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.
Anyone wishing to submit written comments may do so via the Regulatory Town Hall website, www.townhall.virginia.gov, or by mail, email or fax to Preston Smith, 109 Governor Street, 5th Floor, Room 540, Richmond, Virginia 23219; phone (804)864-7468; fax (804)864-7475 or preston.smith@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last date of the public comment period.

Economic impact

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

<p>| Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures. | No projected cost. |
| Projected cost of the new regulations or changes to existing regulations on localities. | Existing facilities are not required to upgrade sewerage facilities unless they expand. Localities may incur some additional costs when regulated facilities are expanded based on requirements for additional sewerage fixtures and modification of an existing or installation sewage treatment works. |
| Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations. | Owners of marinas, other places where boats are moored, and public access facilities (boat ramps). |
| 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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | Type of facility | # of entities affected | # of small businesses affected |
| | Marinas | 525 | 525 |
| | Other places | 402 | 200 |
| | Boating access facility | 25 | 25 |
| All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations. | As noted above, existing facilities are not required to upgrade unless they expand. The numbers shown in the table above are based on the total number of regulated facilities in Virginia and represent the number of businesses that could be affected. A completed marina application submitted by the owner of the facility to the local health department in which the facility is located, providing essential data to determine the sewerage facilities, does not carry a fee. These facilities are inspected annually by the local health department. All records generated on the boating facility are maintained by the local health department. |
| Beneficial impact the regulation is designed 1. Enhanced protection of public health and |</p>
<table>
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<tr>
<th>Alternatives</th>
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<td>Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.</td>
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The alternative would be for the agency to continue administering the current regulations. However, following the agency’s periodic review pursuant to Executive Order 36 (2006), VDH determined that the current regulations are outdated and in need of amendments to reorganize and clarify portions and to update some portions to more closely fit current trends and practices in the marine industry.

<table>
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<tr>
<th>Regulatory flexibility analysis</th>
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<tr>
<td>Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.</td>
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VDH believes that some of the amendments, for instance the change that allows smaller marinas to have unisex bathrooms, are less stringent and improve flexibility for the regulated entities. The amendments establish simplified compliance requirements by eliminating the distinction between seasonal and transient slips. These regulations are necessary to protect public health and the environment and are required by § 32.1-246 of the Code of Virginia. VDH believes the proposed amendments represent the least burdensome alternatives for small business.
Public comment

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

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<tr>
<th>Commenter</th>
<th>Comment</th>
<th>Agency response</th>
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<tbody>
<tr>
<td></td>
<td>NO COMMENTS WERE RECEIVED</td>
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Family impact

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

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

Detail of changes

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

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

For changes to existing regulations, use this chart:

<table>
<thead>
<tr>
<th>Current section number</th>
<th>Proposed new section</th>
<th>Current requirement</th>
<th>Proposed change, rationale, and consequences</th>
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<tr>
<td><strong>number, if applicable</strong></td>
<td><strong>As used in these regulations, the following words and terms hereinafter set forth shall have the following meanings respectively, unless the context clearly requires a different meaning.</strong></td>
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<tr>
<td>10</td>
<td>As used in these regulations, the following words and terms hereinafter set forth shall have the following meanings respectively, unless the context clearly requires a different meaning.</td>
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</table>

"Certificate" means a written approval from the Commissioner or his designated representative indicating that plans for sanitary facilities and sewage facilities meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.

"Commissioner" means the State Health Commissioner whose duties are prescribed in § 32.1–19 of the Code of Virginia.

"Division" means the Division of Wastewater Engineering, Department of Health.

"Boating access facility" means any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers. Boating access facilities were previously unregulated despite the fact that the Board has authority to regulate. Under the proposed amendments these facilities will be regulated when there are 50 or more parking spaces for boat trailers. The rationale is to afford the same public health protections afforded to marinas and other places where boats are moored.

"Certificate" means a written approval from the Commissioner or his designated representative indicating that plans for sanitary facilities and sewage facilities, sewerage system and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246, of the Code of Virginia. Certificate to Operate is issued when plans or existing boat facility satisfies the minimum requirements regarding sewerage facilities. Revised for clarity.

"Commissioner" means the State Health Commissioner whose duties are prescribed in § 32.1–19 of the Code of Virginia.

"Department" means State Health Department. Revised for clarity.

"Division" means the Division of Wastewater Engineering, Onsite Sewage and Water Services.
| "Dry storage" means a boat storage or parking space, whether covered or uncovered, at a marina or other place where boats are moored for the purpose of storing boats on land between use. |
| Environmental Engineering, and Marina Programs, Office of Environmental Health Services, Department of State Health Department or its administrative successor. Reflects program realignments within the Office of Environmental Health Services. "Dry storage" means a boat storage, including boatels, valet storage, pigeon hole storage, stackominiums, or parking space, where boats rest on racks or trailers located on land, whether covered or uncovered, at a marina or other place(s) where boats are moored, for the purpose of storing boats on land between use. Clarifies the definition to reflect different means of storing boats out of the water. |
| "Expanded" means any change to a regulated facility that results in an increase in sewerage volume or strength due to the addition of slips, dry storage spaces, boat trailer parking spaces or ancillary operations. New definition added for clarity. |
| "Live-aboard slip" means any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence. Establishes a new category of slips with a higher wastewater flow number. |
| "Local health department" means the branch of the State Health Department, established in accordance with § 32.1-30 of the Code of Virginia, that has jurisdiction in the city or county where the regulated facility is located. Added for clarity. |
| "Marina" means any installation, operating, under public or private ownership, which provides dockage or moorage for boats (exclusive of paddle or rowboats) and provides, through sale, Environmental Engineering, and Marina Programs, Office of Environmental Health Services, Department of State Health Department or its administrative successor. Reflects program realignments within the Office of Environmental Health Services. "Marina" means any installation operating, under public or private ownership, which provides dockage or moorage for boats, other than |
rental or fee basis, any equipment, supply or service (fuel, electricity or water) for the convenience of the public or its leasee, renters or users of its facilities.

"Marine sanitation device" means any equipment, piping and appurtenances such as holding tanks for installation on board a boat which is designed to receive, retain, treat or discharge sewage and any process to treat such sewage.

"Other place(s) where boats are moored" means any installation operating under public or private ownership, which provides dockage, moorage or mooring for boats (exclusive of paddle or rowboats) either on a free, rental or fee basis or for the convenience of the public.

"No Discharge Zone" means an area where a state has received an affirmative determination from the U.S. Environmental Protection Agency that there are adequate facilities for the removal of sewage from vessels (holding tank pump-out facilities) in accordance with §312(f)(3) of the Clean Water Act (33 U.S.C. 1251 et seq.), and where federal approval has been received allowing a complete prohibition of all treated or untreated discharges of sewage from all vessels.

"Office" means the Office of Environmental Health Services.

"Other place(s) where boats are moored" means any installation operating under public or private ownership, which provides dockage, moorage or mooring for boats, other than (exclusive of paddle or rowboats) either on a free, rental or fee basis or for the convenience of the public.
"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm or company organized or existing under the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns a marina or other place where boats are moored.

"Pump-out facilities" means any device, equipment or method of removing sewage from a marine sanitation device. Also, it shall include any holding tanks either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats.

"Sanitary facilities" means bathrooms, toilets, closets and other enclosures where commodes, stools, water closets, lavatories, showers, urinals, sinks or other such plumbing fixtures are installed.

"Seasonal slips" means any slip which is used, rented, leased or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days.

Definition deleted to simplify as the amendments eliminated the distinction between seasonal and the public boater. Revised for clarity.

"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm or company organized or existing under the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns or proposes to own a marina, other place(s) where boats are moored or boating access facility. Revised for clarity.

"Pump-out facilities facility" means any device, equipment or method of for removing sewage from a marine sanitation device, and conveying such sewage to a sewerage system or treatment works. Also, it shall include including any portable, movable, or permanent holding tanks, either portable, movable, or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats. Revised for clarity.

"Sanitary Sewerage facilities facility" means bathrooms, toilets, closets and other enclosures, including portable toilets, where commodes, stools, water closets, lavatories, showers, urinals, sinks, or other such plumbing fixtures are installed. Revised for clarity and to include portable toilets as an option. The term was changed from "sanitary" to "sewerage" in order to better align the regulations with Va. Code § 32.1-246.

"Seasonal slips" means any slip which is used, rented, leased, or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days. Definition deleted to simplify as the amendments eliminated the distinction between seasonal and
<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>&quot;Sewage&quot;</td>
<td>means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks.</td>
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<td>&quot;Sewage treatment or disposal systems&quot;</td>
<td>means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration.</td>
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<tr>
<td>&quot;Sewerage facilities&quot;</td>
<td>means entire sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system.</td>
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<td>&quot;Sewage dump station&quot;</td>
<td>means a facility specifically designed to receive waste from portable sewage containers carried on boats and conveys such sewage to a sewerage system or a treatment works. Definition added for clarity.</td>
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<tr>
<td>&quot;Sewage treatment or disposal systems&quot;</td>
<td>means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration. Deleted for clarity. Other terms in common usage were added- &quot;sewerage systems&quot; and &quot;treatment works.&quot;</td>
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"Sewage" means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks, water-carried and non-water-carried human excrement, kitchen, laundry, shower, bath, or lavatory wastes, separately or together with such underground, surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, boats, industrial establishments or other places. Revised for clarity and to conform to Va. Code § 32.1-163.
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<td>stations and force mains and all other construction, devices, and appliances used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal. Definition revised for clarity and to conform to the definition found in Va. Code § 32.1-163.</td>
</tr>
<tr>
<td>&quot;Transient slips&quot; means temporary docking or mooring space which may be used for short periods of time, including overnight, days, or weeks, but less than 30 days.</td>
<td>&quot;Transient slips&quot; means temporary docking or mooring space which may be used for short periods of time, including lodging overnight, days, or weeks, but less than 30 days. Definition deleted to simplify the regulation, as the distinction between seasonal and transient slips has been eliminated.</td>
<td></td>
</tr>
<tr>
<td>&quot;Slip&quot; means a berth or space where a boat may be secured to a fixed or floating structure, including a dock, finger pier, boat lift, or mooring buoy. Definition added to simplify the regulation, as the distinction between seasonal and transient slips has been eliminated.</td>
<td>&quot;Treatment works&quot; means any device or system used in the storage, treatment, disposal or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks, and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment. Definition added for clarity. Definition conforms to the definition of “treatment works” found in Va. Code § 32.1-163.</td>
<td></td>
</tr>
<tr>
<td>&quot;VMRC&quot; means the Virginia Marine Resources Commission. Added for clarity.</td>
<td>Sections 32.1-12 and 32.1-246 of the Code of Virginia provides that the State</td>
<td>Sections 32.1-12 and 32.1-246 of the Code of Virginia provides that</td>
</tr>
<tr>
<td>14</td>
<td>Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food.</td>
<td>the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements for adequate sewerage facilities at marinas and other place(s) where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and other place(s) where boats are moored are designed to accommodate, regardless of whether such establishments serve food. Section 32.1-164 provides that the Board’s regulations may require a sewerage system or treatment works for such residences, buildings, structures and other places designed for human occupancy as the Board may prescribe. Revised for clarity and to delineate the Board’s authority to regulate boating access facilities (Va. Code § 32.1-164).</td>
</tr>
<tr>
<td>30.</td>
<td>This chapter has been promulgated by the State Board of Health to:</td>
<td>This chapter has been promulgated by the State Board of Health to:</td>
</tr>
<tr>
<td></td>
<td>1. Ensure adequate sanitary facilities and pump-out facilities, as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, are provided at all marinas and other places where boats are moored;</td>
<td>1. Protect public health and water quality by ensuring that adequate sanitary sewerage facilities, and pump-out facilities, sewage dump stations, and sewerage systems as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, are provided at all marinas, and other place(s) where boats are moored; and boating access facilities.</td>
</tr>
<tr>
<td></td>
<td>2. Establish minimum requirements as to the adequacy of sewerage facilities at marinas and other places where boats are moored;</td>
<td>2. Establish minimum requirements as to the adequacy of sewerage facilities and sewerage systems at all marinas, and other place(s) where boats are moored; and boating access facilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Protect public health and the</td>
</tr>
</tbody>
</table>
3. Guide the State Board of Health in its determination of the adequacy of the sewerage facilities to serve marinas and other places where boats are moored;

4. Guide the State Board of Health in its approval of plans and other data and the issuance of a certificate as to the adequacy of sanitary and sewerage facilities.

5. Notify the Marine Resources Commissioner that a certificate has been issued; and

6. Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70)

These regulations are administered by the following parties:

1. The State Board of Health has responsibility for promulgating, amending and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.

2. The State Health Commissioner.

Amendments in this section are for clarity and to ensure that proposed or existing regulated facilities address sewerage facility and sewerage system needs. Boating access facilities are added as a new group of regulated facilities.

These regulations are administered by the following parties:

1. The State Board of Health has responsibility for promulgating, amending, and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.

A. The State Health Commissioner is the chief executive officer of the State Department of Health. The Commissioner has the authority to act for the Board when it is impossible to do so.
3. The Division of Wastewater Engineering is designated as the primary reviewing agent of the board for the purpose of administering this chapter. It examines and passes upon the technical aspects of all applications, plans and specifications for sewerage facilities to serve marinas and other places where boats are moored. It issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission when a certificate is issued or denied.

4. The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in the administration of assigned duties and responsibilities under the chapter.

5. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) inspect sites and facilities provided, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided.
6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.

50. A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15, 1975 [repealed], shall comply with this chapter.

B. All planned or new marinas or other places where boats are moored which do not exist on the effective date of this chapter shall comply with all provisions of this chapter prior to commencing operation.

6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.

Revised for clarity and to update language to reflect the current command structure and delegations of authority within the agency.
C. All sanitary or sewerage facilities shall conform to the requirements of this chapter when the marina or other places where boats are moored are either expanded, altered or modified.

C. All sanitary or sewerage facilities and sewerage systems shall conform to the requirements of this chapter when the marina or other place(s) where boats are moored or boating access facility that is served by the sewerage facilities and sewerage systems is either expanded, altered or modified. Revised for clarity.

D. This chapter shall apply to sewerage facilities and sewerage systems serving marinas, other place(s) where boats are moored or boating access facilities and located on property owned by the marina, other place(s) where boats are moored or boating access facility owner. Sewerage systems or treatment works installed or proposed to be installed on property owned by someone other than the marina, other place(s) where boats are moored or boating access facility owner are regulated by Chapter 6 of Title 32.1 of the Code of Virginia or Title 62.1 of the Code of Virginia, as applicable.

New section that clarifies that this chapter applies only to those sewerage systems and facilities that are located on the owner’s property. Remote facilities are subject to other applicable regulations.

| 60. | No owner shall operate a marina or other place where boats are moored unless he complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and this chapter. Owners shall have in their possession a permit from the Marine Resources Commission to operate a marina or place where boats are moored when so required by § 62.1-3 of the Code of Virginia. Where state-owned bottom lands are involved, a plan approved by the department shall be regulation, shall comply with all provisions of this chapter prior to commencing operation. Revised for clarity. |
| No owner shall operate a marina, other place(s) where boats are moored or a boating access facility unless he has obtained a construction permit in accordance with complies with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and this chapter, these regulations. No owner shall operate a marina, other place(s) where boats are moored or boating access facility until the local |
| A completed application form which shall set forth the essential data to determine the sewerage facilities necessary to serve the proposed installation; |
| Maps, plans and specifications of the sanitary and sewerage facilities describing how and what facilities will be provided. The plans shall establish the location of the sanitary facilities in relation to other facilities; |

| Any owner, or his duly authorized representative, may make application for a certificate of approval of sanitary or sewerage facilities by applying to the local health department in the jurisdiction where the proposed marina or other place where boats are moored is to be located. The application shall be made on a form supplied by the local health department. The application shall consist of the following: |
| Any owner, or his duly authorized representative, shall apply for a construction permit certificate of approval of sanitary or sewerage facilities by applying submitting an application to the local health department in the jurisdiction where the proposed marina, or other place(s) where boats are moored, or boating access facility is to be located. The application shall be made on a form approved by the Division supplied by the local health department. The application shall consist of the following: |

- A completed application form which shall set forth the essential data to determine the sewerage facilities and sewerage system necessary to serve the proposed installation;

- Maps, plans and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what type of facilities that will be provided, and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish the location of the sanitary sewerage facilities and

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70. The health department has inspected and approved construction and has issued a certificate to operate. Owners shall have in their possession obtain a permit from the Marine Resources Commission VMRC to operate a marina, or other place(s) where boats are moored, or boating access facility when so required by § 62.1-3 of the Code of Virginia. Where state-owned bottom lands are involved, the owner shall submit a plan preliminary design and receive approval by the Department shall be issued Division prior to construction and the issuance of a certificate to operate.

Revised for clarity and to add boating access facilities as a regulated category.
3. A description of the proposed method of sewage treatment or disposal. Approval of the treatment works or disposal system must be applied for and obtained under other sections of the Code of Virginia and other regulations; and

4. Any other data as may be pertinent to show the adequacy of sanitary or sewerage facilities to be provided.

Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.

A. Construction. Upon completion of construction of the sanitary and sewerage facilities at marinas and other places where boats are moored, the owner of the facility, or his duly authorized representative, shall notify the local health department. A sewerage system in relation to other facilities they are intended to serve;

3. C. A description of the proposed or existing offsite sewerage system or treatment works used for the ultimate method of sewage treatment and disposal of sewage. The applicant shall apply for and obtain approval of new the offsite sewerage systems or treatment works or disposal system and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter, must be applied for and obtained under other sections of the Code of Virginia and other regulations; and

4. D. Any other data as may be pertinent to show the adequacy of the sanitary or sewerage facilities and sewerage system to be provided.

E. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.

Revised for clarity and to add boating access facilities as a regulated category.

A. Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.

B. A. Construction. Upon completion of construction of the sanitary sewerage facilities and sewerage system facilities at marinas, and other place(s) where boats are moored, or boating access facility, the owner of the facility, or his duly authorized representative, shall notify the
A certificate to operate shall be issued by the Health Department when it has been determined that construction is in compliance with the approved plan.

B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia.

The commissioner may grant a variance to any requirement of this chapter if, after investigation, it is determined that the hardship imposed upon the owner or the public by compliance with this chapter outweighs the benefits that the chapter confers, or that there is no potential or actual public health hazard.

A. Effect of variance. A variance is a conditional waiver of a specific regulation which is granted to a particular or designated marina or other place where boats are moored. It is nontransferrable and it shall be attached to the certificate of the marina or other place where boats are moored to which it was granted. The variance is a condition of the certificate which is revoked if the certificate is revoked.

A. The commissioner Commissioner may grant a variance to any requirement of this chapter if, after investigation, it is determined that the hardship imposed upon the owner or the public by compliance with this chapter outweighs the benefits that the chapter confers, and that granting a variance will not result in a or that there is no potential or actual public health hazard.

AB. Effect of variance. A variance is a conditional waiver of a specific regulation which is granted to a an owner of a marina, other place(s) where boats are moored or boating access facility, particular or designated marina or other place where boats are moored. Variances are not transferrable between owners and any variance it shall be attached to the certificate of the marina, or other place(s) where boats are moored, or boating access facility to which it was granted. The variance is a condition of the certificate which is

local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it has been determined that construction is in compliance with the approved plan--it shall issue a certificate.

B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia.

B. The owners shall post the certificate in a place where it is readily observable by members of the public who transact business with the facility.

Revised for clarity and to conform to the definitions of section 10 and the applicable delegations of authority.
<table>
<thead>
<tr>
<th>B. Application for a variance. Any owner of a marina or other place where boats are moored may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina or other place where boats are moored is located. This application shall include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A citation to the chapter from which a variance is requested;</td>
</tr>
<tr>
<td>2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; and</td>
</tr>
<tr>
<td>3. Facts supporting the need and justification for the variance.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Application for a variance. Any owner of a marina or other place where boats are moored may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina or other place where boats are moored is located. This application shall include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A citation to referencing the specific requirements of this chapter from which a variance is requested; and a statement describing the hardship(s) imposed by the specific requirements of this chapter;</td>
</tr>
<tr>
<td>2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; and</td>
</tr>
<tr>
<td>3. Facts supporting the need and justification for the variance;</td>
</tr>
<tr>
<td>4. The nature and duration of the variance request;</td>
</tr>
<tr>
<td>5. Other information, if any, believed by the applicant to be pertinent; and</td>
</tr>
<tr>
<td>6. Such other information as the Division, local health department or the Commissioner may require.</td>
</tr>
</tbody>
</table>

D. If the Commissioner denies any request for a variance, such denial shall be in writing and shall state the reasons for the denial.

Revised for clarity and to conform to the agency processes for variances in other programs.
### 100.

The board may revoke or suspend a certificate for failure to construct and operate the sewerage facilities in accordance with the conditions of the application and certificate issued or for any violation of this chapter.

*Either by emergency order under the authority of Code § 32.1-13 or following an opportunity for an informal fact-finding proceeding as provided by Code § 2.2-4019. The Board Commissioner or his designee may revoke or suspend a certificate for failure to construct and operate the sewerage facilities and sewerage facilities system in accordance with the conditions of the application and certificate issued or for any violation of this chapter.*

*Revised for clarity and to conform to applicable delegations of authority. The authority to suspend has been eliminated.*

### 110.

Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia.

*Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia. (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the decision of cases under this chapter.*

*Revised for clarity and to conform to the requirements of the Administrative Process Act.*

### Part II Article I

#### 120.

**Required Facilities for Marinas and Other Places Where Boats are Moored and Their Operation**

- **A. All marinas or other places where boats are moored shall provide the minimum number of sanitary facilities for their patrons. These facilities shall**

**Required Sewerage Facilities and Sewerage Systems for Marinas, and Other Place(s) Where Boats are Moored, and Boating Access Facilities and Their Operation**

- **Title revised for clarity.**

- **A. All owners of marinas or other place(s) where boats are moored, and boating access facilities shall provide the minimum number of**
be maintained in a clean and sanitary condition. They shall be equipped with toilet tissue, lights where electricity is available and soap and towels where handwashing facilities are required. These facilities shall be available to patrons and users of these facilities at all times during the normal boating season.

B. Marinas which are operated as part of residential developments, overnight lodging facilities, restaurants or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted from providing separate sanitary facilities, as long as the sanitary facilities at the residence, lodging establishment, restaurant or commercial establishment are available to all users of the marina. This exemption does not apply to

(i) marinas associated with restaurants or commercial establishments which allow overnight occupancy of boats and

(ii) marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.

C. Exempt from the requirements of subsection A of this section are other places where boats are moored which serve residents of homes (houses, condominiums, apartments or mobile homes), their bona fide house guests, or registered guests of tourist establishments which provide adequate sanitary facilities that are located within 1,000 feet of the shore end of the pier.

sanitary sewerage facilities required by this chapter for their patrons. These Owners shall maintain their facilities shall be maintained in a clean and sanitary operable condition. They Owners shall equip their facilities shall be equipped with toilet tissue, lights where electricity is available and soap and towels where handwashing facilities are required. These Owners shall make their facilities shall be available during normal business hours to patrons and users of these facilities at all times during the normal boating season for that facility.

B. Marinas which are located within 1,000 feet of the shore end of the pier that are operated as part of residential developments, overnight lodging facilities, restaurants or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted from providing separate sanitary sewerage facilities, as long as the sanitary sewerage facilities at the residence, lodging establishment, restaurant or commercial establishment are made available to all users of the marina. The exemption set forth in this subsection does not apply to:

(i) marinas associated with restaurants or commercial establishments which allow overnight occupancy of boats; and

(ii) marinas

2. Marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.

C. Exempt from the requirements of subsection A are other Other place(s) where boats are moored which and boating access facilities are exempt from the requirements of subsection A, provided that the other place(s) where boats are moored or boating access facility:
D. In order to qualify for an exemption under subsections B or C of this section, the owner of such marinas or other places where boats are moored shall provide to the department a signed, notarized statement that all conditions set forth in the aforementioned sections will be complied with by users of the facilities.

| 130. | Adequate sanitary facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they are intended to serve or within a reasonable distance under unusual circumstances as determined by the division. It may be necessary to provide sanitary facilities in more than one location in order to meet the needs of the particular site developed. |

Adequate owners shall conveniently locate their sewage sanitary facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they are intended to serve. On a case by case basis the division may approve a greater or within a reasonable distance if under unusual circumstances such as topography or resource protection areas prevent compliance with this requirement, as determined by the division. The division may be necessary require the owner to provide sewage sanitary facilities in more than one location in order to meet the needs of the particular site developed. In addition, the division may require additional fixtures, beyond the minimum number specified in Table 1, if it determines that additional fixtures are necessary to accommodate the site layout and use of the marina, other place(s) where boats are moored, or boating access facility.

Allows the division to approve sewage facilities at distances greater than 500' on a case by case basis;
allows the Division to require additional facilities on a case by case basis when necessary to accommodate the specific needs of a particular facility.

140. The sanitary facilities shall be so located that they are available and readily accessible to users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities.

Owners shall locate the sewerage sanitary facilities shall be so located so that they are available and readily reasonably accessible to all users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities. The location and use of all sewerage facilities shall be clearly indicated by appropriate signage.

Revised for clarity.

150. A. Minimum number of fixtures to be provided in sanitary facilities. It shall be understood that in many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the Board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined. Where dry storage space is provided, each dry storage space is equivalent to one-third of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate facilities for male and female personnel shall be provided in a structure or structures.

B. many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the Board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined. Where dry storage space is provided, each dry storage space is equivalent to one-third (1/3) of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate sewerage facilities for male and female personnel shall be provided in a structure or structures but shall not be counted toward the minimum number of fixtures required to accommodate users of the marina.

Revised for clarity.

<table>
<thead>
<tr>
<th>Number of Seasonal Slips</th>
<th>Fixtures</th>
<th>Commodes</th>
<th>Urinals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>0-49</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>50-99</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>100-149</td>
<td></td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Number of Seasonal Slips</td>
<td>Lavatories</td>
<td>Showers</td>
<td></td>
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<td>-------------------------</td>
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<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
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<tr>
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<tr>
<td>50-99</td>
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<td>1</td>
<td>0</td>
</tr>
<tr>
<td>100-149</td>
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<td>0</td>
</tr>
<tr>
<td>150-199</td>
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<td>3</td>
<td>0</td>
</tr>
<tr>
<td>200-249</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Slips</th>
<th>Fixtures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
</tr>
<tr>
<td>1-24</td>
<td>1</td>
</tr>
<tr>
<td>25-49</td>
<td>2</td>
</tr>
<tr>
<td>50-99</td>
<td>1</td>
</tr>
<tr>
<td>100-149</td>
<td>2</td>
</tr>
<tr>
<td>150-199</td>
<td>3</td>
</tr>
<tr>
<td>200-249</td>
<td>4</td>
</tr>
</tbody>
</table>

| Table #1 |
|-----------------|----------|
| Number of Slips | Fixtures |
|                 | Comodes | Urinals |
|                 | Male | Female | Male | Female | Male | Female |
| 0-49            | 1    | 1      | 0    | 0      | 0    | 0      |
| 50-99           | 1    | 2      | 1    | 1      | 1    | 1      |
| 100-149         | 2    | 2      | 1    | 1      | 1    | 1      |
| 150-199         | 3    | 4      | 2    | 2      | 2    | 2      |
| 200-249         | 3    | 5      | 2    | 2      | 2    | 2      |
When the number of seasonal slips exceeds those above on Table No. 1 additional fixtures shall be provided. One commode, lavatory and shower will be provided for each sex for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.

B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required. These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.

<table>
<thead>
<tr>
<th>Number of Transient Slips</th>
<th>Fixtures</th>
<th>Commerodes</th>
<th>Female</th>
<th>Urinals</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-24</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>25-49</td>
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<td>3</td>
<td>2</td>
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<td>75-100</td>
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<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
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</tbody>
</table>

C. When the number of seasonal slips exceeds those above on prescribed by Table No. 1, the owner shall provide additional fixtures shall be provided. The owner shall provide one commode, lavatory and shower will be provided for each sex for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.
For each 24 or fraction thereof of transient slips or moorings in excess of those shown in Table No. 2 above, one commode, lavatory and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. #2.

Eliminates “seasonal” and “transient” slips as the basis for determining sewerage fixture needs. Combining the sewerage fixture requirements into one table will lessen the restrictions placed on facility owners allowing them to attract different types of boaters as well as making it easier for the Department to estimate sewage flow. The proposed number of fixtures will provide for the protection of public health and the environment.

160. Where piped water is available, sanitary facilities shall consist of a minimum of one commode and one lavatory for females and one commode and one lavatory for males for each 100 seasonal slips or fraction thereof and each 50 transient slips or fraction thereof. Requirements for dry storage boat usage shall be identical to those specified in 12VAC5-570-150 for marinas. Sanitary facilities may consist of privies where piped water is not available. Walking distance to these facilities shall comply with 12VAC5-570-130.

A. Sewerage facilities are required at other place(s) where boats are moored and boating access facilities in accordance with this section.

B. Where piped potable water is available, sewerage sanitary facilities for other place(s) where boats are moored shall consist of a minimum of one commode, and one lavatory, and one shower for females and one commode and one lavatory for males for each gender, for each 100 seasonal slips, or fraction thereof and each 50 transient slips or fraction thereof.
C. Requirements for dry storage boat usage shall be identical to those specified in 12VAC5-570-150 for marinas.

D. Where piped potable water is not available, sanitary sewerage facilities for other place(s) where boats are moored may consist of privies, where piped water is not available.

E. Sewerage facilities at boating access facilities shall consist of at least one privy or portable toilet and shall be sufficient in number to accommodate facility usage.

F. Walking distance to these facilities shall comply with 12VAC5-570-130.

This section was revised for clarity. New sewerage facility requirements added for boat ramps with more than 50 parking spaces for boat trailers. Requiring the availability of sewerage facilities at these types of boating facilities will ensure the protection of public health and the environment.

170. Public or municipal sewage treatment facilities shall be used if there is reasonable access to sewers. When such municipal means of disposal is not available, the owner shall have designed and installed an approved method of sewage treatment. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5-580-10 et seq.) Sewage Handling and Disposal Regulations (1982, as amended), 12VAC5-610-10 et seq. If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division.

A. Public or municipal sewerage systems and sewage treatment works facilities shall be used if there is reasonable access to sewers. When such municipal means of disposal is not available, the owner shall have designed and installed an approved sewerage system or treatment works method of sewage treatment. An approved sewerage system or treatment works is (1) a system for which a certificate to operate has been issued jointly by the Department and the Department of Environmental Quality, (2) a system approved by the Department of Environmental Quality in accordance with Title 62.1 of the Code of Virginia, or (3) a system approved by the Commissioner in accordance with Title 32.1 of the Code of Virginia. Approved methods of sewage treatment are set forth in the...
A. The following shall be used to determine the amount of sewage flow. It is assumed that each slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 10 gallons per person per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. In addition, for marinas or other places where boats are moored which have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.

B. The following shall be used to determine the amount of sewage flow. It is assumed that each seasonal or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 10 gallons per person per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. Where dry storage is provided, each dry storage space shall be equivalent to one-third (1/3) of a slip. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. The sewage design flow for each live-aboard slip shall be 50 gallons per slip per day. When a marina or other place(s) where boats are moored is constructed in conjunction with another structure or facility, the sewage design flows prescribed in this section shall be added to the sewage design flow governing the associated structure or facility.

C. In addition, for marinas or other place(s) where boats are moored which have that has a boat launching ramp and provide boat trailer parking spaces only while the boat is in use, boating access facility, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.

Revised for clarity and to conform to § 32.1-164 of the Code of Virginia.

Sewerage Regulations (1977) (12VAC5-580-10 et seq.) or the Sewage Handling and Disposal Regulations (1982, as amended). If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division.
<table>
<thead>
<tr>
<th>B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motels - 65 gallons per person per day or a minimum of 130 gallons per room per day.</td>
</tr>
<tr>
<td>Restaurant - 50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.</td>
</tr>
<tr>
<td>C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5-570-170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is located shall make such determination.</td>
</tr>
</tbody>
</table>

The revisions simplify the method for estimating sewage flows by basing flows on “slips” rather than the existing method which relies on “seasonal,” “transient” and other slip designations. The revisions also establish a new requirement for “live-aboard” slips that are used as residences. The proposed sewage design flows provide a more accurate representation of the volume of sewerage waste generated at the boating facility. The sewage design flows also factor in the use of showers and laundry facilities.
provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other places where boats are moored which do not allow boats with an installed toilet with a discharge overboard or a sewage holding tank to use any of the services provided, including moorage, except in an emergency. In order to qualify for this exemption, the owner of such marina or other place(s) where boats are moored shall provide the department with a signed notarized statement that boats with installed toilets with overboard discharges or sewage holding tanks shall not be permitted to use the marina or other places facilities.

A. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service.

boats and owners of all marinas, regardless of size or number of boat mooring slips, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other place(s) where boats are moored which do not have live-aboard slips or allow boats with a marine sanitation device installed toilet with a discharge overboard or a sewage holding tank to use any of the services provided, including moorage, except in an emergency. In order to qualify for this exemption, the owner of such marina or other place(s) where boats are moored shall provide the Department with a signed notarized statement indicating that there are no live-aboard slips and that boats with marine sanitation devices installed toilets with overboard discharges or sewage holding tanks shall not be permitted to use the marina or other places facilities except in an emergency.

A. B. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service. The owner shall make sewage pump-out facilities available to all users of the marina or other place(s) where boats are moored during normal operating hours. The owner shall maintain the
B. Alternate pump-out service. Marinas and other places where boats are moored which provide less than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted from the requirement to install pump-out facilities. Such exemption will be granted by the director of the division whenever alternate pump-out service is provided at a nearby marina or other place where boats are moored, and is evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the division. Such alternate pump-out service will only be approved by the division when the following criteria are met:

1. That the alternate pump-out service will not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the boat sewage holding tank pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed twenty minutes;

2. That the alternate pump-out service shall be located within three miles, as measured along the water route, of the facility using the agreement unless the alternate pump-out equipment in serviceable condition and shall keep the equipment located in an area convenient for utilization.

C. The owner shall use placards or signs to identify the sewage pump-out location and use restrictions.

B. Alternate pump-out service. Marinas and other places where boats are moored which provide less than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted from the requirement to install pump-out facilities, unless such marinas and other place(s) where boats are moored is located in a No Discharge Zone. Such exemption shall be granted by the Director of the Division whenever alternate pump-out service is provided at a nearby marina or other place(s) where boats are moored, and is evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the Division. The Division shall only approve such alternate pump-out service when in accordance with the following criteria are met:

1. That the alternate pump-out service will not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the boat sewage holding tank, marine sanitation device pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed twenty minutes;

2. That the alternate pump-out service shall be located within three nautical miles, as measured along the water
pump-out service is located along the normal travel route to open water, in which case the facility using the agreement shall be within five miles of the alternate pump-out service;

3. That the alternate pump-out service capacity is sufficient to handle the demand for pump-out service, in accordance with subsection C of this section, that is expected for all of the marinas or other places where boats are moored entering into the above-mentioned agreement;

4. That a notice shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service; and

5. The terms of the agreement provide:
   a. That the alternate pump-out service will be available to all boats moored at each facility and it will state that the alternate pump-out facility will furnish pump-out services to anybody referred to it by the establishment using the agreement to provide pump-out service, as specified by this chapter; and

   b. That the agreement will be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day notice.

\[\text{route, of the exempt facility using the agreement unless the alternate pump-out service is located along the normal travel route to open water, in which case the exempt facility using the agreement shall be within five 5 nautical miles of the alternate pump-out service;}

3. That the alternate pump-out service capacity shall be sufficient to handle the demand for pump-out service, in accordance with subsection C of this section, that is expected for all of the marinas or other place(s) where boats are moored entering into the above-mentioned agreement;

4. That a notice The owner of the exempt facility shall post in a conspicuous location appropriate signage that specifies the location of the alternate pump-out service and the associated charge for its use; shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service; and

5. The terms of the agreement shall provide that:
   a. That the alternate pump-out service will be available to all boats moored at each facility and it will state that the alternate pump-out facility will furnish pump-out services to anybody referred to it by the exempt facility establishment using the agreement to provide pump-out service, as specified by this chapter; and

   b. That the agreement will be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day notice.
termination notice to the other and to the director of the division prior to the renewal date.

6. If a termination notice is issued to a facility using an agreement to provide alternate pump-out service, in accordance with 12VAC5-570-180 B, then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with 12VAC5-570-180 B, by the effective date of the termination of alternate pump-out service.

C. Minimum design criteria for pump-out facilities. The purpose of these minimum design criteria is to provide the owner and the Department of Health with acceptable methods for pumping, storing, conveying and treatment of the contents from boat holding tanks. The owner shall furnish the following information for each proposed pump-out facility:

1. Pumping equipment. Pump equipment may be fixed or portable; however, this equipment shall be conveniently located for usage and clearly identified or placarded by signs or other notices, indicating any fees, restrictions or other operating instructions, as necessary. A minimum pump capacity of 10 gallons per minute (gpm) is acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. Pumps shall be of a macerator type or have sufficient size suction and discharge openings to prevent clogging. Manually operated pumps are not permitted. Pump date, unless either party gives at least a 60-day termination notice to the other and to the Director of the Division prior to the renewal date.

6. If a termination notice is issued to an exempt facility using an agreement to provide alternate pump-out service, in accordance with 12VAC5-570-180 B this subsection, then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with 12VAC5-570-180 B this subsection, by the effective date of the termination of alternate pump-out service.

C. E. Minimum design criteria for pump-out facilities. The purpose of these minimum design criteria is to provide the owner and the Department of Health with acceptable methods for pumping, storing, conveying and treatment of the contents from boat holding tanks, marine sanitation devices. The owner shall furnish the following information for each proposed pump-out facility:

1. Pumping equipment. Pump equipment may be fixed or portable; however, this equipment shall be conveniently located for usage and clearly identified or placarded by signs or other notices, indicating any fees, restrictions or other operating instructions, as necessary. A minimum pump capacity of 10 gallons per minute (gpm) is acceptable at the operating head required to transport the flow to the proper collection or treatment location with such residual head as may be required; however, at marinas with 51 or more slips, greater pump-out service.
data from the manufacturer shall include:

- a. The type of pump (diaphragm or centrifugal, and power);
- b. Rated capacity (gpm, hp. and head);
- c. Motor type (electric or gas); and
- d. Suction and discharge opening size.

Pumping capacity may be required. To prevent clogging, pumps shall be of a macerator type or the pumps shall be able to pass a 2-inch spherical solid, have sufficient size suction and discharge openings to prevent clogging. Manually operated pumps are not permitted acceptable at marinas and other place(s) where boats are moored that offer fewer than 26 slips. Pump data from the manufacturer shall include:

- a. The type of pump (diaphragm, positive displacement, or centrifugal, vacuum, macerator, etc. and power);
- b. Rated capacity (gpm, hp., and head); Pump power source (electric motor, gasoline engine, etc.) and output (HP);
- c. Motor type (electric or gas); and Pump capacity, including a performance curve; and
- d. Suction and discharge opening size. Pump solids-handling ability; and
- e. A schematic showing relevant pump dimensions, such as height, size and location of suction and discharge openings, etc.

2. Location schematic. If fixed pump-out equipment is proposed, a schematic of the location with elevations for subsections a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below:

A schematic of the proposed facilities shall be provided and include the following.
minimum information:

a. Mean low water level;
b. Suction hose diameter, length, and highest elevation;
c. Pump elevation; Greatest elevation of suction center line of pump;
d. Discharge hose/pipe diameter(s), length(s), and highest elevation; Elevation of discharge point;
e. Discharge point elevation; Highest point in discharge line;
f. Type of dock (floating or stationary); and
g. Greatest elevation of any dock; and

h. Distance between pump-out location and slips.

All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.

3. Fittings and hoses (piping) – fittings and hoses (piping) which are used in operation of a pump-out facility shall meet the following:

a. Suction hose.
   (1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from 1.5 to 4 inches in diameter.

(2) A check valve shall be
<p>| | | |</p>
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</table>
| provided on the suction hose at the nozzle. | in diameter. (2) A check valve shall be provided on the suction hose at the nozzle. (3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis by the Division. (4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a gate valve shall be provided on the pump end of the suction line. | b. Discharge hose and piping.  
(1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections. (2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing. |
| (3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis. |   |   |
| (4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a gate valve shall be provided on the pump end of the suction line. |   |   |
|   | b. Discharge hose and piping.  
(1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections. (2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing. |   |
| (1) A gate valve shall be provided on the discharge line at the pump;  
(2) Suitable connections on the end of the discharge line shall be provided to prevent it from coming loose during discharge; all nozzles and fittings are to be positive locking, male and female. |   |   |
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<tbody>
<tr>
<td>(3) The discharge line must not be subject to freezing or leaking into the water course.</td>
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</tr>
<tr>
<td>(4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (12VAC5-590-10 et seq.) and the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).</td>
<td>(4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (12VAC5-590-10 et seq.) and the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).</td>
</tr>
<tr>
<td>(5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from coming loose during discharge.</td>
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</tr>
<tr>
<td><strong>d. Rinse equipment.</strong> Pump-out facilities shall include equipment for rinsing the boats' holding tanks. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.</td>
<td><strong>d. Rinse equipment.</strong> Pump-out facilities shall include equipment for rinsing the boats' holding tanks. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.</td>
</tr>
<tr>
<td><strong>4. Other devices or methods of removal.</strong> Other devices or methods of removal of contents from boat holding tanks may be approved by the Commissioner on an individual case basis.</td>
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</tr>
</tbody>
</table>
5. Onshore facilities. Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.

a. For discharge to a public wastewater collection system, the following will be required:
   The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.

b. If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria.

   (1) Size of holding tank.
   Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:

<table>
<thead>
<tr>
<th>Total</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(2) Construction of holding tank.
(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.
(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.
(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.
(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.
(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump-out unit.

<table>
<thead>
<tr>
<th>Number of Boats Serviced</th>
<th>Onshore Holding Tank Volume (gallons) Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-20</td>
<td>250</td>
</tr>
<tr>
<td>21-40</td>
<td>500</td>
</tr>
<tr>
<td>41-60</td>
<td>725</td>
</tr>
<tr>
<td>61-80</td>
<td>1000</td>
</tr>
<tr>
<td>81-100</td>
<td>1200</td>
</tr>
<tr>
<td>100+</td>
<td>2000</td>
</tr>
</tbody>
</table>

(2) Construction of holding tank.
(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.
(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.
(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.
(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.
(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.

(g) The holding tank shall be adequately vented. Screened, elbowed down vents installed at the top of the tank will serve this requirement.

(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.

(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.

(3) Holding tank location. Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).

(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).

c. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or

(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump-out unit.

(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.

(g) The holding tank shall be adequately vented. Screened, elbowed down vents installed at the top of the tank will serve this requirement.

(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.

(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.

(3) Holding tank location. Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).

(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).
| 190. | A. All marinas and other places where boats are moored, regardless of size or number of boat moorings, shall have an acceptable receiving station for sewage from portable toilets used on boats. The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision are marinas or other places where boats are moored, which also qualify for the 12VAC5-570-120 B or C exemption, provided the owner of the sanitary facility will | A. All marinas and other place(s) where boats are moored, regardless of size or number of boat moorings, shall have an acceptable proper and adequate receiving station for sewage from portable toilets containers used on boats. The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision subsection are marinas or other place(s) where boats are |

This section was edited for clarity. Adds marinas and other place(s) where boats are moored that do not allow live-aboard slips and claim an exemption from the requirement to provide pump-out facilities. Adds requirement that pump-out facilities be conveniently located in order to accommodate users of the facility. Adds a number of technical requirements for pumps (must pass 2-inch spherical solid), plans and specifications, etc. to more accurately reflect current technology and industry standards. Changes are intended to simplify the need for additional information while educating the facility owner as to where the pump-out equipment should be located. These changes will also assist the health department in evaluating the system so as to assure the safe and sanitary conveyance and disposal of sewage.
allow the dumping of the contents of portable toilets into the sanitary facilities.

B. Availability and operation. Where a sewage dump station is required, the owner shall install, maintain in good operating condition and provide the facilities to users of the marina or other places where boats are moored.

C. Minimum design criteria for a sewage dump station. The purpose of these minimum design criteria is to provide the owner and the Department of Health with acceptable methods of discharging sewage from a portable container into a sewage holding tank or a sewage treatment system. The same criteria as set forth in 12VAC5-570-180 C 5 for contents from boat holding tanks will apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12 inches in diameter and be equipped with a cover that has a lip of sufficient size to prevent it from accidentally being removed. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.

D. Exempt from the requirements of subsection C are marinas and other place(s) where boats are moored which also qualify for the exemption contained in 12VAC5-570-120 B or C exemption, provided that the owner of the sewerage sanitary facility will allow consents to the dumping of the contents of portable toilets sewage containers into the sewerage sanitary facilities.

B. Availability and operation. Where a sewage dump station is required, the owner shall install, and maintain in good operating condition, it in a serviceable and sanitary condition and in compliance with the regulations, and The owner shall make provide the facilities available to users of the marina or other place(s) where boats are moored. The owner shall locate the sewage dump station in an area convenient for use and the owner shall use placards or signs to identify its location and restrictions.
Revised for clarity. Provides owners with facilities that have proper sanitary waste pump-out services an alternative to installing a sanitary waste dump station. The wand attachment is now commonly used at boating facilities with sanitary waste pump-out systems because it is easy to use and limits the boater’s opportunity to spill sanitary waste into the water thereby protecting the environment. Requirement for convenient location added to accommodate facility users and the public.

| (None) | 200. Onshore facilities | (None) | A. Contents from marine sanitation devices and portable sewage containers used on boats shall be discharged to:

1. a public sewerage system for conveyance to an approved treatment works as described in 12VAC-570-170 A.;

2. a holding tank whereby sewage may be stored until it is transported in accordance with the Sewage Handling and Disposal Regulations to an approved treatment works as described in 12VAC-570-170 A. or

3. to an approved sewage treatment works as described in 12 VAC-570-170 A.

B. Disposal of sewage waste from a marine sanitation device shall be prohibited at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewerage system of a large sewage treatment facility or transported for eventual treatment at a large sewage treatment facility.

C. For discharge to a public sewerage system the owner of the marina or other place(s) where boats
are moored shall submit to the Division, in writing:

1. written evidence of consent to the discharge from the owner of the conveyance system;

2. written evidence of consent to discharge from the owner of any conveyance systems located downstream which may be affected.

3. written evidence of consent to discharge from the owner of the treatment works where the sewage is to be disposed of;

4. and the owner shall verify that there are satisfactory provisions for emptying the contents from portable sewage containers in a sanitary manner.

D. If sewage is to be stored by the marina or other place(s) where boats are moored in a holding tank, the holding tank or tanks shall be sized, constructed and located to meet the following criteria:

1. Sewage holding tanks shall be sized in accordance with the requirements of Table 2.

<table>
<thead>
<tr>
<th>Total Number of Boats Serviced Annually with Marine Sanitation Devices</th>
<th>Minimum Holding Tank Volume (gallons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 60</td>
<td>725</td>
</tr>
<tr>
<td>61 - 80</td>
<td>1000</td>
</tr>
<tr>
<td>81 - 100</td>
<td>1200</td>
</tr>
<tr>
<td>100+</td>
<td>2000</td>
</tr>
</tbody>
</table>

2. Holding tanks shall be constructed in accordance with the following
criteria:

a. The holding tank shall be watertight and not subject to any infiltration or leakage;

b. When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.

c. When holding tanks are made of material other than concrete, the outside external surface of the holding tank shall be protected from corrosion.

d. The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.

e. The holding tank shall be located onshore and fixed in place unless it is part of an approved mobile pump-out unit.

f. Provisions shall be made to the satisfaction of the Department to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.

g. The holding tank shall be adequately vented. This requirement may be met with screened, elbows down vents.
4. Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner in accordance with the Sewage Handling and Disposal Regulations, (12VAC5-610-20 et seq.).

Clarifies the requirement that all sewage must be properly disposed of, either to an approved treatment works, or by conveyance to an approved treatment works.

Construction criteria for holding tanks intended to protect public health and the environment from sewage leakage is included.

Technical changes are intended to make the regulation more consistent with other regulations and to better reflect the state of the wastewater and marina industries. Setback requirements and pump and haul requirements are derived from the Board’s Sewage Handling and Disposal Regulations which regulate the safe and sanitary treatment, conveyance and disposal of sewage.
For new chapters, use this chart:

<table>
<thead>
<tr>
<th>Section number</th>
<th>Proposed requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of proposed requirements</th>
</tr>
</thead>
</table>

Enter any other statement here
12VAC5-570-10. Definitions.

As used in these regulations, the words and terms hereinafter set forth when used in this chapter shall have the following meanings, respectively, unless the context clearly requires a different meaning, indicates otherwise:

"Board" means the State Board of Health.

"Boat" means any vessel or other watercraft, privately owned or owned by the Commonwealth or any political subdivision thereof, whether moved by oars, paddles, sails, or other power mechanism, inboard or outboard, or any other vessel or structure floating on water in the Commonwealth of Virginia, whether or not capable of self-locomotion, including but not limited to cruisers, cabin cruisers, runabouts, houseboats and barges. Excluded from this definition are commercial, passenger and cargo carrying vessels subject to the Quarantine Regulation of the United States Public Health Service adopted pursuant to Title 42 of the United States Code and ships or vessels of the U.S. Government and boats which are tenders to larger boats moored or stored at the same facility.

"Boating access facility" means any installation operating under public or private ownership that provides a boat launching ramp and has 50 or more parking spaces for boat trailers.

"Certificate" means a written approval from the Commissioner or his designated representative indicating that plans for sanitary facilities and sewage sewerage facilities, sewerage system and treatment works meet or satisfy the minimum requirements of this chapter and § 32.1-246 of the Code of Virginia.

"Commissioner" means the State Health Commissioner, whose duties are prescribed in § 32.1-19 of the Code of Virginia.

"Department" means State Health Department.

"Division" means the Division of Wastewater Engineering, Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs, Office of Environmental Health Services, Department of State Health Department or its administrative successor.

"Dry storage" means a boat storage, including boatels, valet storage, pigeon hole storage, stackominiums or parking space, where boats rest on racks or trailers located on land, whether covered or uncovered, at a marina or other place(s) where boats are moored, for the purpose of storing boats on land between use.

"Expanded" means any change to a regulated facility that results in an increase in sewage volume or strength due to the addition of slips, dry storage spaces, boat trailer parking spaces or ancillary operations.

"Live-aboard slip" means any slip where a boat is moored and used principally as a residence or a place of business. Charter and commercial fishing boats are not included unless used as a residence.
"Local health department" means the branch of the State Health Department, established in accordance with §32.1-30 of the Code of Virginia, that has jurisdiction in the city or county where the regulated facility is located.

"Marina" means any installation operating, under public or private ownership, which provides dockage or moorage for boats, other than (exclusive of paddle or rowboats) and provides, through sale, rental, or fee, or free basis, any equipment, supply, or service, including (fuel, electricity, or water) for the convenience of the public or its the lessee lessee, renters, or users of the facilities.

"Marine sanitation device" means any equipment, piping, holding tanks, and appurtenances such as holding tanks for installation onboard a boat which is designed to receive, retain, treat, or discharge sewage, and any process to treat such sewage.

"No Discharge Zone" means an area where a state has received an affirmative determination from the U.S. Environmental Protection Agency that there are adequate facilities for the removal of sewage from vessels (holding tank pump-out facilities) in accordance with §312(f)(3) of the Clean Water Act (33 U.S.C. 1251 et seq.), and where federal approval has been received allowing a complete prohibition of all treated or untreated discharges of sewage from all vessels.

"Office" means the Office of Environmental Health Services.

"Other place(s) where boats are moored" means any installation operating under public or private ownership, which provides dockage, or moorage or mooring for boats, other than (exclusive of paddle or rowboats) either on a free, rental or fee basis or for the convenience of the public boater.

"Owner" means the Commonwealth or any of its political subdivisions and any public or private institution, corporation, association, firm or company organized or existing under the laws of this or any other state or county, or any person or group of persons acting individually or as a group who owns or proposes to own a marina, other place(s) where boats are moored or boating access facility.

"Pump-out facilities facility" means any device, equipment or method of for removing sewage from a marine sanitation device, and conveying such sewage to a sewerage system or treatment works. Also, it shall include including any portable, movable, or permanent holding tanks, either portable, movable or permanently installed, and any sewage treatment method or disposable equipment used to treat, or ultimately dispose of, sewage removed from boats.

"Sanitary Sewerage facilities facility" means bathrooms, toilets, closets and other enclosures, including portable toilets, where commodes, stools, water closets, lavatories, showers, urinals, sinks, or other such plumbing fixtures are installed.

"Seasonal slips" means any slip which is used, rented, leased, or otherwise made available for mooring or docking of boats during the normal boating season, usually from April through September, or for any period greater than 30 days.

"Sewage" means the spent water or wastewater containing human excrement coming from toilets, bathrooms, commodes and holding tanks, water-carried and non-water-carried human excrement, kitchen, laundry, shower, bath or lavatory wastes, separately or together with such underground, surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, boats, industrial establishments or other places.

"Sewage dump station" means a facility specifically designed to receive waste from portable sewage containers carried on boats and conveys such sewage to a sewerage system or a treatment works.

"Sewage treatment or disposal systems" means device, process or plant designed to treat sewage and remove solids and other objectionable constituents which will permit the discharge
to another approved system, or an approved discharge to state waters or disposal through an approved subsurface drainfield or other acceptable method, such as incineration.

"Sewerage facilities system" means entire sewage collection and disposal system including commodes, toilets, lavatories, showers, sinks and all other plumbing fixtures which are connected to a collection system consisting of sewer pipe, conduit, holding tanks, pumps and all appurtenances, including the sewage treatment or disposal system, pipelines or conduits, pump stations and force mains and all other construction, devices and appliances used for the collection and conveyance of sewage to a treatment works or point of ultimate disposal.

“Slip” means a berth or space where a boat may be secured to a fixed or floating structure, including a dock, finger pier, boat lift, or mooring buoy.

"Transient slips" means temporary docking or mooring space which may be used for short periods of time, including lodging overnight, days, or weeks, but less than 30 days.

"Treatment works" means any device or system used in the storage, treatment, disposal or reclamation of sewage or combinations of sewage and industrial wastes, including but not limited to pumping, power and other equipment and appurtenances, septic tanks, and any works, including land, that are or will be (i) an integral part of the treatment process or (ii) used for ultimate disposal of residues or effluents resulting from such treatment.

"VMRC" means the Virginia Marine Resources Commission.

Article 2
General Information

12VAC5-570-20. Authority, for regulations.

Sections 32.1-12 and 32.1-246 of the Code of Virginia provides that the State Board of Health is empowered and directed to promulgate all necessary rules and regulations establishing minimum requirements for adequate sewerage facilities at marinas and other place(s) where boats are moored according to the number of slips and persons such marinas and other place(s) where boats are moored are designed to accommodate, as to adequacy of sewerage facilities at marinas and other places where boats are moored. These facilities should be sufficient to serve the number of boat slips or persons such marinas and places are designed to accommodate, regardless of whether such establishments serve food. Section 32.1-164 provides that the Board’s regulations may require a sewerage system or treatment works for such residences, buildings, structures and other places designed for human occupancy as the Board may prescribe.

12VAC5-570-30. Purpose of regulations.

This chapter has been promulgated by the State Board of Health to:

1. A. Protect public health and water quality by ensuring that adequate sanitary sewerage facilities, and pump-out facilities, sewage dump stations, and sewerage systems as defined in 12VAC5-570-10 and required by 12VAC5-570-130 of this chapter, are provided at all marinas and other place(s) where boats are moored, and boating access facilities.

2. B. Establish minimum requirements as to the adequacy of sewerage facilities and sewerage systems at all marinas and other place(s) where boats are moored, and boating access facilities.

C. Protect public health and the environment by ensuring that all sewage generated from all regulated facilities is conveyed to an approved sewerage system or treatment works.

D. Guide the State Board Commissioner or his designee of Health in its determination of the adequacy of the sewerage systems and sewerage facilities to serve
serving all marinas, and other place(s) where boats are moored, and boating access facilities.

E. Guide the State Board Commissioner or his designee of Health in its his approval evaluation of plans and other data and in the issuance of a certificate as to the adequacy of sanitary and sewerage facilities and sewerage systems; .

5F. Notify the Marine Resources Commission that a certificate has been issued; and

6G. Assist the owner or his authorized engineer in the preparation of an application and supporting data, as may be required. (See 12VAC5-570-70).

12VAC5-570-40. Administration of regulations.

These regulations are administered by the following parties:

1. The State Board of Health has responsibility for promulgating, amending, and repealing regulations which ensure minimum requirements as to adequacy of sewerage facilities at marinas and other places where boats are moored.

2. A. The State Health Commissioner is the chief executive officer of the State Department of Health. The Commissioner has the authority to act for the Board when it is not in session. The Commissioner may delegate his powers under this chapter with the exception of his power to issue variances under 12VAC5-570-90.

3. B. The Division of Wastewater Engineering Division is designated as the primary reviewing agent of the board Commissioner for the purpose of administering these regulations this chapter. Upon receipt of the application from the local health department, the Division examines and passes upon grants or denies the application the technical aspects of all applications, plans and specifications for sewerage facilities to serve marinas, and other place(s) where boats are moored, and boating access facilities. The Division issues all certificates attesting to the adequacy of the sewerage facilities and notifies the Marine Resources Commission when a certificate is issued or denied.

4. The Deputy Commissioner for Community Health Services directs and supervises the activities of the local health departments in the administration of assigned duties and responsibilities under the chapter.

5. C. The local health department in each jurisdiction, city, town or county in which there exists, or is proposed, a marina or other place where boats are moored shall (i) be responsible for the processing of all applications submitted by owners, (ii) and inspecting sites and facilities provided, for compliance with this chapter, (iii) issue such permits as required by law, rules or regulations for sewerage facilities and, (iv) lacking in authority to issue a permit, will process such applications in accordance with the policies and procedures of the department. The local health department shall conduct a surveillance program and enforce the provisions of this chapter to ensure proper sanitation and cleanliness of the facilities provided.

6. The Office of Water Programs of the Department of Health of the Commonwealth of Virginia is responsible for the review and approval of sewage treatment works where there is a discharge to state waters, in accordance with the chapter, policies and procedures of the Health Department and the State Water Control Law, §§ 62.1-44.2 through 62.1-44.34 of the Code of Virginia.

12VAC5-570-50. Applicability. Application of regulations to marinas and other places where boats are moored.

A. Marinas or other places where boats are moored which are not in compliance with the Rules and Regulations of the Board of Health Governing Sanitary and Sewerage Facilities at Marinas and Other Places Where Boats Are Moored which became effective November 15,
1975 [repealed], shall comply with this chapter. Marinas, other place(s) where boats are moored, and boating access facilities in operation prior to the effective date of this chapter shall be subject to the regulations in effect at the time the marina, other place(s) where boats are moored or boating access facility was permitted unless such marina, other place(s) where boats are moored or boating access facility is expanded after the effective date of this chapter.

B. This chapter shall apply to all marinas, other place(s) where boats are moored, and boating access facilities planned or new marinas or other places where boats are moored which do not exist placed into operation on or after the effective date of this regulation. shall comply with all provisions of this chapter prior to commencing operation.

C. All sanitary or sewerage facilities and sewerage systems shall conform to the requirements of this chapter when the marina, other place(s) where boats are moored or boating access facility that is served by the sewerage facilities and sewerage systems is expanded, altered or modified.

D. This chapter shall apply to sewerage facilities and sewerage systems serving marinas, other place(s) where boats are moored or boating access facilities and located on property owned by the marina, other place(s) where boats are moored or boating access facility owner. Sewerage systems or treatment works installed or proposed to be installed on property owned by someone other than the marina, other place(s) where boats are moored or boating access facility owner are regulated by Chapter 6 of Title 32.1 of the Code of Virginia or Title 62.1 of the Code of Virginia, as applicable.

### Article 3

#### Procedure

**12VAC5-570-60. Certification general. Permits and Certificate.**

No owner shall construct or operate a marina, or other place(s) where boats are moored or a boating access facility unless he has obtained a construction permit in accordance with the provisions of §§ 32.1-12 and 32.1-246 of the Code of Virginia and this chapter. No owner shall operate a marina, other place(s) where boats are moored or boating access facility until the local health department has inspected and approved construction and has issued a certificate to operate. Owners shall have in their possession a permit from the Marine Resources Commission VMRC to operate a marina, or other place(s) where boats are moored or boating access facility when so required by § 62.1-3, of the Code of Virginia. Where state-owned bottom lands are involved, the owner shall submit a plan preliminary design and receive approved approval by the Department shall be issued Division prior to construction and the issuance of a certificate to operate.

**12VAC5-570-70. Application for certificate, construction permit.**

Any owner, or his duly authorized representative, may apply for a construction permit certificate of approval of sanitary or sewerage facilities by applying submitting an application to the local health department in the jurisdiction where the proposed marina, or other place(s) where boats are moored, or boating access facility is to be located. The application shall be made on a form approved by the Division supplied by the local health department. The application shall consist of the following:

1. A. completed application form which shall set forth the essential data to determine the sewerage facilities and sewerage system necessary to serve the proposed installation;

2. B. Maps, plans and specifications of the sanitary sewerage facilities and sewerage facilities system describing how and what type of facilities that will be provided, and how the facilities will provide for the safe and sanitary disposal of all sewage generated at the facility. The preliminary design plans shall establish with the location of the
sanitary sewerage facilities and sewerage system in relation to other facilities they are intended to serve;

3. C. A description of the proposed or existing offsite sewerage system or treatment works used for the ultimate method of sewage treatment and disposal; of sewage. The applicant shall apply for and obtain approval of new the offsite sewerage systems or treatment works or disposal system and demonstrate that the existing sewerage systems or treatment works are approved and in accordance with this chapter, must be applied for and obtained under other sections of the Code of Virginia and other regulations; and

4. D. Any other data as may be pertinent to show the adequacy of the sanitary or sewerage facilities and sewerage system to be provided.

E. An application pursuant to this section shall contain sufficient detail and clarity necessary to demonstrate that the sewerage facility and sewerage system meet all the applicable requirements of this chapter.

12VAC5-570-80. Receipt of data application.

A. Upon receipt of the data set forth in 12VAC5-570-70 in sufficient detail and clarity so as to show that the sewerage facilities meet requirements of this chapter, a plan approval or disapproval will be issued by the Department of Health.

A. Construction. Upon completion of construction of the sanitary sewerage facilities and sewerage system facilities at marinas, and other place(s) where boats are moored, or boating access facility, the owner of the facility, or his duly authorized representative, shall notify the local health department so that it may inspect the construction. A certificate to operate shall be issued by the Health Department when it has been determined that construction is in compliance with the approved plan.

B. Operation. All marinas and other places where boats are moored shall hold a valid certificate to operate in the Commonwealth of Virginia.

B. The owner shall post the certificate in a place where it is readily observable by members of the public who transact business with the facility.

12VAC5-570-90. Variances.

A. The commissioner may grant a variance to any requirement of this chapter if, after investigation, it is determined that the hardship imposed upon the owner or the public by compliance with this chapter outweighs the benefits that the chapter confers, and that granting a variance will not result in a potential or actual public health hazard.

B. Effect of variance. A variance is a conditional waiver of a specific regulation which is granted to an owner of a marina, other place(s) where boats are moored or boating access facility, particular or designated marina or other place where boats are moored. Variances are nontransferable between owners and any variance it shall be attached to the certificate of the marina, or other place(s) where boats are moored, or boating access facility to which it was granted. The variance is a condition of the certificate which is revoked if the certificate is revoked.

B. Application for a variance. Any owner of a marina, or other place(s) where boats are moored, or boating access facility may apply in writing for a variance. This application shall be submitted to the local health department in the jurisdiction in which the marina, or other place(s) where boats are moored, or boating access facility is located. This application shall include:
1. A citation to referencing the specific requirements of this chapter from which a variance is requested; and a statement describing the hardship(s) imposed by the specific requirements of this chapter;

2. A statement of reasons why the public health and environment would not be detrimentally affected if a variance is granted, and a list of suggested measures that would be implemented to prevent any potential detrimental impacts; and

3. Facts supporting the need and justification for the variance;

4. The nature and duration of the variance request;

5. Other information, if any, believed by the applicant to be pertinent; and

6. Such other information as the Division, local health department or the Commissioner may require.

D. If the Commissioner denies any request for a variance, such denial shall be in writing and shall state the reasons for the denial.

12VAC5-570-100. Suspension or Revocation of a certificate.

Either by emergency order under the authority of Code § 32.1-13 or following an opportunity for an informal fact-finding proceeding as provided by Code § 2.2-4019, the Board Commissioner or his designee may revoke or suspend a certificate for failure to construct and operate the sewerage facilities and sewerage systems in accordance with the conditions of the application and certificate issued or for any violation of this chapter.


Any applicant or certificate holder who is aggrieved by an adverse decision of the commissioner may appeal in writing within 30 days after the notification of the adverse decision and request a fair hearing. Within 30 days of receipt of notification of appeal, the commissioner shall set a date and place for such hearing. Not later than 30 days following the hearing, the commissioner shall issue a final order with respect to the disposition of the appeal. Such hearing, notice and proceedings shall be conducted pursuant to the Administrative Process Act, Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia. (§ 2.2-4000 et seq. of the Code of Virginia) shall govern the decision of cases under this chapter.

Part II

Required Sewerage Facilities and Sewerage Systems for Marinas, and Other Place(s) Where Boats are Moored, and Boating Access Facilities and Their Operation

12VAC5-570-120. General.

A. All owners of marinas, or other place(s) where boats are moored, and boating access facilities shall provide the minimum number of sanitary sewerage facilities required by this chapter for their patrons. These Owners shall maintain their facilities shall be maintained in a clean and sanitary operable condition. They Owners shall equip their facilities shall be equipped with toilet tissue, lights where electricity is available and soap and towels where handwashing facilities are required. These Owners shall make their facilities shall be available during normal business hours to patrons and users of these facilities at all times during the normal boating season for that facility.

B. Marinas which are located within 1,000 feet of the shore end of the pier that are operated as part of residential developments, overnight lodging facilities, restaurants or commercial establishments, which are located within 1,000 feet of the shore end of the pier, are exempted from providing separate sanitary sewerage facilities, as long as the sanitary sewerage facilities at the residence, lodging establishment, restaurant or commercial establishment are made available to all users of the marina. This The exemption set forth in this subsection does not apply to:
(i) Marinas
1. Marinas associated with restaurants or commercial establishments which allow overnight occupancy of boats; and
(ii) Marinas
2. Marinas associated with overnight lodging establishments where overnight occupancy of boats is permitted by persons not registered at the overnight lodging establishment.

C. Exempt from the requirements of subsection A are other places where boats are moored and boating access facilities are exempt from the requirements of subsection A, provided that the other place(s) where boats are moored or boating access facility:
1. serve Serves residents of homes (houses, condominiums, apartments or mobile homes), their bona fide house guests, or registered guests of tourist establishments; which and
2. provide Provides adequate sanitary sewerage facilities that are located within 1,000 feet of the shore end of the pier.

D. In order to qualify for an exemption under subsections B or C of this section, the owner of such a marina, or other place(s) where boats are moored, or a boating access facility shall provide to the department a signed, notarized statement that all conditions set forth in the aforementioned sections will be complied with by users of the facilities.

12VAC5-570-130. Location.

Adequate Owners shall conveniently locate their sewerage sanitary facilities shall be conveniently located within 500 feet walking distance from the shore end of any dock they are intended to serve. On a case by case basis the Division may approve a greater distance if unusual circumstances such as topography or resource protection areas prevent compliance with this requirement, as determined by the division. It may be necessary require the owner to provide sewerage sanitary facilities in more than one location in order to meet the needs of the particular site, as developed. In addition, the Division may require additional fixtures, beyond the minimum number specified in Table 1, if it determines that additional fixtures are necessary to accommodate the site layout and use of the facility marina, other place(s) where boats are moored, or boating access facility.

12VAC5-570-140. Availability, and marking of sanitary facilities.

Owners shall locate The sewerage sanitary facilities shall be so located so that they are available and readily reasonably accessible to all users. They shall be appropriately marked with signs readily identifiable to all personnel who might desire to use the facilities. The location and use of all sewerage facilities shall be clearly indicated by appropriate signage.

12VAC5-570-150. Sewerage facilities for marinas. Marinas.

A. Minimum The minimum number of sewerage fixtures to be provided in sanitary facilities, as found is understood that in Table 1.

B. many instances the site layout and the use of the marina may require more fixtures than are shown in the table below. If the board, after observation and study, determines that additional fixtures or buildings housing sanitary facilities are necessary, the owner shall provide the additional fixtures so determined. Where dry storage space is provided, each dry storage space is equivalent to one-third (1/3) of a seasonal slip. The minimum number of fixtures required is contained in Table No. 1 and is based upon the total number of seasonal slips or their equivalent. Separate sewerage facilities for male and female personnel shall employees may be provided in a structure or structures but shall not be counted toward the minimum number of fixtures required to accommodate users of the marina.

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<th>Number of</th>
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<th>Lavatories</th>
<th>Showers</th>
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### Table 1

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</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Number of Transient Slips</th>
<th>Commodes</th>
<th>Urinals</th>
<th>Lavatories</th>
<th>Showers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>0-24</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>25-49</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>50-74</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>100-149</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>150-199</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>200-249</td>
<td>4</td>
<td>6</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

C. When the number of seasonal slips exceeds those above as prescribed by Table No. 1, the owner shall provide additional fixtures. The owner shall provide one commode, one lavatory and one shower for each 100 additional seasonal slips. A urinal may be substituted for a commode when the number of seasonal slips exceeds 100 of the Table No. 1 values. Showers are not required for dry storage boat usage.

B. Transient slip. When transient slips are available additional sanitary facilities shall be provided. Table No. 2 below shows the minimum number of additional fixtures required. These fixtures may be included in a structure or structures with those fixtures provided for the seasonal slip, provided the accessibility and convenience standards of 12VAC5-570-130 and 12VAC5-570-140 of this chapter are met.
For each 24 or fraction thereof in excess of those shown in Table No. 2 above, one commode, lavatory, and shower shall be provided for each sex. In addition, one urinal shall be provided for each 50 or fraction thereof transient slips in excess of the number shown in Table No. 2.

12VAC5-570-160. Sewerage Sanitary facilities at other place(s) where boats are moored, and boating access facilities. §

A. Sewerage facilities are required at other place(s) where boats are moored and boating access facilities in accordance with this section.

B. Where piped potable water is available, sewerage sanitary facilities for other place(s) where boats are moored shall consist of a minimum of one commode, one lavatory, and one shower for females and one commode and one lavatory for males for each gender, for each 100 seasonal slips, or fraction thereof and each 50 transient slips or fraction thereof.

C. Requirements for dry storage boat usage shall be identical to those specified in 12VAC5-570-150 for marinas.

D. Where piped potable water is not available, Sanitary sewerage facilities for other place(s) where boats are moored may consist of privies, where piped water is not available.

E. Sewerage facilities at boating access facilities shall consist of at least one privy or portable toilet and shall be sufficient in number to accommodate facility usage.

F. Walking distance to these facilities shall comply with 12VAC5-570-130.


A. Public or municipal sewerage systems and sewage treatment works facilities shall be used if there is reasonable access to sewers. When such municipal means of disposal is not available, the owner shall have designed and installed an approved sewerage system or treatment works. An approved sewerage system or treatment works is (1) a system for which a certificate to operate has been issued jointly by the Department and the Department of Environmental Quality, (2) a system approved by the Department of Environmental Quality in accordance with Title 62.1 of the Code of Virginia, or (3) a system approved by the Commissioner in accordance with Title 32.1 of the Code of Virginia. Approved methods of sewage treatment are set forth in the Sewerage Regulations (1977) (12VAC5-580-10 et seq.) or the Sewage Handling and Disposal Regulations (1982, as amended).

If permanent water conservation devices are provided, the sewage flow requirements specified in subsections A and B of this section may be reduced upon written approval of the division.

B. The following shall be used to determine the amount of sewage flow. It is assumed that The sewage design flow for each seasonal slip or dry storage space represents two persons. At marinas providing toilet facilities only, the flow figure shall be 40 25 gallons per person slip per day. At marinas providing toilet and shower facilities, the flow figure shall be 16 gallons per person per day except at marinas with only seasonal slips, where the flow figure shall be 10 gallons per person per day for the first 99 slips, regardless of whether showers are available, and 16 gallons per person per day for all slips above the 99 slips. Where dry storage is provided, each dry storage space shall be equivalent to one-third (1/3) of a slip. For dry storage facilities the sewage flow shall be calculated using one-third the number of dry storage spaces. The sewage design flow for each live-aboard slip shall be 50 gallons per slip per day. When a marina or other place(s) where boats are moored is constructed in conjunction with another structure or facility, the sewage design flows prescribed in this section shall be added to the sewage design flow governing the associated structure or facility.
C. In addition, for a marina or other place(s) where boats are moored which have a boat launching ramp and provide boat trailer parking spaces only while the boat is in use, the design sewage flow shall be increased by 10 gallons per day per boat trailer parking space.

D. The Division may approve a reduction in the sewage flow requirements specified in subsection B if the owner provides documented flow data sufficient to justify the reduction.

B. Where restaurants or motels are operated in connection with a marina or place where boats are moored the following shall be used as a basis for determining the amount of sewage flow:
- Motels - 65 gallons per person per day or a minimum of 130 gallons per room per day.
- Restaurant - 50 to 180 gallons per seat per day. Each installation will be evaluated according to conditions.

C. The occupancy level of boats used for design of sewage treatment or disposal facilities will be those levels listed in 12VAC5-570-170 A. It is recognized that the type of activity and utilization of marina or other places where boats are moored varies and, therefore, additional facilities to provide capacity up to maximum may be required if the need arises. The local health director serving the area in which the marina is located shall make such determination.

12VAC5-570-180. Pump-out.

A. Owners of other place(s) where boats are moored which allow overnight docking or mooring of boats and owners of all marinas, regardless of size or number of boat moorings slips, shall provide pump-out facilities for pumping or removing sewage from boats. These pump-out facilities shall include all the equipment, structures and treatment or disposal facilities necessary to ultimately discharge or dispose of this boat sewage in an efficient and sanitary manner without causing an actual or potential public health hazard. Exempt from this requirement are marinas and other place(s) where boats are moored which do not have live-aboard slips or allow boats with a marine sanitation device installed toilet with a discharge overboard or a sewage holding tank to use any of the services provided, including moorage, except in an emergency. In order to qualify for this exemption, the owner of such marina or other place(s) where boats are moored shall provide the Department with a signed notarized statement indicating that there are no live-aboard slips and that boats with marine sanitation devices installed toilets with overboard discharges or sewage holding tanks shall not be permitted to use the marina or other places facilities, except in an emergency.

A. Availability and operation. Where pump-out facilities are required, the owner shall install, maintain in good operating condition and provide pump-out during normal working hours to users of the marina or other places where boats are moored except in those cases where adequate facilities are provided in accordance with subsection B of this section, then, the normal working hours requirement will apply to the facility using the agreement, as well as the facility with the alternate pump-out service. The owner shall make sewage pump-out facilities available to all users of the marina or other place(s) where boats are moored during normal operating hours. The owner shall maintain the pump-out equipment in serviceable condition and shall keep the equipment located in an area convenient for utilization.

C. The owner shall use placards or signs to identify the sewage pump-out location and use restrictions.

B. Alternate pump-out service. Marinas and other place(s) where boats are moored which provide less than 50 seasonal (or transient) slips for boats of 26 feet or more in length and less than 20 seasonal (or transient) slips for boats of 40 feet or more in length may be exempted from the requirement to install pump-out facilities, unless such marinas and or other place(s) where boats are moored is located in a No Discharge Zone. Such exemption shall be granted by the Director of the Division whenever alternate pump-out service is provided at a
nearby marina or other place(s) where boats are moored, and is as evidenced by an agreement signed and notarized by both parties in accordance with the requirements of this section, and filed with the Division. The Division shall only approve such such alternate pump-out service will only be approved by the division when in accordance with the following criteria are met:

1. That the alternate pump-out service will shall not require more than 20 minutes to complete from the time a boater has the boat ready to receive the service and has previously requested to have the boat sewage holding tank marine sanitation device pumped. The pump-out service for holding tanks of 50-gallon capacity or more (sewage holding) may exceed twenty 20 minutes;

2. That the alternate pump-out service shall be located within three 3 nautical miles, as measured along the water route, of the exempt facility using the agreement unless the alternate pump-out service is located along the normal travel route to open water, in which case the exempt facility using the agreement shall be within five 5 nautical miles of the alternate pump-out service;

3. That the alternate pump-out service capacity shall be sufficient to handle the demand for pump-out service, in accordance with subsection C of this section, that is expected for all of the marinas or other place(s) where boats are moored entering into the above-mentioned agreement;

4. That a notice the owner of the exempt facility shall post in a conspicuous location appropriate signage that specifies the location of the alternate pump-out service and the associated charge for its use; shall be posted in a conspicuous location, at the marina or other place where boats are moored not installing pump-out service, that specifies the location of the alternate pump-out service;

5. The terms of the agreement shall provide that:
   a. That the alternate pump-out service will shall be available to all boats moored at each facility and it will state that the alternate pump-out facility will furnish pump-out services to anybody boaters referred to it by the exempt facility establishment using the agreement to provide pump-out service, as specified by this chapter; and
   b. That the agreement will shall be valid for one year and will be automatically renewable on the anniversary date, unless either party gives at least a 60-day termination notice to the other and to the Director of the division Division prior to the renewal date.

6. If a termination notice is issued to a an exempt facility using an agreement to provide alternate pump-out service, in accordance with 12VAC5-570-180-B this subsection, then that facility shall either provide pump-out service or obtain a new written agreement, in accordance with 12VAC5-570-180-B this subsection, by the effective date of the termination of alternate pump-out service.

C. E. Minimum design criteria for pump-out facilities. The purpose of these minimum design criteria is to provide the owner and the Department of Health Department with acceptable methods for pumping, storing, and conveying and treatment of the contents from boat-holding tanks, marine sanitation devices. The owner A proposed pump-out facility shall meet the following minimum design criteria: shall furnish the following information for each proposed pump-out facility:

1. Pumping equipment. Pump equipment may be fixed or portable; however, this equipment shall be conveniently located for usage and clearly identified or placarded by signs or other notices, indicating any fees, restrictions or other operating instructions, as necessary. A minimum pump capacity of 10 gallons per minute (gpm) is acceptable at the operating head required to transport the flow to the proper collection or treatment
location with such residual head as may be required; however, at marinas with 51 or more slips, greater pumping capacity may be required. To prevent clogging, pumps shall be of a macerator type or the pumps shall be able to pass a 2-inch spherical solid, have sufficient size suction and discharge openings to prevent clogging. Manually operated pumps are not permitted acceptable at marinas and other place(s) where boats are moored that offer fewer than 26 slips. Pump data from the manufacturer shall include:

a. The type of pump (diaphragm, positive displacement, or centrifugal, vacuum, macerator, etc., and power);
b. Rated capacity (gpm, hp, and head); Pump power source (electric motor, gasoline engine, etc.) and output (HP);
c. Motor type (electric or gas); and Pump capacity, including a performance curve;
d. Suction and discharge opening size. Pump solids-handling ability; and
e. A schematic showing relevant pump dimensions, such as height, size and location of suction and discharge openings, etc.

2. Location schematic. If fixed pump-out equipment is proposed, a schematic of the location with elevations for a, b, c, d and e, as described below, shall be included, or if portable pump-out equipment is proposed, a schematic shall indicate elevations for subsections a, c, f and g, as described below. A schematic of the proposed facilities shall be provided and include the following, minimum information:

a. Mean low water elevation; level;
b. Suction hose diameter, length, and highest elevation; Elevation of dock;
c. Pump elevation; Greatest elevation of suction center line of pump;
d. Discharge hose/pipe diameter(s), length(s), and highest elevation; Elevation of discharge point;
e. Discharge point elevation; Highest point in discharge line;
f. Type of dock (floating or stationary); and
g. Greatest elevation of any dock; and
h. Distance between pump-out location and slips.
All elevations shall be measured with respect to mean low water. If the elevation of mean low water is not known, assume it to be zero.

3. Fittings and hoses (piping) – fittings. This subdivision sets forth the minimum design criteria for fittings and hoses (piping) which are used in the operation of a pump-out facility shall meet the following:

a. Suction hoses shall meet the following criteria:
   (1) A friction nozzle (right angle preferred) or wand-type attachment is to be provided on the end of the suction hose. Adapters shall be provided to fit any discharge connection from 1.25 to 4 1/2 inches in diameter.
   (2) A check valve shall be provided on the suction hose at the nozzle.
   (3) The hose shall be made of flexible, heavy-duty material that will be noncollapsing and nonkinking. The length of this line shall be determined on an individual case basis by the Division.
   (4) If the suction line is to be installed in such a manner that sewage would discharge from the line when the pump is removed for service, a gate full port ball valve shall be provided on the pump end of the suction line.

b. Discharge hose and piping shall meet the following criteria:
(1) The discharge hose or piping shall be equipped with watertight, permanent or positive locking type fittings and connections.
(2) Where flexible discharge hose is used, the hose shall be made of heavy-duty material and be nonkinking and noncollapsing.

c. Discharge lines shall meet the following criteria:
(1) A gate full port ball valve shall be provided on the discharge line at the pump;
(2) Suitable connections on the end of the discharge line shall be provided to prevent it from coming loose dislodging during discharge; all nozzles and fittings are to be positive locking, male and female.
(3) The discharge line must not be subject to freezing or leaking into the water course.
(4) Sewer lines on piers shall be located below water distribution lines. Water and sewer line separation and sewer line, and water source separation requirements are set forth in the Waterworks Regulations (12VAC5-590-10 et seq.) (12VAC5-590) and the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.) (12VAC5-610-20 et seq.).
(5) The discharge line connection to the pump-out receiving facility shall be fixed in place in such a manner as to prevent it from coming loose dislodging during discharge.

d. Rinse equipment. Pump-out facilities shall include equipment for rinsing the boats' holding tanks associated with marine sanitation devices. Where potable water will be used for rinsing the holding tank, a backflow prevention device shall be installed on the water service line. A minimum of a hose bib type vacuum breaker shall be provided.

4. Other devices or methods of removal. Other devices or methods of removal of contents from boat holding tanks marine sanitation devices may be approved by the Commissioner Division on an individual case basis.

5. Onshore facilities. Contents from boat holding tanks shall be discharged to (i) a public wastewater collection system in which sewage is conveyed to an approved treatment facility; (ii) a holding tank whereby sewage may be stored until it is taken in an approved manner to an approved treatment facility; or (iii) directly to an approved sewage treatment facility.

a. For discharge to a public wastewater collection system, the following will be required: The owner of the marina or other place where boats are moored shall submit evidence, in writing, (i) of consent from the owner of the system, (ii) from the owner of any conveyance systems located downstream, which may be affected, and (iii) from the owner of the ultimate treatment facility. Verification shall be given that there are satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.

b. If sewage is to be stored in a holding tank, the holding tanks shall be sized, constructed and located to meet the criteria.

(1) Size of holding tank.
Marinas or other places where boats are moored shall size the holding tanks based upon the following tabulations:

<table>
<thead>
<tr>
<th>Total Number of Boats Serviced with Holding Tanks</th>
<th>Required Onshore Holding Tank - Volume (gallons) Minimum</th>
</tr>
</thead>
</table>

14
(2) Construction of holding tank.
(a) The holding tank shall be designed so that it is watertight and not subject to any infiltration or any leakage.
(b) When holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.
(c) When holding tanks are made of material other than concrete, the outside surface of the holding tank shall be protected from corrosion.
(d) The holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.
(e) The holding tank shall be fixed in place unless it is part of an approved mobile pump-out unit.
(f) Provisions shall be made to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.
(g) The holding tank shall be adequately vented. Screened, elbowed down vents installed at the top of the tank will serve this requirement.
(h) The inlet/outlet of the holding tank shall be compatible with the proposed method of removal.
(i) There shall be satisfactory provisions for emptying the contents from portable toilets in a sanitary manner.

(3) Holding tank location.
Separation distance between holding tank and various structures and features are contained in Table 4.4 of the Sewage Handling and Disposal Regulations (12VAC5-610-10 et seq.).

(4) Any person who removes, or contracts to remove, and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner (see the Sewage Handling and Disposal Regulations, 12VAC5-610-10 et seq.).

c. Sewage treatment plant. Disposal of holding tank wastes shall not be allowed at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewer system of a large sewage treatment facility or transported for eventual treatment at a large plant.

12VAC5-570-190. Sewage dump station.
A. All marinas and other place(s) where boats are moored, regardless of size or number of boat moorings, shall have an acceptable proper and adequate receiving station for sewage from
portable toilets containers used on boats. The owner shall install, maintain in good operating condition and provide a sewage dump station to users of the marina or other places where boats are moored. Exempt from this provision subsection are marinas or other place(s) where boats are moored which also qualify for the exemption contained in 12VAC5-570-120 B or C exemption, provided that the owner of the sewerage sanitary facility will allow consents to the dumping of the contents of portable toilets sewage containers into the sewerage sanitary facilities.

B. Availability and operation. Where a sewage dump station is required, the owner shall install, and maintain in good operating condition, it in a serviceable and sanitary condition and in compliance with the regulations, and The owner shall make provide the facilities available to users of the marina or other place(s) where boats are moored. The owner shall locate the sewage dump station in an area convenient for use and the owner shall use placards or signs to identify its location and restrictions.

C. Minimum design criteria for a sewage dump station. The purpose of these the minimum design criteria is to provide the owner and the Department of Health with acceptable methods of discharging sewage from a portable container into a sewage holding tank or a sewage treatment works. The same criteria as set forth in 12VAC5-570-180 C 5 12VAC5-570-200 A for contents from boat holding tanks marine sanitation devices will shall apply for sewage dump stations. The sewage dump station receiving unit shall be a minimum of 12 inches in diameter and be equipped with a cover that has a lip of sufficient size to prohibit accidental removal. If the unit is designed to drain, the drain shall be a minimum of four inches in diameter and equipped with a fly tight cover.

D. Exempt from the requirements of subsection C are marinas and other place(s) where boats are moored that have an operational pump-out facility equipped with a device to pump portable sewage containers.

12VAC5-570-200. Onshore facilities.

A. Contents from marine sanitation devices and portable sewage containers used on boats shall be discharged to:

1. a public sewerage system for conveyance to an approved treatment works as described in 12VAC-570-170 A;

2. a holding tank whereby sewage may be stored until it is transported in accordance with the Sewage Handling and Disposal Regulations to an approved treatment works as described in 12VAC-570-170 A; or

3. an approved sewage treatment works as described in 12 VAC-570-170 A.

B. Disposal of sewage waste from a marine sanitation device shall be prohibited at small sewage treatment plants where shock loading may result or disinfectants and odor inhibitors will affect the operation of the treatment facility. Whenever feasible, the collected sewage shall be discharged directly to the sewerage system of a large sewage treatment facility or transported for eventual treatment at a large sewage treatment facility.

C. For discharge to a public sewerage system the owner of the marina or other place(s) where boats are moored shall submit to the Division, in writing;

1. written evidence of consent to the discharge from the owner of the conveyance system;

2. written evidence of consent to discharge from the owner of any conveyance systems located downstream which may be affected;

3. written evidence of consent to discharge from the owner of the treatment works where the sewage is to be disposed of; and
4. the owner shall verify that there are satisfactory provisions for emptying the contents from portable sewage containers in a sanitary manner.

D. If sewage is to be stored by the marina or other place(s) where boats are moored in a holding tank, the holding tank or tanks shall be sized, constructed and located to meet the following criteria:

1. Sewage holding tanks shall be sized in accordance with the requirements of Table 2.

   **Table 2: Minimum Holding Tank Volume**
   
<table>
<thead>
<tr>
<th>Total Number of Boats Serviced Annually with Marine Sanitation Devices</th>
<th>Minimum Holding Tank Volume (gallons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 60</td>
<td>725</td>
</tr>
<tr>
<td>61 - 80</td>
<td>1000</td>
</tr>
<tr>
<td>81 - 100</td>
<td>1200</td>
</tr>
<tr>
<td>100+</td>
<td>2000</td>
</tr>
</tbody>
</table>

2. Holding tanks shall be constructed in accordance with the following criteria;
   a. the holding tank shall be watertight and not subject to any infiltration or leakage;
   b. when holding tanks are made of material other than concrete, the internal surface of the holding tank shall be protected from corrosion. Materials used in the manufacture and installation of holding tanks shall be resistant to deterioration by prolonged or frequent contact with deodorizing chemicals, sewage decomposing chemicals, sewage, freshwater and saltwater.
   c. when holding tanks are made of material other than concrete, the external surface of the holding tank shall be protected from corrosion.
   d. the holding tank shall be constructed of materials capable of withstanding the forces exerted on its walls.
   e. the holding tank shall be located onshore and fixed in place unless it is part of an approved mobile pump-out unit.
   f. provisions shall be made to the satisfaction of the Department to assure that the holding tank can be completely emptied. The tank shall be essentially emptied when pumped out.
   g. the holding tank shall be adequately vented. This requirement may be met with screened, elbowed down vents installed at the top of the tank.
   h. the inlet/outlet of the holding tank shall be compatible with the proposed method of removal.
   i. there shall be provisions for emptying the contents from portable sewage containers in a sanitary manner.

3. The required separation distances between holding tank and various structures and features are contained in Table 4.1 of the Sewage Handling and Disposal Regulations (12VAC5-610-20 et seq.).

4. Any person who removes, or contracts to remove and transport by vehicle, the contents of a holding tank shall have a written sewage handling permit issued by the Commissioner in accordance with the Sewage Handling and Disposal Regulations, (12VAC5-610-20 et seq.).
TO: State Board of Health

FROM: Erik Bodin
   Director, Office of Licensure and Certification

SUBJECT: Proposed Regulations for Licensure of Abortion Facilities (12VAC5-412)

Enclosed for your review are proposed Regulations for Licensure of Abortion Facilities (12VAC5-412). The proposed regulations are intended to ultimately replace the emergency Regulations for Licensure of Abortion Facilities that are currently in effect. Under state law, emergency regulations are only temporary in nature.

As mandated by Chapter 670 of the 2011 Acts of Assembly, the proposed regulations establish minimum standards for construction and maintenance; operation, staffing and equipping; staff qualifications and training; as well as requirements for policies related to infection prevention, disaster preparedness, and facility security.

The Notice of Intended Regulatory Action (NOIRA) pertaining to the proposed regulations was published in The Virginia Register of Regulations on January 15, 2012. A 30-day public comment period on the NOIRA ended on February 16, 2012. A large volume of comments were received during the public comment period. A summary of these comments is contained in the attached Agency Background Document.

Overall, the proposed regulations are substantively similar to the emergency regulations currently in effect. However, in drafting the proposed permanent regulations, some revisions have been made to the provisions contained in the emergency regulations, as follows:

- Revisions to make the permanent regulations more consistent with other VDH health care facility regulations. This consisted of some minor additions including a few definitions but mostly involved moving language for consistency of formatting.
- Revisions to incorporate some interpretative guidance previously issued by VDH, thereby creating more thorough, comprehensive and transparent regulations.
- Revisions to make the permanent regulations consistent with recent amendments to Virginia's Informed Written Consent for Abortion statute.
- Revisions to ensure that those abortion facility employees who are legally mandated to report suspected child abuse comply with those requirements.
The Board of Health is requested to approve the proposed regulations. Should the Board of Health approve the proposed regulations, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Virginia Administrative Process Act. Following Executive Branch review and approval, the proposed regulation will be published on the Virginia Regulatory Town Hall and in the Virginia Register of Regulations for a 60-day public comment period. After closure of the public comment period, and after VDH has reviewed and analyzed all of the comments, this regulatory action will be brought back to the Board for further consideration as draft final regulations.

Thank you for your consideration. I look forward to discussing the proposed regulations with you at the June 15, 2012 Board meeting.
Virginia Department of Health

12 VAC 5 – 412
12 VAC 5 – 410 (amendments)

Regulations for Licensure of Abortion Facilities

Establishes minimum standards for facilities performing five or more first trimester abortions per month.

May 1, 2012

Chapter 670 of the 2011 Virginia Acts of Assembly amended and reenacted §32.1-127 of the Code of Virginia. Chapter 670 (2011) specified that facilities in which five or more first trimester abortions per month are performed shall be classified as a category of hospital and mandated the Board of Health to adopt regulations governing the licensure of such entities within 280 days of its enactment. For that reason, the Board utilized the emergency rulemaking process authorized by the Administrative Process Act for promulgating emergency regulations and filing a Notice of Intended Regulatory Action. Following that regulatory action, the Virginia Department of Health has developed proposed permanent regulations to replace the emergency regulations upon their expiration. The permanent regulations are necessary to support the implementation of the amendments to §32.1-127 enacted by Chapter 670 (2011). The proposed regulations contain provisions pertaining to definitions, procedures for licensure or license renewal, organization and management, infection prevention, patient care, quality assurance, medical records and reports, disaster preparedness, facility security, functional safety and maintenance, and design and construction.
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.

The acronyms that appear in this document are as follow:
(i) CDC as an abbreviation of Centers for Disease Control and Prevention
(ii) HIPAA as an abbreviation of Health Insurance Portability and Accountability Act
(iii) NOIRA as an abbreviation of Notice of Intended Regulatory Action
(iv) OLC as an abbreviation of Office of Licensure and Certification
(v) VDH as an abbreviation of Virginia Department of Health

Legal basis

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

Section 32.1-127 of the Code of Virginia, as amended by Chapter 670 of the 2011 Acts of Assembly, mandated the State Board of Health to promulgate emergency regulations. Chapter 670 further authorizes the Board of Health to continue to regulate facilities in which five or more first trimester abortions per month are performed as a category of hospital after the emergency regulations expire. The Board of Health, in accordance with the Administrative Process Act (§2.2-2000 et seq. of the Code of Virginia) has been directed to adopt regulations to implement the provisions of the Act which became effective on March 26, 2011. Having adopted the emergency regulations the Board now seeks to make appropriately revised regulations permanent.

Purpose

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

The intent of this regulatory action is to promote and assure the health and safety of patients who receive first trimester abortion services. The need for these regulations has been extensively and publically articulated over the past several years during the annual sessions of the Virginia General Assembly. The statutory language of §32.1-127 of the Code of Virginia as amended by Chapter 670 (2011) mandates that the regulatory action include minimum standards for facilities performing five or more first trimester abortions per month. The standards are required to include those for construction and maintenance, operation, staffing and equipping, qualifications and training of staff, and infection prevention, disaster preparedness and facility security.
Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The majority of the provisions in this regulatory action are currently contained in the Emergency Regulations. However, some revisions to the provisions of the Emergency Regulations have been proposed as part of this action. The following is a summary of key provisions of the proposed regulations:

**Definitions**

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

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

"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.

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

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

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

"Minor" means a patient under the age of 18.

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

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

"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.

"Trimester" means a 12-week period of pregnancy.

**Procedures for Licensure or License Renewal**

A license is valid for one year.

It is the responsibility of the abortion facility's governing body to maintain a current and accurate license at all times.

The Department may deny, suspend or revoke a license.

The Commissioner may allow a temporary variance to the regulatory provisions.
The Commissioner may rescind or modify a temporary variance.

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

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

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

A list of patients receiving services on the day of the inspection, as well as a list of all the abortion facility's patients for the previous 12 months, shall be provided to the inspector within 2 hours of arrival if requested.

A facility must submit a plan of correction within 15 working days to address any deficiencies.

OLC has the responsibility to investigate any complaints regarding violations of the regulations.

The facility has the right to contest the denial, revocation or suspension of a license.

Organization and Management

Each facility shall have a governing body.

Each facility shall develop, implement and maintain policies and procedures, including obtaining informed written consent prior to the initiation of any procedures.

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

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

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

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

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

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

Each 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 abortion facility shall establish and maintain complaint handling procedures and any patient seeking an abortion shall be given a copy of the complaint procedures in language or manner she understands at the time of admission to service.

Quality Management and Infection Prevention

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

**Patient Care**

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.

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

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

Use of additional medical testing shall be based on an assessment of patient risk.

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

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

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

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

Elective general anesthesia shall not be used.

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

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

A facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope, and intensity of services provided. Such 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 Advanced Cardiovascular Life Support.

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.

A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment.
Health Information Records and Reports

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

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

Provisions shall be made for the safe storage of health records or accurate and eligible reproductions thereof according to applicable federal and state law including HIPAA.

The facility 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).

The abortion facility shall report to the OLC within 24 hours any patient, staff or visitor death, any serious injury to a patient, medication errors that necessitate a clinical intervention other than monitoring, 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 any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990.

Records that are confidential under federal or state law shall be maintained as confidential by OLC and shall not be further disclosed except as permitted by law.

Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.

Functional Safety and Maintenance

The 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.

Each 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 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.

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

Design and Construction

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

Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 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.

This regulatory action also proposes the following amendments to 12VAC5-410 (Regulations for the Licensure of Hospitals in Virginia.)
<table>
<thead>
<tr>
<th>Current section number</th>
<th>Proposed new section number, if applicable</th>
<th>Current requirement</th>
<th>Proposed change and rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 VAC 5-410-10</td>
<td></td>
<td>Definition of &quot;Outpatient Hospital&quot;</td>
<td>The following text is stricken from the definition: &quot;Outpatient abortion clinics are deemed a category of outpatient hospitals.&quot;. Rationale - Abortion facilities will be regulated pursuant to 12 VAC5-412, not 12 VAC5-410.</td>
</tr>
<tr>
<td>12 VAC 5-410-60</td>
<td>Separate License</td>
<td></td>
<td>Deletes the term &quot;outpatient abortions&quot; from the provision authorizing VDH to require a hospital to have separate licenses for different types of services. Rationale - Abortion facilities will be regulated pursuant to 12 VAC 5-412, not 12 VAC 5-410.</td>
</tr>
</tbody>
</table>

**Issues**

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

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

The primary advantages of the proposed regulatory action to the public are the requirements for health and safety protections at abortion facilities. The primary disadvantage to the public associated with the proposed action is some abortion facilities may need to renovate or relocate their facility in order to comply with the regulations. Section 370 of the proposed regulations allows entities operating as of the effective date of the emergency regulations to be licensed in their current buildings if the abortion facility submits a plan with the application for licensure that will bring the facility into full compliance with the provisions of Section 370 within two years from the date of licensure. The costs of those renovations or relocations might be passed on to the facilities' patients, or potentially, result in some facilities electing to cease operations at some point in the future. The primary advantage to the agency and the Commonwealth is the promotion of public health and safety. There are no disadvantages associated with the proposed regulations in relation to the agency or the Commonwealth.*
Requirements more restrictive than federal

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

There are no applicable federal requirements associated with these regulations.

Localities particularly affected

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

It is not anticipated that any one locality will bear a disproportionate material impact that would not be experienced by other localities.

Public participation

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

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

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (http://www.townhall.virginia.gov), or by mail, email or fax to Erik Bodin, Director of Office of Licensure and Certification, Virginia Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, (804) 367-2127 (phone), (804) 367-2149 (fax), or erik.bodin@vdh.virginia.gov (email). Written comments must include the name and address of the commenter. In order to be considered, comments must be hand delivered by the close of business on the last date of the public comment period or submitted by fax, email or to the Regulatory Town Hall website by midnight on the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the Virginia Register of Regulations and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (http://www.townhall.virginia.gov) and on the Commonwealth Calendar website (http://www.virginia.gov/cmsportal3/cqi-bin/calendar.cqi). Both oral and written comments may be submitted at that time.
Economic impact

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

| Economic Impact | VDH anticipates that the implementation and enforcement of these regulations will require the addition of two full time medical facility inspector positions at an estimated annual cost of $145,600. Funds would be non-general fund licensing fees (1%) and general fund (99%) and would be on-going expenditures. VDH has received additional funding in the 2012 Appropriation Act which will enable it to cover this expense. |
| Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures. |  |
| Projected cost of the new regulations or changes to existing regulations on localities. | VDH anticipates that the implementation of these regulations will not create any cost to localities. |
| Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations. | Twenty abortion facilities required to be licensed under the emergency regulations are currently in operation in the Commonwealth. All have submitted an application for licensure and a letter expressing their readiness for an onsite survey. VDH will schedule each of the applicant abortion facilities into the weekly licensed/certified facility inspection survey schedule. To date nine of the twenty abortion facilities have had their on-site inspection or are scheduled to be surveyed. |
| 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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | All twenty of these abortion facilities in operation in the Commonwealth will be affected as all twenty facilities have applied for licensure and thus, must comply with the regulations. |
| All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations. | The twenty abortion facilities in operation in the Commonwealth are small businesses. VDH has no data on the square footage size of the abortion facilities or on the amount of renovation or new equipment that will be required to be compliant with the regulations. However, it is expected that the abortion facilities will range in size, the degree of modification, and new equipment required. VDH anticipates that abortion facilities will be able to be grouped into one of three classifications based on the modifications that will be required to meet deficiencies identified on the initial licensure survey: a) none to minor renovations and equipment purchases, at an estimated average cost of $5 per square foot, b) moderate renovations and equipment purchases, at an estimated average cost of $130 per square foot, and c) major renovations and equipment purchases, at an |
estimated average cost of $525 per square foot. VDH anticipates that the administrative costs to comply with the regulations (develop application, participate in an onsite inspection survey, develop a plan of correction) will vary but should not require more than 16 man-hours per year on average. Section 370 of the proposed regulations allows entities operating as of the effective date of the emergency regulations to be licensed in the facility’s current buildings if the facility submits a plan with the application for licensure that will bring the facility into full compliance with the provisions of Section 370 within two years from the date of licensure.

| Beneficial impact the regulation is designed to produce. | This regulation is designed to promote and assure the health and safety of patients who receive first trimester abortion services. |

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts §32.1-127 of the Code of Virginia to mandate that the Board of Health promulgate these regulations. Therefore there are no non-regulatory alternatives to this regulatory action.

**Regulatory flexibility analysis**

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

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts §32.1-127 of the Code of Virginia and classifies facilities that perform more than five first trimester abortions per month as a category of hospital. In developing these regulations, VDH examined the regulatory provisions of 22 other states that already regulate abortion facilities, reviewed national and international standards, criteria and guidelines, consulted with a panel of OB/GYNs from Virginia's academic medical centers, examined the regulatory provisions governing hospitals and other types of health care facilities in Virginia, and received legal advice from the Office of the Attorney General. Chapter 670 (2011) does not authorize VDH to exempt small businesses from the provisions of the regulations. The proposed regulations are generally consistent with approaches taken by many other states, while also reflecting current best practices and
national recommendations in areas such as infection prevention. The regulatory provisions governing facility design and construction are based on Virginia Code § 32.1-127.001.

**Small business impact review result**

In order to minimize the economic impact of regulations on small businesses, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency’s determination of whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

**NOTE:** If the NOIRA Agency Background Document did not contain an announcement that you were conducting a small business impact review, please delete this entire small business impact review section. Otherwise, report the result of the small business impact review by completing this section.

Chapter 670 of the 2011 Virginia Acts of Assembly amends and reenacts §32.1-127 of the Code of Virginia to classify facilities that perform five or more first trimester abortions per month as a category of hospital and mandates the Board of Health to promulgate these regulations. Therefore, there is a continued and ongoing need for regulation. All twenty known abortion facilities in the Commonwealth have applied for licensure although none has yet been licensed. The nature of complaints and comments received concerning the regulation from the public center around the necessity of specific designated construction requirements, exempting existing facilities from building design and construction requirements, and differentiating between facilities that perform medication abortion and those that perform surgical abortion. These comments and complaints are elaborated in more detail below. The regulation is of moderate complexity. The regulation does not overlap, duplicate or conflict with federal or state law or regulation. The emergency regulations went into effect on 12/29/2011.

**Public comment**

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

A 30-day public comment period was held from January 16, to February 15, 2012. VDH received 1,539 comments during the public comment period. Two public hearings were held during the public comment period, on January 27, 2012 in Richmond and on February 3, 2012 in Alexandria. VDH has reviewed and summarized all of the public comments received concerning the NOIRA as part of its work to develop permanent replacement regulations.

<table>
<thead>
<tr>
<th>Comment</th>
<th>Agency response</th>
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<tbody>
<tr>
<td>Dr. James B. Kenley on behalf of the Virginia Coalition to Protect Women’s Health, Patrick J. Hurd on behalf of Planned Parenthood of Southeastern Virginia, Shelley Abrams on behalf of A Capital Women’s Health Clinic, and Jill Abbey on behalf of Richmond Medical Center for Women</td>
<td>12 VAC 5-412-370 is written based on Virginia Code § 32.1-127.001. VDH has subsequently issued interpretive guidance concerning the design and construction requirements. Please note in the proposed regulations this provision appears in 12 VAC5-412-370.</td>
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</table>
commented the facility design and construction requirements located in 12 VAC 5-412-380 are inappropriate. The Emergency Regulations require facilities to comply with Part 1 and Sections 3.1 and 3.7 of the 2010 Guidelines for Design and Construction of Health Care Facilities. The commenters state that the Facility Guidelines Institute (FGI) created the Guidelines as a guide for designing and constructing new health care facility projects, and did not intend for them to apply to existing facilities. The commenters also state that while other VDH regulations for licensure of hospitals, outpatient surgical hospitals and nursing facilities incorporate the Guidelines, those regulations govern only new construction and not existing facilities.

The Virginia Coalition to Protect Women's Health commented the emergency regulations should distinguish between facilities that offer medication abortion and those that offer medication and/or surgical abortion. The commenter stated that it is medically inappropriate to require facilities that provide only medication abortion to meet the extensive physical plant requirements imposed on abortion facilities under the regulations. According to the commenter, the same is true of the regulations' requirements for anesthesia services, examination of fetal tissue, and certain staffing, equipment and emergency services requirements.

The Virginia Coalition to Protect Women's Health, A Women's Clinic, and the Richmond Medical Center for Women commented that the regulatory provisions concerning issuance of variances should be consistent with comparable regulations for all other health care facilities licensed by VDH. The Emergency Regulations only authorize the Commissioner to issue "temporary" variances, and only upon a showing that the requirement "would be an impractical hardship unique to the abortion facility." The commenters stated the authority of the Commissioner to issue a variance from regulatory requirements for an abortion facility is different from the Commissioner's variance authority with respect to general hospitals, outpatient surgical hospitals and nursing facilities. In those cases, the Commissioner has the authority to issue a "permanent" variance if the enforcement of a regulation would be "clearly impractical."

Dr. James B. Kenley on behalf of the Virginia Coalition to Protect Women's Health, Patrick J. Hurd on behalf of Planned Parenthood of Southeastern Virginia, Shelley Abrams on behalf of A Capital Women's Health Clinic, and Jill Abbey on behalf of Richmond Medical Center for Women commented the regulatory provisions pertaining to patient and provider confidentiality need

Virginia law does not distinguish between medication and surgical abortions and thus, the Board of Health does not have authority to do so.

As VDH completes periodic reviews of the regulations governing hospitals, outpatient surgical hospitals and nursing facilities, it will work to develop a consistent approach to the issuance of variances.

VDH disagrees. Section 32.1-25 of the Code of Virginia provide the Commissioner or his designee the right to enter onto any property to inspect, investigate, evaluate, conduct tests or take samples for testing as necessary in order to determine compliance with the provisions of any regulations of the Board of Health. Further, VDH has an agency confidentiality policy that addresses
The commenters state that the permanent regulations should allow VDH to access patient records and related materials only after health care facilities have a reasonable period of time to redact the records and other materials of all identifying information. The commenters also state that VDH should revise the regulations to specify that 1) VDH employees should not remove patient records from the premises of the facility, and 2) VDH employees may not interview current patients without their explicit permission. In addition, the commenters state the permanent regulations should provide stringent confidentiality protections for all information concerning health care facilities that provide abortion care and concerning individuals who provide that care. For example, VDH should accept redacted disaster and other emergency plans, facility operations policies and protocols, and require disclosure of abortion patients to VDH representatives only for those patients scheduled on the day of the onsite survey.

| The Richmond Medical Center for Women and A Capital Women's Health clinic commented that required transfer agreements between abortion facilities and general hospitals are not necessary. If a person comes to a hospital’s emergency department with an emergency medical condition, the Emergency Medical Treatment and Labor Act (EMTALA) requires the hospital to treat and stabilize the patient or transfer the patient to another facility. As a result, the commenters state, “it adds nothing to patient safety to force individual health care providers to arrange transfer agreements with local hospitals…” According to the commenters, the permanent regulations should eliminate the required transfer agreement provision. | VDH disagrees. The purpose of EMTALA is to prevent facilities from refusing to treat patients due to their inability to pay. EMTALA requires a hospital to provide treatment “within its capacity” and if the hospital does not have the capability to treat a patient’s condition to make an “appropriate” transfer. Thus, although EMTALA requires hospitals to admit and treat patients presenting with an emergency medical condition, if the hospital does not have the equipment or personnel necessary to treat the patient EMTALA requires the hospital to transfer the patient to a medical facility that can. Thus, if VDH were to rely solely on EMTALA, a patient who presents with an emergency medical condition in an abortion facility could potentially be transferred twice before receiving the medical care they need, once from the abortion facility to a nearby hospital and again to a hospital that is qualified to treat the patient. The “transfer agreement” provision, VAC 5-412-290 (C), not only ensures needed emergency treatment of abortion patients but is intended to have a clinic determine the closest hospital with the necessary and appropriate equipment and personnel before an emergency presents to prevent a patient from undergoing multiple transfers. |

| The Virginia Coalition to Protect Women's Health, A Capital Women's Clinic and Richmond Medical Center for Women commented that VDH should eliminate from the permanent regulations the incorporation of “Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia.” Section 12 VAC5-412-130 of the Emergency Regulations allows for denial, suspension or revocation of a license for any violation of any provision of Article 1 of Chapter 5 of the Code of Virginia. | This section is written in conformance with Virginia Code § 32.1-135. VDH has subsequently issued interpretative guidance to abortion facilities identifying specific Code sections for which it will take enforcement action against abortion facilities in the event of violations. |
Title 32.1 of the Code of Virginia or of any applicable regulation. According to the commenters, VDH can take such action no matter “however minor and unrelated to patient safety” a violation may be. The commenters also state that the regulations are unclear about which statutes and regulations abortion facilities must comply with in order to obtain a license and remain licensed. The commenters recommend that the permanent regulations only require abortion facilities to comply with applicable sections of the statute.

Planned Parenthood of Southeastern Virginia commented that guidance and interpretive information provided by the VDH Office of Licensure and Certification should be incorporated into the permanent regulations. A comment provided recommended amending language, which would incorporate guidance provided by VDH subsequent to approval of the Emergency Regulations, for the following sections 12 VAC5-412: 20, 110C, 170G, 210D, and 240B.

VDH has proposed amendments to the emergency regulations to address this comment. VDH has proposed the following changes:
- 12VAC5-412-100(C) - Clarification of the meaning of current patients, by adding the language “A list of patients receiving services on the day of survey as well as a list of all the abortion facility’s patients for the previous 12 months shall be provided to the surveyor within 2 hours of arrival if requested.”
- 12VAC5-412-180(F) - Addition of the language “Electronic availability of the personnel files to the OLC surveyor will meet this requirement.” This clarifies the record requirements of the facility.
- 12VAC5-412-200(D) - Addition of the language "Any patient seeking an abortion," clarifying which patients must receive counseling.
- 12VAC5-412-230(E) - Addition of the language "Patient seeking abortion services," clarifying which patients must receive copies of complaint procedures.

The Virginia Coalition to Protect Women’s Health commented that the permanent regulations should not derive standards from external sources. The Emergency Regulations require abortion facilities to comply with a number of outside statutes, guidelines and other materials, which is problematic for a number of reasons. First, the regulations require compliance with “current” versions. Second, some of the referenced material does not seem to exist or is difficult to find. Third, the referenced materials may not be the most medically appropriate or the only source of guidance on the particular issue.

VDH disagrees. Incorporation by reference is a common practice in Virginia state regulations. However, VDH acknowledges that some of this information may not appear readily accessible to entities coming under licensure for the first time. Therefore, a dedicated page has been established on the agency web site at: [http://www.vdh.virginia.gov/OLC/AcuteCare/abortionfacilities.htm](http://www.vdh.virginia.gov/OLC/AcuteCare/abortionfacilities.htm) that contains a variety of information of use to providers and interested persons. This web page is updated frequently. VDH welcomes meaningful suggestions or additions to this page.

The Institute for Policy Integrity commented the Board has failed to consider reasonable regulatory alternatives. The commenter states “the current administrative record indicates that the Board has thus far failed to adequately identify and consider viable alternatives to the proposed regulations.” While tacitly acknowledging that legislation

VDH disagrees. In preparing the emergency regulations VDH analyzed regulatory provisions from twenty-two other states which already regulated abortion facilities. Also, VDH consulted with a panel of OB/GYNs and reviewed standards and criteria from numerous other entities, international guidelines and recommendations, and
mandated the Board to promulgate regulations, the comments also stated “The notion that Senate Bill 924 precluded the Board from considering a range of alternatives strains basic rules of interpretation.” This commenter also stated the Board has not yet considered economic impacts nor relied upon the best available information. The commenter also stated, “The lack of analysis conducted during the emergency rulemaking stage suggests that the Board has engaged in, and may be continuing to engage in, an incomplete, cursory and inadequate rulemaking process.”

268 commenters submitted a form comment, which stated the regulations threaten the availability of safe, legal first-trimester abortion and preventive reproductive health care in multiple locations throughout the state. These commenters stated requirements for clinic buildings were extensive and burdensome and further that they are unrelated to the services health centers provide and have no proven medical benefit. These commenters are concerned that the building requirements will reduce or eliminate patient access to health care by increasing the financial hurdles to health care for patients. These commenters believe the high standard of care provided by women's health centers is proven by their impressive safety record. They go on to state overregulation will limit access to a wide range of preventive reproductive health care services provided by women's health clinics, including life-saving cancer screenings, family planning, and sexually transmitted infection testing and treatment.

This commenter also stated the Board has not yet considered economic impacts nor relied upon the best available information. The commenter also stated, “The lack of analysis conducted during the emergency rulemaking stage suggests that the Board has engaged in, and may be continuing to engage in, an incomplete, cursory and inadequate rulemaking process.”

234 commenters submitted a form comment, which stated they strongly support the current regulations on abortion centers approved last year. These commenters believe regulations should be made permanent and should continue to include the strongest standards. These commenters went on to say Virginia’s abortion centers must be licensed, regulated, and inspected to protect women’s health and safety and they reject the premise that abortion is “health care” because it ends lives instead of healing them, but as long as the abortion industry is allowed to operate within the health care system it must be required to adhere to well-defined health and safety standards.

This comment does not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to the emergency regulations based on:

- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.

50 commenters submitted a form comment, which stated they wished the Board to enact the strongest possible regulations on abortion clinics.

VDH notes the support for the emergency regulations that are currently in effect. For the permanent regulations, VDH has proposed certain changes to the emergency regulations based on:

- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).
- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

20 commenters submitted a form comment, which stated Virginians want these regulations to be permanent for the protection of women, and the prevention of heinous incidences like the kind linked with Dr. Brigham. These commenters further expressed concern that Dr. Brigham owns abortion facilities in the state of Virginia.

VDH notes the support for the emergency regulations that are currently in effect. VDH has proposed certain changes to the emergency regulations based on:
- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

Andrea Alford, Ellen Shapiro and Joe Laughton Fields-Johnson representing Medical Students for Choice - Blacksburg Chapter commented these regulations will not make abortion care safer, but will just make it more difficult for abortion providers to remain open and for women to continue to access the abortion care they need. These commenters went on to state that the emergency regulations are being supported by a minority of Virginians with an ideological agenda, and not the medical community. They went on to argue that the Board of Health heard testimony from abortion providers and members of the medical community opposing these medically unnecessary regulations and they still chose to reject numerous amendments offered to protect the safety and confidentiality of both providers and patients with little to no debate.

This comment does not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to the emergency regulations based on:
- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.

Joanne Merrifield R.N and Donald Schwab commented abortion centers should be held to the regulations (12VAC5-412-220) require abortion facilities to comply with OSHA’s blood-borne...
same strict regulations as Out Patient Surgical Centers and have to be inspected and follow OSHA standards.

264 commenters expressed general support for the emergency regulations as written.

VDH notes the support for the emergency regulations that are currently in effect. VDH has proposed certain changes to the emergency regulations based on:

- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

567 commenters expressed general opposition to the emergency regulations as written.

These comments do not provide any suggested amendments to specific sections of the Emergency Regulations. VDH has proposed certain changes to the emergency regulations based on:

- Review and analysis of the public comments submitted to VDH during the 30 day public comment period on the NOIRA, which contained some specific recommendations for amendments;
- OLC’s review of the emergency regulations, and recommendations for certain amendments to make the abortion facility regulations more consistent with OLC’s other health care facility regulations; and
- Ensuring that the regulatory provisions are consistent with the provisions of §18.2-76 of the Code of Virginia (informed consent).

The regulatory provisions pertaining to facility design at construction are written based on Virginia Code § 32.1-127.001.

131 comments did not express support or opposition to the regulations. Some of these comments encouraged a complete ban on abortion, some were individuals who believed they were commenting concerning the ultrasound bill (HB 462 of 2012) or the personhood bill (HB 1 of 2012), some were incomprehensible and some were the result of an individual improperly filling out the comment page on the Town Hall website (i.e. title but no comment)

VDH believes that no response is necessary for these comments, as they do not speak to the regulations.
Family impact

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

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

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

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

The proposed regulations are intended to replace emergency regulations. Listed below are 1) all differences between the pre-emergency regulation and this proposed regulation:

<table>
<thead>
<tr>
<th>Current section number</th>
<th>Proposed new section number, if applicable</th>
<th>Current requirement</th>
<th>Proposed change, intent, rationale, and likely impact of proposed requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-410-10. Definitions.</td>
<td>N/A</td>
<td>&quot;Outpatient hospital&quot; means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. Outpatient abortion clinics are deemed a category of outpatient hospitals.</td>
<td>Proposed change: &quot;Outpatient hospital&quot; means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. Outpatient abortion clinics are deemed a category of outpatient hospitals. Intent: Abortion facilities will be governed by 12VAC5-412, not 12VAC5-410.</td>
</tr>
<tr>
<td>12VAC5-410-60.</td>
<td>N/A</td>
<td>A separate license shall be required by hospitals</td>
<td>Proposed change: A separate license shall be required by hospitals</td>
</tr>
</tbody>
</table>
B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, outpatient surgery, outpatient abortions).

Intent: Abortion facilities will be governed by 12VAC5-412, not 12VAC5-410.

<table>
<thead>
<tr>
<th>Section number</th>
<th>Proposed requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of proposed requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-412-10.</td>
<td>The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise: &quot;Abortion&quot; 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. &quot;Abortion facility&quot; means a facility in which five or more first trimester abortions per month are performed. &quot;Administrator&quot; 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. &quot;Commissioner&quot; means the State Health Commissioner. &quot;Department&quot; means the Virginia Department of Health. &quot;First trimester&quot; means the first twelve weeks from conception based on an appropriate clinical estimate.</td>
<td>N/A</td>
<td>Intent: Define key terms used in the regulations. Likely impact: Clear understanding of terms used in the regulations.</td>
</tr>
</tbody>
</table>
by a licensed physician. "Informed written consent" means the knowing and voluntary written consent to an abortion by a pregnant woman of any age in accordance with Virginia Code § 18.2-76. "Licensee" means the person, partnership, corporation, association, organization, or professional entity who owns or on whom rests the ultimate responsibility and authority for the conduct of the abortion facility. "Minor" means a patient under the age of 18. "Patient" means any person seeking or obtaining services at an abortion facility. "Physician" means a person licensed to practice medicine in Virginia. "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. "Trimester" means a 12-week period of pregnancy.

<table>
<thead>
<tr>
<th>Section</th>
<th>Text</th>
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</thead>
<tbody>
<tr>
<td>12VAC5-412-20. General.</td>
<td>A license to establish or operate an abortion facility shall be issued only when the abortion facility is in compliance with all applicable federal, state and local statutes and regulations, the provisions of this chapter, and when the application fee has been received by the department. No 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.</td>
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<tr>
<td>12VAC5-412-30. Classification.</td>
<td>Abortion facilities shall be classified as a category of hospital.</td>
</tr>
<tr>
<td>12VAC5-412-40. Separate license.</td>
<td>An abortion facility operating at more than one location shall be required to obtain separate licenses for each location in which abortion services are provided. Abortion facilities which have separate organized sections, units or buildings to provide services of a</td>
</tr>
<tr>
<td>Classification covered by provisions of other state statutes or regulations shall be required to have any additional applicable license required for that type or classification of service. Facilities licensed as either a general hospital or an outpatient surgical hospital by the department are not subject to the provisions of these regulations.</td>
<td>Likely impact: Effective VDH oversight of abortion facilities.</td>
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<td><strong>12VAC5-412-50. Request for issuance.</strong></td>
<td>N/A</td>
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<tr>
<td>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). B. Each abortion facility shall be designated by a distinct identifying name which shall appear on the application for licensure. Any change of name shall be reported to the OLC within 30 days. C. Application for initial licensure of an abortion facility shall be accompanied by a copy of the abortion facility's certificate of use and occupancy. D. The OLC shall consider an application complete when all requested information and the appropriate nonrefundable application fee is submitted. E. Written notification from the applicant to OLC that it is ready for the on-site survey must be received 30 days prior to OLC scheduling of the initial licensure survey. Applicants for initial licensure shall be notified of the time and date of the initial licensure survey, after the notice of readiness is received by the OLC. F. A license shall not be assigned or transferred. A new application for licensure shall be made at least 30 days in advance of a change of ownership or location.</td>
<td>Intent: Specify process for issuing abortion facility licenses</td>
</tr>
<tr>
<td><strong>12VAC5-412-60. License expiration and renewal.</strong></td>
<td>N/A</td>
</tr>
<tr>
<td>A. Licenses shall expire at midnight April 30th following the date of issue, and shall be renewable annually, upon filing of a renewal application and payment of the appropriate 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. B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted. C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal. D. Any license issued before April 30, 2012 shall not expire until April 30, 2013. No additional fee will be required for the period from May 1, 2012 until April 30, 2013.</td>
<td>Intent: Specify process for license expiration and renewal.</td>
</tr>
<tr>
<td><strong>12VAC5-412-70. Return</strong></td>
<td>N/A</td>
</tr>
<tr>
<td>A. It is the responsibility of the facility's governing body to maintain a current and accurate license at all times.</td>
<td>Intent: Specify process for</td>
</tr>
<tr>
<td>and/or Reissuance of License.</td>
<td>12VAC5-412-80. Allowable variances.</td>
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<td>B. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes: 1. Change of location. 2. Change of ownership. 3. Change of name. 4. Voluntary closure. 5. Change of administrator. 6. Change of operator. Notices shall be sent to the attention of the director of the OLC. 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 5 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. 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 facility during the process of evaluating a change. E. The facility will be notified in writing by the OLC whether a license can be re-issued or a new application is needed.</td>
<td>A. The commissioner may authorize a temporary variance only to a specific regulation of this Chapter. An abortion facility may request a temporary variance to a particular regulation or requirements contained in a particular regulation 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 regulation constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the requirements 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. B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known which 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.</td>
</tr>
</tbody>
</table>
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.
D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation to which the temporary variance was granted shall be resumed.

### 12VAC5-412-90. Right of entry.

Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any such employee shall properly identify himself or herself as an inspector designated by OLC; the abortion facility may verify the identity of the inspector prior to his or her 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.

### 12VAC5-412-100. On-site inspection.

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

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 shall be redacted by the abortion facility before removal.

C. If the OLC's representative arrives on the premises to conduct a survey and the administrator,
the nursing director, or a person authorized to give access to patient records, is not available on the premises, such person or the designated alternate, shall be available on the premises within 1 hour of the surveyor’s arrival. A list of 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 2 hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-27 and denial, suspension or revocation of the facility’s license in accordance with 12VAC5-412-130.

12VAC5-412-110. Plan of correction.

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

B. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan of correction as determined by the OLC. The plan of correction shall contain for each violation cited:
   1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
   2. The expected correction date, not to exceed 30 working days from the exit date of the survey;
   3. A description of the measures implemented to prevent a recurrence of the violation; and
   4. The signature of the person responsible for the validity of the report.

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

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

12VAC5-412-120. OLC complaint investigations.

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.

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 12 VAC 5- 412- 110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-412- Article 1 of

N/A

Intent: Define responsibilities of OLC and facility administrator pertaining to complaint investigations.

Likely impact: Effective VDH oversight of abortion facilities.
<table>
<thead>
<tr>
<th>130. Violation of this chapter or applicable law; Denial, revocation or suspension of license.</th>
<th>facility is (i) in violation of any provision of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) or of any applicable regulation, or (ii) is permitting, aiding, or abetting the commission of any illegal act in the abortion facility, the department may deny, suspend, or revoke the license to operate an abortion facility in accordance with § 32.1-135 of the Code of Virginia. B. If a license or certification is revoked as herein provided, a new license or certification may be issued by the commissioner after satisfactory evidence is submitted to him that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with all provisions of Article 1 of Chapter 5 of Title 32.1 of the Code of Virginia and applicable state and federal law and regulations hereunder has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may restore a suspended license when he determines that the conditions upon which suspension was based have been corrected and that the interests of the public will not be jeopardized by resumption of operation. No additional fee shall be required for restoring such license. D. The 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 (Virginia Code § 2.2-4000 et seq.).</th>
<th>Chapter 5 of Title 32.1 of the Code of Virginia (§ 32.1-123 et seq.) Regulation of Medical Care Facilities and Services. §32.1-135 of the Code of Virginia - Revocation or suspension of license or certification; restriction or prohibition of new admissions to nursing home. §2.2-4000 of the Code of Virginia - Administrative Process Act process for denial, revocation or suspension of an abortion facility license. Likely impact: Effective VDH oversight of abortion facilities.</th>
</tr>
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<tbody>
<tr>
<td>12VAC5-412-140. Management and administration</td>
<td>A. The abortion facility shall comply with: 1. This chapter (12VAC5 412); 2. Other applicable federal, state or local laws and regulations; and 3. The abortion facility's policies and procedures. B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law. C. The abortion facility shall permit OLC inspectors to conduct inspections to: 1. Verify application information; 2. Determine compliance with this chapter and applicable law; 3. Review necessary records and documents; and 4. Investigate complaints. D. An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes: 1. Change of location. 2. Change of ownership. 3. Change of name. 4. Voluntary closure. 5. Change of administrator.</td>
<td>Other applicable federal, state or local laws and regulations. Intent: Specify requirements for management and administration of abortion facilities. Likely impact: Effective VDH oversight of abortion facilities.</td>
</tr>
</tbody>
</table>
6. Change of operator. Notices shall be sent to the attention of the director of the OLC.
E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.

12VAC5-412-150. Governing body.

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the abortion facility.
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.
C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.
D. The governing body shall have a formal organizational plan with written bylaws. These shall clearly set forth organization, duties and responsibilities, accountability, and relationships of professional staff and other personnel. The bylaws shall identify the person or organizational body responsible for formulating policies.
E. The bylaws shall include at a minimum the following:
   1. A statement of purpose;
   2. Description of the functions and duties of the governing body, or other legal authority;
   3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;
   4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and
   5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.


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:
   1. Personnel;
   2. Types of elective services performed in the abortion facility;
   3. Types of anesthesia that may be used;
   4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
   5. Obtaining informed written consent of the patient pursuant to §18.2-76 prior to the initiation of any

Intent: Specify the requirements and responsibilities of a facility's governing body.
Likely impact: Facilitate VDH oversight of abortion facilities.
| 12VAC5-412-170. Administrator. | 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: 1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights; 2. Employing qualified personnel and ensuring appropriate personnel orientation, training education and evaluation; 3. Ensuring the accuracy of public information materials and activities; 4. Ensuring an effective budgeting and accounting system is implemented; and 5. Maintaining compliance with applicable laws and regulations and implementing corrective action. B. Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing. C. A qualified individual shall be appointed in writing to act in the absence of the administrator. | N/A | Intent: Specify the responsibilities the administrator. Likely impact: Clarity of process, requirements and facilitation of VDH oversight of abortion facilities. |
| § 32.1-126.02 Hospital pharmacy employees; criminal records check required. | | 12VAC5-412-180. Personnel. | 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 clinicians based on the level, intensity, and scope of services provided. 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, | | Likely impact: Clarity of
and appropriate professional licensure, if applicable.  

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

D. 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.  

E. Job Descriptions.  
1. Written job descriptions that adequately describe the duties of every position shall be maintained.  
2. Each job description shall include position title, authority, specific responsibilities and minimum qualifications.  
3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.  

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 and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.  

G. Personnel policies and procedures shall include, but not be limited to:  
1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;  
2. Process for verifying current professional licensing or certification and training of employees or independent contractors;  
3. Process for annually evaluating employee performance and competency;  
4. Process for verifying that contractors and their employees meet the personnel qualifications of the abortion facility; and  
5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.  

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

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<tbody>
<tr>
<td>A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and non-physician health care practitioners shall be clearly defined.</td>
<td>N/A</td>
</tr>
<tr>
<td>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.</td>
<td>Intent: Specify requirements and responsibilities of clinical staff of abortion facilities.</td>
</tr>
<tr>
<td>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 the patient until she is discharged from the abortion facility.</td>
<td>Likely impact: Clarity of requirements and responsibilities of clinical staff. Promotion of patient health and safety.</td>
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<td>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.</td>
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**12VAC5-412-200. Patients’ rights.**

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<td>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.</td>
<td>N/A</td>
</tr>
<tr>
<td>B. The abortion facility shall establish and maintain complaint handling procedures which specify the:</td>
<td>Intent: Specify the required protocol regarding patients’ rights, including the requirements regarding the handling of complaints.</td>
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<tr>
<td>1. System for logging receipt, investigation and resolution of complaints; and</td>
<td>Likely impact: Clarity of process, requirements and procedure regarding patient rights, specifically for handling of complaints.</td>
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<td>2. Format of the written record of the findings of each complaint investigated.</td>
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<td>C. The abortion facility shall designate staff responsible for complaint resolution, including:</td>
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<td>1. Complaint intake, including acknowledgment of complaints;</td>
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<td>2. Investigation of the complaint;</td>
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<td>3. Review of the investigation findings and resolution</td>
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for the complaint; and
4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.

D. 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.

E. The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:
1. Abortion facility contact person; and
2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.

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.

| 12VAC5-412-210. Quality management. | A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary. B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.
C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:
1. A physician;
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of | N/A | Intent: Specify the requirements and process for quality management. Likely impact: Clarity of requirements and process for quality management. Promotion of patient health and safety. |
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<td>care and services provided to patients. D. Measures shall be implemented to resolve problems or concerns that have been identified. E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.</td>
<td>Regulations for Disease Reporting and Control 12VAC5-90 OSHA Blood Borne Pathogen Requirements 29 CFR 1910.1030 OSHA Reporting of workplace-associated Injuries or Exposure to Infection Requirements 29 CFR 1952.4</td>
</tr>
<tr>
<td>Intent: Specify the requirements for abortion facilities’ infection prevention plans and the process for implementing these plans. Likely impact: Clarity of process and requirements regarding infection prevention plans. Prevention of infectious disease. Promotion of patient health and safety.</td>
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<td><strong>12VAC5-412-220. Infection prevention.</strong> 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 &quot;Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care,&quot; published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the abortion facility shall have received training in basic infection prevention, and shall also be involved in the annual review. B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the abortion facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety &amp; Health Administration; 6. Use of personal protective equipment;</td>
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7. Use of safe injection practices; 
8. Plans for annual retraining of all personnel in infection prevention methods; 
9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 
10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

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

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

E. The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities:
1. A procedure for surveillance, documentation and tracking of reported infections; and
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.

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<td>A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician.</td>
<td>Intent: Specify the required restrictions on abortions performed and requirements regarding patient counseling and discharge.</td>
<td>Likely impact: Clarity of restrictions on abortion procedures as well as the requirements regarding patient counseling and discharge.</td>
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<td>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.</td>
<td>§16.1-241 of the Code of Virginia - Jurisdiction; consent for abortion.</td>
<td>§18.2-76 of the Code of Virginia - Informed written consent required; civil penalty.</td>
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<td>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.</td>
<td>§16.1-241 of the Code of Virginia - Jurisdiction; consent for abortion.</td>
<td>§18.2-76 of the Code of Virginia - Informed written consent required; civil penalty.</td>
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<td>D. When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.</td>
<td>§16.1-241 of the Code of Virginia - Jurisdiction; consent for abortion.</td>
<td>§18.2-76 of the Code of Virginia - Informed written consent required; civil penalty.</td>
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<td>E. The abortion facility shall offer each patient seeking an abortion, in a language or manner they understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.</td>
<td>§16.1-241 of the Code of Virginia - Jurisdiction; consent for abortion.</td>
<td>§18.2-76 of the Code of Virginia - Informed written consent required; civil penalty.</td>
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<td>F.</td>
<td>There shall be an organized discharge planning process that includes an evaluation of the patient's capacity for self-care and discharge instructions for patients to include instructions to call or return if signs of infection develop.</td>
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| 12VAC5-412-240. Medical testing and laboratory services. | A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to §18.2-76, shall be completed for each patient.  
1. Use of any additional medical testing shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.  
2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.  
3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.  
4. A written report of each laboratory test and examination shall be a part of the patient's record.  
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).  
1. Facilities for collecting specimens shall be available on site.  
2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.  
3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.  
C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.  
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 (9 VAC20-120). |
| 12VAC5-412-250. Anesthesia | A. The anesthesia service shall comply with the Office-Based Anesthesia provisions of the Regulations Governing the Practice of Medicine, Office-Based Anesthesia provisions of |

**Intent:** Specify the medical testing to be performed prior to an abortion procedure and the policies and procedures a facility must implement regarding medical testing and laboratory services.  
Likely impact: Clarity of requirements, policies and procedures facilities must implement and observe regarding medical testing and laboratory services. Promotion of patient health and safety.
The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia. 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. An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies and pharmacological agents, as required by 18VAC85-20-360 B:

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

Elective general anesthesia shall not be used. 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.

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:

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

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

A. Controlled substances, as defined in § 54.1-3401
of the Drug Control Act of the Code of Virginia, shall
be stored, administered and dispensed in
accordance with federal and state laws. The
dispensing of drugs, excluding manufacturers’
samples, shall be in accordance with Chapter 33 of
Title 54.1 of the Code of Virginia, Regulations
Governing the Practice of Pharmacy (18VAC110-
20), and Regulations for Practitioners of the Healing
Arts to Sell Controlled Substances (18VAC110-30).
B. Drugs, as defined in § 54.1-3401 of the Drug
Control Act of the Code of Virginia, whose intended
use is to induce a termination of pregnancy shall
only be prescribed, dispensed or administered by a
physician.
C. Drugs maintained in the 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.
D. The mixing, diluting or reconstituting of drugs for
administration shall be in accordance with
regulations of the Board of Medicine (18VAC85-20-
400 et seq.).
E. Records of all drugs in Schedules I-V received,
§ 54.1-3401 of
the Drug
Control Act of
the Code of
Virginia
Chapter 33 of
Title 54.1 of
the Code of
Virginia-
Pharmacy
Regulations
Governing the
Practice of
Pharmacy
18VAC110-20
Regulations
for
Practitioners
of
the Healing
Arts to Sell
Controlled
Substances
18VAC110-30
Regulations

Intent: Specify requirements
abortion
facilities must
comply with
regarding
administration,
storage and
dispensing of
controlled
substances.

Likely impact:
Clarity of
requirements
abortion
facilities must
comply with
regarding
administration,
storage and
dispensing of
controlled
substances.

Promotion of
patient health
and safety.
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<th>Intent</th>
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<td>12VAC5-412-270. Equipment and supplies.</td>
<td>An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include: 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; 5. Emergency medications, intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light; 8. Containers for soiled linen and waste materials with covers; and 9. Refrigerator.</td>
<td>N/A</td>
<td>Clarity of required equipment and supplies abortion facilities are required to maintain.</td>
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<td>12VAC5-412-280. Emergency equipment and supplies.</td>
<td>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 Advanced Cardiovascular Life Support. Drugs shall include, at a minimum, those to treat the following conditions: 1. Cardiopulmonary arrest; 2. Seizure; 3. Respiratory distress; 4. Allergic reaction; 5. Narcotic toxicity; 6. Hypovolemic shock; and 7. Vasovagal shock.</td>
<td>N/A</td>
<td>Clarity of required emergency equipment and supplies abortion facilities are required to maintain.</td>
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<td>12VAC5-412-</td>
<td>A. An abortion facility shall provide ongoing urgent or</td>
<td>N/A</td>
<td>Specify emergency equipment and supplies abortion facilities are required to maintain.</td>
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<td>Title: Specify emergency equipment and supplies abortion facilities are required to maintain.</td>
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<td>Promotion of patient health and safety.</td>
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<td>290. Emergency services.</td>
<td>emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for resuscitation and control of hemorrhage and other complications. B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support. C. A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.</td>
<td>requirements abortion facilities must comply with regarding emergency services. Likely impact: Clarity of requirements of abortion facilities regarding emergency services. Promotion of patient health and safety.</td>
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<td>12VAC5-412-300. Health Information records.</td>
<td>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist’s report of tissue, and radiologist’s report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses’ progress notes; h. Condition at time of discharge; i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies; and 6. Any other information required by law to be maintained in the health information record.</td>
<td>N/A Intent: Specify requirements abortion facilities must comply with regards to Health Information records. Likely impact: Clarity of requirements of abortion facilities regarding Health Information records. Effective VDH oversight of abortion facilities.</td>
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<td>12VAC5-412-310. Records storage.</td>
<td>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.).</td>
<td>Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.) Intent: Specify requirements abortion facilities must comply with regards to records storage. Likely impact:</td>
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<td>12VAC5-412-320. Required Reporting.</td>
<td>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). B. The abortion facility shall report the following events to OLC: 1. Any patient, staff or visitor death. 2. Any serious injury to a patient. 3. Medication errors that necessitate a clinical intervention other than monitoring; 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 5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 U.S.C. §301 et seq. - PL 101-629). C. Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the: 1. Abortion facility name; 2. Type and circumstance of the event being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. 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. 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. F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.</td>
<td>Board of Health Regulations Governing Vital Records (12VAC5-550-120). Safe Medical Devices Act of 1990 (21 U.S.C. §301 et seq. - PL 101-629). §8.01-581.17 of the Code of Virginia. Privileged communication of certain committees and entities. §63.2-1509 of the Code of Virginia. Physicians, nurses, teachers, etc., to report certain injuries to children; penalty for failure to report.</td>
<td>Specify requirements of abortion facilities in regards to reporting. Clarity of abortion facility requirements in regards to reporting. Effective VDH oversight of abortion facilities.</td>
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<td>12VAC5-412-330. Abortion Facility Security and Safety.</td>
<td>A. 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: 1. Abortion facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and</td>
<td>N/A</td>
<td>Specify required policies and procedures abortion facilities must implement in regards to facility security.</td>
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services; and

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

| 12VAC5-412-340. Disaster preparedness. | A. Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

B. An abortion facility that participates in community disaster planning shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care. | N/A | Intent: Specify required policies and procedures abortion facilities must implement with regards to disaster preparedness.

Likely impact: Clarity of the required policies and procedures abortion facilities must implement in regards to facility security and safety. Promotion of patient health and safety.
| 12VAC5-412-350. Maintenance. | 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 non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.  
B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. | N/A | Intent: Specify requirements abortion facilities must comply with in regards to facility maintenance.  
Likely impact: Clarity of requirements abortion facilities must comply with in regards to facility maintenance. Promotion of patient health and safety. |
| 12VAC5-412-360. Fire-fighting equipment and systems | A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.  
B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.  
C. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia). | Statewide Fire Prevention Code § 27-94 et seq. of the Code of Virginia | Intent: Specify requirements abortion facilities must comply with in regards to firefighting equipment and systems.  
Likely impact: Clarity of requirements abortion facilities must comply with in regards to firefighting equipment and systems. Promotion of patient health and safety. |
| 12VAC5-412-370. Local and state codes and standards. | Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through | Uniform Statewide Building Code §32.1-127.001  
Fetal death or induced termination of pregnancy report items. 12VAC5-550-120 | Intent: Specify that abortion facilities are required to comply with state, local codes and additional standards.  
Likely impact: Clarity |
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.

Regarding what standards besides the “Regulations for Licensure of Abortion Facilities” facilities must comply with.

Summary of changes made to the regulatory language from the emergency to the proposed stage:

VDH has made a few revisions to the regulations from the emergency/NOIRA stage to the proposed stage. These revisions are mostly of a relatively minor nature. First VDH made amendments to make these regulations more consistent with other VDH health care facility regulations. This consisted of some minor additions including a definition but mostly consisted of moving language in order for the formatting to be more consistent. Also, VDH amended the regulations to incorporate some interpretative guidance previously issued by VDH, thereby creating more thorough, comprehensive and transparent regulations. In addition, minor changes were made in order for these regulations to be consistent with recent amendments to Virginia Code § 18.2-76. Finally, VDH added language to specify that abortion facility employees who are mandated reporters under Virginia Code § 63.2-1509 are required to report suspected child abuse. These changes are described in more detail below.

VDH has added the term and definition of the term "Administrator" in order to remain consistent with other VDH Health Care Facility Regulations.

VDH removed the term "Ownership/person" as it was duplicative of the definition of "Licensee".

VDH has added the term and definition of the term "Spontaneous miscarriage."

VDH has amended 12VAC5-412-70 in order to be consistent with other VDH health care facility regulations.

VDH has added to sub-section C to 12VAC5-412-70 Return and/or Reissuance of a License to be consistent with other VDH health care facility regulations. This addition was moved from the section 320 of the Emergency Regulations "Records Storage" with some additions and clarifications.

VDH has amended 12VAC5-412-80. Allowable variances in order to be consistent with other VDH health care facility regulations. This amendment provides more detail and creates more thorough regulations. VDH amended 12VAC5-412-100. On-site inspection. This amendment incorporates certain interpretative guidance previously issued by VDH, thereby creating more thorough, comprehensive and transparent regulations. This change clarifies the meaning of current patients, as well as what materials must be available to surveyors.

VDH has added 12VAC5-412-120. OLC complaint investigations in order to be consistent with other VDH health care facility regulations.

VDH has added 12VAC5-412-140. Management and administration in order to be consistent with other VDH health care facility regulations.

VDH has made several changes to 12VAC5-412-160. Policies and procedures. The first change was removing the term manual. Removal of this term allows for on-line or electronic policies and procedures. Next VDH made some amendments in order to be consistent with the amendment to Virginia Code § 18.2-76. Finally VDH made amendments in order to be consistent with other VDH health care facility regulations.

VDH made several changes to 12VAC5-412-170. Administrator in order to be consistent with other VDH health care facility regulations.

VDH has moved the Consent of the Patient and Minors sections to the Patient Care Management section beginning at 12VAC5-412-230.

VDH moved Section 300 of the Emergency Regulations "Quality assurance" to section 210 and renamed this section Quality management. This change was made in order to be consistent with other VDH health care facility regulations.
Section 230 Patient services; patient counseling the beginning of Part IV Patient Care Management has several additions taken from elsewhere in the regulations. These amendments were made in order to be consistent with other VDH health care facility regulations.

VDH made a few minor changes to section 240 Medical testing and laboratory services due to the amendment to the Informed Consent statute.

Section 300 as stated earlier was moved to section 210 and renamed Quality Management in order to be consistent with other VDH health care facility regulations.

VDH made several changes to Section 320 Required Reporting in order to be consistent with other VDH health care facility regulations. VDH also added provision F in this section which requires abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.
12VAC5-410-10. Definitions.

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

"Board" means the State Board of Health.

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

"Commissioner" means the State Health Commissioner.

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

"Department" means an organized section of the hospital.

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

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

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

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

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

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

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

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

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

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

"Organized" means administratively and functionally structured.

"Organized medical staff" means a formal organization of physicians and dentists with the delegated responsibility and authority to maintain proper standards of medical care and to plan for continued betterment of that care.
"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. Outpatient abortion clinics are deemed a category of outpatient hospitals.

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

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

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

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

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

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

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

12VAC5-410-60. Separate license.

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

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

CHAPTER 412
REGULATIONS FOR LICENSURE OF ABORTION FACILITIES

Part I
Definitions and Requirements for Licensure

12VAC5-412-10. Definitions.

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

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

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

"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.

"Commissioner" means the State Health Commissioner.

"Department" means the Virginia Department of Health.

"First trimester" means the first twelve weeks from conception based on an appropriate clinical estimate by a licensed physician.
"Informed written consent" means the knowing and voluntary written consent to an abortion by a pregnant woman of any age in accordance with Virginia Code § 18.2-76.

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

"Minor" means a patient under the age of 18.

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

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

"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.

"Trimester" means a 12-week period of pregnancy.

12VAC5-412-20. General.

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

No 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.

12VAC5-412-30. Classification.

Abortion facilities shall be classified as a category of hospital.

12VAC5-412-40. Separate license.

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

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

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

12VAC5-412-50. Request for issuance.

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

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

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

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

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

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

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

A. Licenses shall expire at midnight April 30th following the date of issue, and shall be renewable annually, upon filing of a renewal application and payment of the appropriate 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.
B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.

C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal.

D. Any license issued before April 30, 2012 shall not expire until April 30, 2013. No additional fee will be required for the period from May 1, 2012 until April 30, 2013.

12VAC5-412-70. Return and/or Reissuance of License.

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

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

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.

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

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 5 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.

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 facility during the process of evaluating a change.

E. The facility will be notified in writing by the OLC whether a license can be re-issued or a new application is needed.

12VAC5-412-80. Allowable variances.

A. The commissioner may authorize a temporary variance only to a specific regulation of this Chapter. An abortion facility may request a temporary variance to a particular regulation or requirements contained in a particular regulation 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 regulation constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the requirements 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.

B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known which 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.

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.

D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation to which the temporary variance was granted shall be resumed.
12VAC5-412-90. Right of entry.

Pursuant to § 32.1-25 of the Code of Virginia, any duly designated employee of the Virginia Department of Health shall have the right to enter upon and into the premises of any licensed abortion facility, or any entity the department has reason to believe is operated, or maintained as an abortion facility without a license, in order to determine the state of compliance with the provisions of this chapter and applicable laws. Any such employee shall properly identify himself or herself as an inspector designated by OLC; the abortion facility may verify the identity of the inspector prior to his or her 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.

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

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

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 shall be redacted by the abortion facility before removal.

C. If the OLC's representative arrives on the premises to conduct a survey and the administrator, the nursing director, or a person authorized to give access to patient records, is not available on the premises, such person or the designated alternate, shall be available on the premises within 1 hour of the surveyor’s arrival. A list of 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 2 hours of arrival if requested. Failure to be available or to respond shall be grounds for penalties in accordance with Virginia Code § 32.1-27 and denial, suspension or revocation of the facility's license in accordance with 12VAC5-412-130.

12VAC5-412-110. Plan of correction.

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

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

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
2. The expected correction date, not to exceed 30 working days from the exit date of the survey;
3. A description of the measures implemented to prevent a recurrence of the violation; and
4. The signature of the person responsible for the validity of the report.

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

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

12VAC5-412-120. OLC complaint investigations.

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.
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 12 VAC 5-412-110 and shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-412-130. Violation of this chapter or applicable law; Denial, revocation or suspension of license.

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

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

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

D. The 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 (Virginia Code § 2.2-4000 et seq.).

Part II
Organization and Management

12VAC5-412-140. Management and administration

A. The abortion facility shall comply with:

1. This chapter (12VAC5 412);
2. Other applicable federal, state or local laws and regulations; and
3. The abortion facility's policies and procedures.

B. The abortion facility shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.

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

1. Verify application information;
2. Determine compliance with this chapter and applicable law;
3. Review necessary records and documents; and
4. Investigate complaints.

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

1. Change of location.
2. Change of ownership.
3. Change of name.
4. Voluntary closure.
5. Change of administrator.

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

E. The current license from the department shall be posted at all times in a place readily visible and accessible to the public.

12VAC5-412-150. Governing body.

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

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

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

E. The bylaws shall include at a minimum the following:
   1. A statement of purpose;
   2. Description of the functions and duties of the governing body, or other legal authority;
   3. A statement of authority and responsibility delegated to the administrator and to the clinical staff;
   4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and
   5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical staff.


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:
   1. Personnel;
   2. Types of elective services performed in the abortion facility;
   3. Types of anesthesia that may be used;
   4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
   5. Obtaining informed written consent of the patient pursuant to §18.2-76 prior to the initiation of any procedures;
   6. When to use sonography to assess patient risk;
   7. Infection prevention;
   8. Quality and risk management;
   9. Management and effective response to medical and/or surgical emergency;
   10. Management and effective response to fire;
   11. Ensuring compliance with all applicable federal, state, and local laws;
   12. Abortion facility security;
   13. Disaster preparedness;
   14. Patient rights;
   15. Functional safety and abortion facility maintenance; and
   16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.

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.

12VAC5-412-170. Administrator.

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:
   1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;
2. Employing qualified personnel and ensuring appropriate personnel orientation, training education and evaluation;
3. Ensuring the accuracy of public information materials and activities;
4. Ensuring an effective budgeting and accounting system is implemented; and
5. Maintaining compliance with applicable laws and regulations and implementing corrective action.

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

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

12VAC5-412-180. Personnel.

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 clinicians based on the level, intensity, and scope of services provided.

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.

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

D. 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.

E. Job Descriptions.

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

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

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

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 and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.

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

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

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

3. Process for annually evaluating employee performance and competency;

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

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

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.
12VAC5-412-190. Clinical staff.
A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physician and non-physician health care practitioners shall be clearly defined.
B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The 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.
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 the patient until she is discharged from the abortion facility.
D. Licensed practical nurses, working under direct supervision and direction of a physician or a registered nurse, may be employed as components of the clinical staff.

12VAC5-412-200. Patients' rights.
A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.
B. The abortion facility shall establish and maintain complaint handling procedures which specify the:
   1. System for logging receipt, investigation and resolution of complaints; and
   2. Format of the written record of the findings of each complaint investigated.
C. The abortion facility shall designate staff responsible for complaint resolution, including:
   1. Complaint intake, including acknowledgment of complaints;
   2. Investigation of the complaint;
   3. Review of the investigation findings and resolution for the complaint; and
   4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.
D. 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.
E. The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:
   1. Abortion facility contact person; and
   2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.
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.

Part III
Quality Management and Infection Prevention

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

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

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

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

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

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

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

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

12VAC5-412-220. Infection prevention.

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.

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

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

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

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

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

E. The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities:
1. A procedure for surveillance, documentation and tracking of reported infections; and
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.

Part IV
Patient Care Management

12VAC5-412-230. Patient services; patient counseling.
A. Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician.
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.
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.
D. When abortions are being performed, a staff member currently certified to perform cardio-pulmonary resuscitation shall be available on site for emergency care.
E. The abortion facility shall offer each patient seeking an abortion, in a language or manner they understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.
F. There shall be an organized discharge planning process that includes an evaluation of the patient’s capacity for self-care and discharge instructions for patients to include instructions to call or return if signs of infection develop.

12VAC5-412-240. Medical testing and laboratory services.
A. Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all the requirements of informed written consent pursuant to §18.2-76, shall be completed for each patient.
   1. Use of any additional medical testing shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.
   2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.
   3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.
   4. A written report of each laboratory test and examination shall be a part of the patient's record.
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).
   1. Facilities for collecting specimens shall be available on site.
   2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.
   3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly.
C. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.
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 (9 VAC20-120).

12VAC5-412-250. Anesthesia service.

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

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

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.

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:

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

E. Elective general anesthesia shall not be used.

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.

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:

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

H. 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.

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

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

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

C. Drugs maintained in the 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.

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

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

12VAC5-412-270. Equipment and supplies.

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

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

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

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

1. Cardiopulmonary arrest;
2. Seizure;
3. Respiratory distress;
4. Allergic reaction;
5. Narcotic toxicity;
6. Hypovolemic shock; and
7. Vasovagal shock.
12VAC5-412-290. Emergency services.
A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for resuscitation and control of hemorrhage and other complications.
B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of the American Heart Association's Guidelines for Advanced Cardiovascular Life Support.
C. A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment. The agreement shall be with a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.

Part V
Support Services
Health Information Records And Reports

12VAC5-412-300. Health Information records.
An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:

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

12VAC5-412-310. Records storage.
Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

12VAC5-412-320. Required Reporting.
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).
B. The abortion facility shall report the following events to OLC:
   1. Any patient, staff or visitor death.
   2. Any serious injury to a patient.
   3. Medication errors that necessitate a clinical intervention other than monitoring.
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

5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990 (21 U.S.C. §301 et seq. - PL 101-629).

C. Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the:

1. Abortion facility name;
2. Type and circumstance of the event being reported;
3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

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.

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.

F. Abortion facilities shall ensure that employees mandated to report suspected child abuse or neglect under Virginia Code § 63.2-1509 comply with the reporting requirements of § 63.2-1509.

Part VI
Functional Safety and Maintenance


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:

1. Abortion facility security;
2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and
3. Provisions for disseminating safety-related information to employees and users of the abortion facility.

12VAC5-412-340. Disaster preparedness.

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

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


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 non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

B. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.
12VAC5-412-360. Fire-fighting equipment and systems.
   A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.
   B. All fire protection and alarm systems and other firefighting equipment shall be inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.
   C. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions in accordance with the current edition of the Virginia Statewide Fire Prevention Code (§ 27-94 et seq. of the Code of Virginia).

Part VII
Design and Construction

12VAC5-412-370. Local and state codes and standards.
   Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Uniform Statewide Building Code pursuant to Virginia Code § 32.1-127.001.
   Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 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.
June 15, 2012

Memorandum

To: State Board of Health

From: Maureen E. Dempsey, MD, FAAP
Chief Deputy Commissioner for Public Health

Subject: Proposed Guidelines Regarding Mammography Services with Respect to Breast Density

House Bill No. 83/Senate Bill No. 544 were enacted by the Virginia General Assembly to amend and reenact § 32.1-229 of the Code of Virginia relating to mammogram reports. The legislation requires the Board of Health to establish: guidelines that shall also require the licensed facility or physician’s office where mammography services are performed to (i) include information on breast density in mammogram letters sent to patients pursuant to regulations implementing the Mammography Quality Standards Act promulgated by the U.S. Food and Drug Administration, and (ii) include in letters sent to patients who have dense breast tissue, as determined by the interpreting physician based on standards promulgated by the American College of Radiology, the following notice:

"YOUR MAMMOGRAM DEMONSTRATES THAT YOU MAY HAVE DENSE BREAST TISSUE, WHICH CAN HIDE CANCER OR OTHER ABNORMALITIES. A REPORT OF YOUR MAMMOGRAPHY RESULTS, WHICH CONTAINS INFORMATION ABOUT YOUR BREAST DENSITY, HAS BEEN SENT TO YOUR REFERRING PHYSICIAN'S OFFICE, AND YOU SHOULD CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT THIS REPORT."

The legislation was signed by the Governor and will go into effect July 1, 2012. A letter has been sent to all mammography facilities informing them of the new legislative requirement under the State Health Commissioner’s signature dated May 1, 2012.

The Division of Radiological Health has developed a procedure for handling the review of medical records indicating the existence of dense breast tissue. The proposed guidelines are offered as Attachment 1 to this correspondence for your review and discussion at the June 15, 2012 meeting of the Board of Health. These proposed guidelines have been reviewed and approved by the Office of the Attorney General and are included as an attachment to this documentation package.

If the Board approves these guidelines, inspection verification will begin July 1, 2012. This will be incorporated during the Mammography Quality Standards Act (MQSA) annual inspection conducted by Radiological Health staff.
1. When the Division of Radiological Health (DRH) schedules a facility’s Mammography Quality Standards Act (MQSA) Inspection, the scheduling confirmation letter will indicate that six patient records will be reviewed, at least one of which is to contain the wording of “dense breast” or equivalent. Inspectors will verify appropriate terminology is included in the radiologist’s interpretation and the “lay” letter sent to the patient reflecting the requirements of HB83/SB 544 (32.1-229(7) effective July 1, 2012). HB83/SB 544 requires:
   - “the licensed facility or physician’s office where mammography services are performed to (i) include information on breast density in mammogram letters sent to patients pursuant to regulations implementing the Mammography Quality Standards Act promulgated by the U.S. Food and Drug Administration, and (ii) include in letters sent to patients who have dense breast tissue, as determined by the interpreting physician based on standards promulgated by the American College of Radiology, the following notice: "YOUR MAMMOGRAM DEMONSTRATES THAT YOU MAY HAVE DENSER BREST TISSUE, WHICH CAN HIDE CANCER OR OTHER ABNORMALITIES. A REPORT OF YOUR MAMMOGRAPHY RESULTS, WHICH CONTAINS INFORMATION ABOUT YOUR BREAST DENSITY, HAS BEEN SENT TO YOUR REFERRING PHYSICIAN'S OFFICE, AND YOU SHOULD CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT THIS REPORT."

2. The inspector will verify the following during the MQSA inspection:
   - A policy is in place stating that patients with dense breasts will have their referring physicians notified through the radiologist’s interpretation and that the patient will be notified using a “lay” letter.
   - Terminology required by HB83/SB 544 is present in both the interpretation and “lay” letter concerning women with dense breasts.

3. If it is determined that the facility fails to meet the State’s requirements, then the inspector will indicate to the facility that a non-compliance letter will be issued from the Central Office requiring a corrective action letter be returned within 30 days. The inspector will notify the X-ray Program Coordinator, who will issue the non-compliance letter to the facility.

4. Continued instances of non-compliance will be forwarded by the X-ray Program Coordinator to the Board of Health Professions for cognizance and licensing action, if appropriate.
COMMONWEALTH of VIRGINIA
Department of Health

KAREN REMLEY, MD, MBA, FAAP
STATE HEALTH COMMISSIONER

May 1, 2012

Dear Registrant,

This year, the General Assembly of Virginia unanimously passed HB83/SB544. This legislation amends the Code of Virginia to require that all mammogram reports include specific information on breast density, and that this information now be reported to all patients, in addition to the referring physician. In anticipation of the Board of Health’s approval at its June 15 meeting, the following guidelines will apply effective July 1, 2012:

- Licensed facilities or physicians’ offices must have a protocol in place to notify patients of increased breast density, if detected in mammograms.

- Such protocol should include, in cases of increased breast density, the following notice based on standards promulgated by the American College of Radiology and as required by § 32.1-229 of the Code of Virginia: “Your mammogram demonstrates that you may have dense breast tissue which can hide cancer or other abnormalities. A report of your mammography results, which contains information about your breast density has been sent to your referring physician’s office, and you should contact your physician if you have any questions or concerns about this report.”

- Such protocol will be documented and evaluated for compliance during annual inspections already conducted by the Division of Radiological Health in compliance with the Mammography Quality Standards Act.

While not required by the statute, the Virginia Department of Health recommends staff responsible for patient notification be trained on the protocol, once established, and on the issuance of subsequent correspondence to patients, when necessary.

The Division of Radiological Health is your primary point of contact for questions regarding this process. Their contact information is available at http://www.vdh.virginia.gov/Epidemiology/RadiologicalHealth/.

Thank you for joining me to ensure that Virginia’s breast cancer screening efforts lead the nation in empowering women to protect themselves and make informed decisions regarding their health and health care. Please share this letter widely with other colleagues who may benefit from this information.

Sincerely,

Karen Remley, MD, MBA, FAAP
State Health Commissioner
An Act to amend and reenact § 32.1-229 of the Code of Virginia, relating to mammogram reports.

Approved February 28, 2012

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-229 of the Code of Virginia is amended and reenacted as follows:

   § 32.1-229. Powers and duties of the Board.
   The Board shall:
   1. Establish a program of effective regulation of sources of radiation for the protection of the public health and safety, including a program of education and technical assistance relating to radon that is targeted to those areas of the Commonwealth known to have high radon levels.
   2. Establish a program to promote the orderly regulation of radiation within the Commonwealth, among the states and between the federal government and the Commonwealth and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized.
   3. Establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety.
   4. Promulgate regulations providing for (i) general or specific licenses to use, manufacture, produce, transfer, receive, acquire, own or possess quantities of, or devices or equipment utilizing, by-product, source, special nuclear materials, or other radioactive material occurring naturally or produced artificially, (ii) registration of the possession of a source of radiation and of information with respect thereto, and (iii) regulation of by-product, source and special nuclear material.
   5. Encourage, participate in and conduct studies, investigations, training, research and demonstrations relating to control of sources of radiation.
   6. Establish fee schedules for the licensure of radioactive materials.
   7. Establish guidelines to require the licensed facilities or physicians' offices where mammography services are performed to offer to the patient, prior to departure, development of such films to ensure integrity and quality of the film. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality. Such guidelines shall also require the licensed facility or physician's office where mammography services are performed to (i) include information on breast density in mammogram letters sent to patients pursuant to regulations implementing the Mammography Quality Standards Act promulgated by the U.S. Food and Drug Administration, and (ii) include in letters sent to patients who have dense breast tissue, as determined by the interpreting physician based on standards promulgated by the American College of Radiology, the following notice:

   "YOUR MAMMOGRAM DEMONSTRATES THAT YOU MAY HAVE DENSE BREAST TISSUE, WHICH CAN HIDE CANCER OR OTHER ABNORMALITIES. A REPORT OF YOUR MAMMOGRAPHY RESULTS, WHICH CONTAINS INFORMATION ABOUT YOUR BREAST DENSITY, HAS BEEN SENT TO YOUR REFERRING PHYSICIAN'S OFFICE, AND YOU SHOULD CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT THIS REPORT."

   8. Issue such orders or modifications thereof as may be necessary in connection with proceedings under this title.
VIRGINIA ACTS OF ASSEMBLY -- 2012 SESSION

CHAPTER 125

An Act to amend and reenact § 32.1-229 of the Code of Virginia, relating to mammogram reports.

Approved March 6, 2012

[S 544]

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-229 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-229. Powers and duties of the Board.
The Board shall:

1. Establish a program of effective regulation of sources of radiation for the protection of the public health and safety, including a program of education and technical assistance relating to radon that is targeted to those areas of the Commonwealth known to have high radon levels.

2. Establish a program to promote the orderly regulation of radiation within the Commonwealth, among the states and between the federal government and the Commonwealth and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized.

3. Establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety.

4. Promulgate regulations providing for (i) general or specific licenses to use, manufacture, produce, transfer, receive, acquire, own or possess quantities of, or devices or equipment utilizing, by-product, source, special nuclear materials, or other radioactive material occurring naturally or produced artificially, (ii) registration of the possession of a source of radiation and of information with respect thereto, and (iii) regulation of by-product, source and special nuclear material.

5. Encourage, participate in and conduct studies, investigations, training, research and demonstrations relating to control of sources of radiation.

6. Establish fee schedules for the licensure of radioactive materials.

7. Establish guidelines to require the licensed facilities or physicians' offices where mammography services are performed to offer to the patient, prior to departure, development of such films to ensure integrity and quality of the film. When film developing is not available or the patient chooses not to wait, the patient shall be notified within two business days if another mammogram is necessary. This requirement does not imply or require that a diagnostic opinion be made at the time of the mammogram. The interpreting physician may require that the mammogram be retaken if, in the opinion of the physician, the study is of inadequate quality. Such guidelines shall also require the licensed facility or physician's office where mammography services are performed to (i) include information on breast density in mammogram letters sent to patients pursuant to regulations implementing the Mammography Quality Standards Act promulgated by the U.S. Food and Drug Administration, and (ii) include in letters sent to patients who have dense breast tissue, as determined by the interpreting physician based on standards promulgated by the American College of Radiology, the following notice:

"YOUR MAMMOGRAM DEMONSTRATES THAT YOU MAY HAVE DENSE BREAST TISSUE, WHICH CAN HIDE CANCER OR OTHER ABNORMALITIES. A REPORT OF YOUR MAMMOGRAPHY RESULTS, WHICH CONTAINS INFORMATION ABOUT YOUR BREAST DENSITY, HAS BEEN SENT TO YOUR REFERRING PHYSICIAN'S OFFICE, AND YOU SHOULD CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT THIS REPORT."

8. Issue such orders or modifications thereof as may be necessary in connection with proceedings under this title.
May 23, 2012

MEMORANDUM

TO: Members of the State Board of Health

FROM: Gary R. Brown, Director
       Office of Emergency Medical Services

SUBJECT: 2012 Budget Bill (Item 290 #1h) Requiring Payment of Initial Basic Level Emergency Medical Services (EMS) Certification Examination Provided by the National Registry of Emergency Medical Technicians (NREMT) and Development of an Allocation Methodology

Background

§ 32.1-111.5. Code of Virginia requires that the Board of Health shall prescribe by regulation the qualifications required for certification and recertification of emergency medical care attendants. This section further requires that “each person desiring certification as emergency medical services personnel shall apply to the Commissioner upon a form prescribed by the Board. Upon receipt of such application, the Commissioner shall cause the applicant to be examined or otherwise determined to be qualified for certification.”

The “National EMS Education Agenda – A Systems Approach” has been adopted by all states and establishes EMS standards for EMS education and certification. These national standards identified five integrated primary components, one which stipulates National EMS Certification. The only national certifying organization endorsed and recognized by the National Association of State EMS Officials is the National Registry of Emergency Medical Technicians (NREMTs).

Today, the Office of Emergency Medical Services (OEMS), Virginia Department of Health requires an applicant seeking certification at the Emergency Medical Technician (EMT) Intermediate and the EMT Paramedic levels to be examined by taking the respective tests prepared by the National Registry of EMTs (NREMT) and administered by the OEMS.
Beginning July 1, 2012, OEMS proposes that candidates for Emergency Medical Responder (EMR) and Emergency Medical Technician (EMT) certification will be examined by taking the respective tests from the NREMTs, thus all EMS certification levels in Virginia will utilize examinations prepared by NREMT.

Currently Virginia uses exams developed by the Atlantic EMS Council (AEMSC) for the EMR and EMT levels. The AEMSC, formed in 1974 includes New Jersey, Pennsylvania, Delaware, Maryland, Washington D.C., West Virginia, Virginia, North Carolina and South Carolina. All but one AEMSC member states are transitioning to using EMS certification examinations prepared by NREMT by January 2013 or sooner. As such AEMSC states will no longer have access to valid, psychometrically sound and legally defensible examinations developed by AEMSC.

Candidates testing at the EMR and EMT basic levels have never paid a fee to take the written examination in Virginia. The fee for taking the National Registry EMR exam is $65 and the fee to take the National Registry EMT is $70. This will be the first time in the history of Virginia’s EMS system that there will be a fee for testing at these two levels.

There are no known opponents in the EMS system or among the key EMS stakeholders groups that oppose using the National Registry of EMTs for initial testing and certification as this brings Virginia into compliance with national standards and the National EMS Education Agenda. The only concern is the cost of the testing fee for the student, many of whom are volunteers.

As a result of these concerns, several EMS stakeholder groups requested that a budget amendment be introduced in the 2012 session of the Virginia General Assembly allowing the use of dedicated EMS special funds for payment of the initial test fee for students seeking certification at the basic EMR and EMT levels. This budget amendment has been unanimously approved by the 2012 Virginia General Assembly and the Budget Bill has been signed into law by the Governor.

The budget amendment states the following: “Notwithstanding any other provision of law or regulation, funds from the $0.25 of the $4.25 for Life fee shall be provided for the payment of the initial basic level emergency medical services certification examination provided by the National Registry of Emergency Medical Technicians (NREMT). The Board of Health shall determine an allocation methodology upon recommendation by the State EMS Advisory Board to ensure that funds are available for the payment of initial NREMT testing and distributed to those individuals seeking certification as an Emergency Medical Services provider in the Commonwealth of Virginia.”

On August 12, 2011 the State EMS Advisory Board unanimously voted, with one abstention, to implement National Registry testing in Virginia at all levels and pay for the initial cost of testing at the EMR and EMT levels. At the request of the Commissioner, the Chairperson of the State EMS Advisory Board asked the Training and Certification Committee (TCC) to revisit the issue of paying for the test fee. They created and unanimously approved the attached motion and position paper at a special called meeting on March 7, 2012. The TCC met again on April 4, 2012 and reaffirmed their position. This motion was forwarded to the State EMS Advisory
Board for approval. The Board unanimously approved the motion and position paper on May 18, 2012 to utilize dedicated EMS special funds for payment of the initial National Registry of EMTs testing fee for individuals seeking certification at the Emergency Medical Responder and Emergency Medical Technician basic levels.

Approximately 5,000 to 6,000 initial EMS certification written examinations are administered annually. Given that the cost of the National Registry written examination for EMR is $65 and $70 for EMT, the anticipated fiscal impact of paying for the National Registry examination at the EMR and EMT level is between $325,000 and $420,000 on an annual basis. If this recommendation is approved, these funds will come from the dedicated EMS special funds which, if unused, remain within the Rescue Squad Assistance Fund (§ 46.2-694 A. 13 (e) All revenues generated by the remaining $0.25 of the $4.25 fee approved by the 2008 Session of the General Assembly shall be deposited into the Rescue Squad Assistance Fund and used only to pay for the costs associated with the certification and recertification training of emergency medical services personnel). The primary impact of paying for the NREMT exam, therefore, will be on those additional EMS special funds which would have otherwise reverted to the Rescue Squad Assistance Fund.

Action Requested of the State Board of Health

The State EMS Advisory Board and the EMS system stakeholder groups represented by the Board are seeking the State Board of Health’s approval of the attached allocation methodology that utilizes funds from the $0.25 portion of the $4.25 for Life allocation for the payment of fees associated with the initial basic level emergency medical services certification examination provided by the National Registry of Emergency Medical Technicians (NREMT) as stipulated in the approved budget amendment.

Next Steps

Once the new testing process is initiated, the OEMS will examine, review and analyze data and statistics on a month to month basis. The overall testing process and procedure will be reviewed by the State EMS Advisory Board every three (3) years or as warranted by changes in the Code of Virginia or Commonwealth of Virginia budget pertaining to the funding of Emergency Medical Services. The findings and recommendations of this review will be reported to the Board of Health by the State EMS Advisory Board in order to ensure that funds are available for the payment of initial NREMT testing fees for candidates seeking certification as an EMS provider in the Commonwealth of Virginia.
Note: This revenue source and other $4 for Life Funds are used in the funding of BLS Continuing Educations and ALS Courses for certification.
The State EMS Advisory Board, after reviewing all of the available options, adopted and unanimously approved the following motion on May 18, 2012

Motion:

Certification candidates who have completed a Virginia approved initial certification Basic Life Support Training Program (FR/EMR and EMT-Basic/EMT) shall have their initial (first attempt) National Registry written certification examination fee paid from the portion of the EMS funds specifically earmarked in Code § 46.2-694 (A.) (13.) (e.).

A review of this process shall be conducted by the State EMS Advisory Board every three (3) years or as warranted by changes in the Code of Virginia or Commonwealth of Virginia Budget pertaining to the funding of Emergency Medical Services.

Unanimously Approved May 18, 2012 by the State EMS Advisory Board

Position Paper:

- EMS Regulations in Virginia establish EMT as the minimum required staffing level for an ambulance. If OEMS does not fund the initial cost of testing as a result of utilizing the National Registry (NR) certification examination, it is an unfunded mandate.

- Approximately 5,000 to 6,000 initial EMS certification written examinations are administered annually, at no cost to the candidate at the Basic Life Support (BLS) level. The cost of the National Registry written examination for EMR is $65 and $70 for EMT. The anticipated fiscal impact of utilizing the National Registry examination at the EMR and EMT level is between $325,000 and $420,000 on an annual basis.

  Initial start up costs to develop, administer and process a state developed EMS certification examination at five (5) separate levels will cost approximately $1M compared to the projected cost to utilize NR examinations. In addition, if NR examinations are utilized in Virginia, there will be less equipment and printing costs for OEMS and more time available for staff to serve our customers and constituents.

- Implementing National Registry testing in Virginia is the final step in meeting all objectives outlined in the EMS Education Agenda for the Future: A Systems Approach.

- Funding to cover the cost of initial NR testing at the EMR and EMT levels will come from the portion of the EMS funds specifically earmarked in Code § 46.2-694 to pay for the costs associated with the certification and recertification training of emergency medical services personnel. These funds were allocated as a result of HJR 743 (2007) which established the Joint Legislative Subcommittee Studying Incentives for Fire and
Rescue Squad Volunteers. Members of the subcommittee recognized the importance of creating a consistent and reliable source of funding to promote the recruitment and retention of EMS personnel by enacting a $0.25 increase in the $4-for-life vehicle registration fee.

- The National Registry and Pearson Vue have agreed to open a minimum of 12 additional computer testing locations sites, for a total of 17 sites around the state, in order to reduce the amount of travel required by test candidates.

- As the source of these funds is paid by the citizens of the Commonwealth, and having certified EMS Providers, in either of these EMS levels, is a benefit to all of the citizens of the Commonwealth in the event of a medical, traumatic, natural or man-made emergency, the use of these funds should be available to all testing candidates and not just limited to those who are affiliated with licensed EMS Agencies.

- The State of Maryland, an original member of the Atlantic EMS Council, has implemented the process of paying for initial certification testing.
Allocation Methodology
To Initiate Basic Level NREMT Testing
In Virginia
Presented to the State Board of Health
June 15, 2012

The following procedure outlines the allocation methodology to ensure funds are available for the payment of initial NREMT Emergency Medical Responder (EMR) and Emergency Medical Technician (EMT) test fees for EMS certification candidates in Virginia. This methodology only pays for those candidates who are trained in Virginia by certified Virginia EMS educators.

The Office of EMS proposes to pay only for the first (initial) attempt at the basic level EMS certification examination. Candidates are provided multiple attempts to pass each EMS certification level examination but there is no provision for payment of test fees beyond the first attempt. EMS certification candidates who are eligible to have their first attempt paid for must meet the following criteria:

1. The candidate must meet all eligibility requirements as outlined in EMS Regulations (12 VAC 5-31).
2. The candidate must be enrolled in a Virginia approved Emergency Medical Responder/First Responder or EMT program.
3. The candidate must comply with and successfully complete all course requirements as outlined in 12 VAC 5-31, the Office of EMS Training Program Administration Manual, and meet any additional requirements established by the course coordinator and/or the Physician Course Director.
4. The candidate must comply with all course completion expectations as evidenced by the course coordinator marking the student passed in the electronic student tracking program maintained by the Office of EMS.
5. Once marked as pass, the candidate will be issued a test eligibility letter authorizing the candidate to initiate the two part EMS certification process that involves cognitive and psychomotor (practical) components. The first part requires the student to take the Virginia practical skills examination. Successful completion of this practical skills examination is used to demonstrate achievement of entry level psychomotor competence. Successful completion of the psychomotor component of the examination is required prior to taking the written EMS certification examination prepared by NREMT. Only candidates who have passed the psychomotor examination will be granted access to the test site to complete the written examination. Candidates passing the practical skills examination will complete an online National Registry application that must be marked as passed by their Virginia course coordinator. Once the psychomotor examination results are verified, the Office will electronically submit the candidate’s examination results to the National Registry of EMTs which will initiate a National Registry cognitive written test eligibility letter.
6. The candidate receiving the National Registry eligibility letter will then register with an approved Pearson Vue Test Center to take the written EMS certification examination.

7. Once the scheduled written examination has occurred, the National Registry will bill the Office of EMS. Only the initial EMS certification examination fee will be billed. Any subsequent attempts to pass the written examination must be paid for by the candidate. The National Registry will electronically transmit each candidate’s National Registry test results to the Office of EMS. Candidates with a passing score will become eligible for EMS certification in Virginia. This will replace the paper based process currently used by OEMS, resulting in a reduction of printing and mailing costs.

8. National Registry testing is only required to obtain initial Virginia EMS certification. Re-certification of EMS credentials will be processed by OEMS; however, each provider has the option of maintaining their EMS certification issued by NREMT. Any cost associated with maintaining NREMT credentials is the sole responsibility of the provider. The recertification process for EMS credentials issued by OEMS is not changing and there is no associated cost to the provider.

The EMS Advisory Board will review the methodology utilized by this program in three (3) years to assure continued appropriate use of the funds as a recommendation to the Virginia Board of Health.